Form	99	0 Enturn of Org	ganization Exe	-		<b>D</b> x	OMB No 1545-0047
•	ment of t	he Treasury	benefit trust or priva	te foundation)			Open to Public
-		00 <u>6 calendar year, or tax year beginnin</u>		, 2006, and e			
-	k if applicabl		Я	, 2000, and e		0 5-	
	Address	use IRS	NIDAWI ON				ployer identification number
	change Name chan	print or		atroat addraga)	Beem/eurte		1071570
	Initial return	type		street address)	Room/suite		ephone number
	Final return	Specific				F Acco	2) 588-0302
$\vdash$	Amended	Instruc- tions. Lite City or town, state or country,				meth	ן <u></u> <u>-</u>
	return Application	WASHINGTON, DC 20036		1	Lt and L are not an		Other (specify)
L)	pending	<ul> <li>Section 501(c)(3) organizations and trusts must attach a completed Sch</li> </ul>					to section 527 organizations
~ ~				• ==,.	H(a) Is this a grou		
	ebsite:	WWW.WLF.ORG			H(b) If "Yes," ente		╼╶┯ <sup>╼═</sup> ╋╹╼╶┯┯╼┓
-		on type (check only one) $\blacktriangleright X$ 501(c) (3)			H(c) Are all affiliate (If "No." attac		ed? Yes No See instructions )
	neck here	▶ if the organization is not a 509(a			H(d) Is this a separat		led by an []
		e normally not more than \$25,000 A return is r	not required, but if the organ	nization chooses	organization co		
to	file a ret	urn, be sure to file a complete return			I Group Exemp		
					M Check 🕨		he organization is not required
		pts Add lines 6b, 8b, 9b, and 10b to line 12		<u>595,597.</u>		B (Forn	n 990, 990-EZ, or 990-PF)
Part		venue, Expenses, and Changes in Net		ces (See the in	structions)	·	<u></u>
	i	Contributions, gifts, grants, and similar amoui	1				
		Contributions to donor advised funds					
	b	Direct public support (not included on line 1a)		1b	4,326,429.		
ഹ	С	ndirect public support (not included on line 1	a)	1c			
Õ	d (	Bovernment contributions (grants) (not includ	led on line 1a)	1d			
	e ·	otal (add lines 1a through 1d) (cash \$ 4 , 2	04,689. noncash \$	1	L <u>21,740.</u> )	1e	4,326,429.
SCANNED	2	Program service revenue including governme	ent fees and contracts (from	n Part VII, line 93	3)	2	
$\mathbf{m}$	3	Membership dues and assessments				3	
$\bigcirc$	4	nterest on savings and temporary cash invest	ments STMT 1.			4	519,921.
JAN	5	Dividends and interest from securities	STMT. 2.			5	19,247.
ž	6a (	Gross rents		6a			
0	b	ess rental expenses		6b			
2	C	Net rental income or (loss) Subtract line 6b fi	om line 6a			6c	
പ്പു	7	Other investment income (describe 🕨 🕨			)	7	
<del>\$</del> 60%	8a (	Gross amount from sales of assets other	(A) Secunties	(B)	Other		
ž	1	han inventory	830,000.	8a			
	b	ess cost or other basis and sales expenses.	839,422.	8b			
	с (	Gain or (loss) (attach schedule)	-9,422.	8c			
	di	Net gain or (loss) Combine line 8c, columns (	A) and (B)		<u></u>	8d	
	9	Special events and activities (attach schedule	) If any amount is from ga	ming, check he	re 🕨 🔛		
	a	Bross revenue (not including \$	of		RECEIVED	N CI	NRREC
	(	contributions reported on line 1b)		9a	IRS - OS		13
	b	ess direct expenses other than fundraising e	xpenses	9b			
	с	Net income or (loss) from special events Sub	otract line 9b from line 9a		NOV.2	Sclo	07
	10 a 🛛	Gross sales of inventory, less returns and allow	vances	10a			
	b	ess cost of goods sold		10Ь	OGDEN ne 10a		A.A.A
	c	Gross profit or (loss) from sales of inventory	(attach schedule) Subtrac	t line 10b from lii	ne 10a	TUC	
	11 0	Other revenue (from Part VII, line 103)				11	
-	12	otal revenue. Add lines 1e, 2, 3, 4, 5, 6c,	7, 8d, 9c, 10c, and 11 .	<u></u>		12	4,856,175.
		Program services (from line 44, column (B))				13	2,349,127.
Expenses		Aanagement and general (from line 44, colum				14	737,949.
ien:		undraising (from line 44, column (D))					383,194.
Exp		Payments to affiliates (attach schedule)				16	
_		otal expenses Add lines 16 and 44, colur					3,470,270.
ts		Excess or (deficit) for the year Subtract line 1				18	1,385,905.
sse		Net assets or fund balances at beginning of y					17,062,200.
Net Assets		Other changes in net assets or fund balances					17,002,200.
Ne		Net assets or fund balances at end of year C					18,660,314.
For P		ct and Paperwork Reduction Act Notice, se					Form <b>990</b> (2006)
4 1010 2 00	0				C.	, -	=7
	v	4817 11/12/2007 12:25:2	2 V06-5.4 WA78	320	$\mathcal{O}$	-(	4
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orm 990 (2006)		is must complete column		71570	Page 4
		nd section 4947(a)(1) no			
Do not include amounts reported on line 6b, 8b, 9b, 10b, or 16 of Part I		(A) Total	(B) Program services	(C) Management and general	(D) Fundraising
2a Grants paid from donor advised funds (attach schedule)					
(cash \$ noncash \$	_)				
If this amount includes foreign grants, check here	22a				
2b Other grants and allocations (attach schedule)					
(cash \$noncash \$ If this amount includes foreign grants,			-		
If this amount includes foreign grants, check here	22Ь				
3 Specific assistance to individuals			r.		
(attach schedule)	23				
4 Benefits paid to or for members					
(attach schedule)	24				
5a Compensation of current officers,					
directors, key employees, etc. listed in					STMT 4
Part V-A (attach schedule)	25a	624,063.	266,158.	233,092.	124,813
b Compensation of former officers,					
directors, key employees, etc listed in Part V B (attach schodulo)					
Part V-B (attach schedule)	25b				
<ul> <li>C Compensation and other distributions, not includ- ed above, to disqualified persons (as defined</li> </ul>					
under section 4958(f)(1)) and persons described	25c				
In section 4958(c)(3)(B) (attach schedule) 6 Salaries and wages of employees not					
included on lines 25a, b, and c	26	782,844.	643,660.	86,074.	53,11
7 Pension plan contributions not		102,044.	045,000.	00,074.	
included on lines 25a, b, and c	27	817,228.	528,485.	185,393.	103,35
8 Employee benefits not included on		01//220.	520, 405.	103,333.	105,55
lınes 25a - 27		71,794.	46,428.	16,287.	9,07
9 Payroll taxes		70,981.	45,902.	16,102.	8,97
0 Professional fundraising fees	30				
1 Accounting fees		92,858.		92,858.	
2 Legal fees		32,677.	32,677.		
3 Supplies		118,683.	76,750.	26,924.	15,00
4 Telephone		56,303.	36,410.	12,773.	7,12
<b>5</b> Postage and shipping		21,171.	4,073.	1,358.	15,74
6 Occupancy	36				
17 Equipment rental and maintenance	37				
8 Printing and publications	38	572,015.	547,145.		24,87
9 Travel	39	42,429.	35,324.	7,105.	
O Conferences, conventions, and meetings					
1 Interest	41				
2 Depreciation, depletion, etc. (attach schedule		74,335.	48,071.	16,863.	9,40
3 Other expenses not covered above (itemize				<b>34 555</b>	
a INSURANCE	-43a	34,555.		34,555.	
<pre>b OTHER_PROFESSIONAL_FEES c MISCELLANEOUS</pre>	- 43b 43c	<u>6,950.</u>	13 630		6,95
	-	13,629.	13,629.		A 77
d <u>REPAIRS_AND_MAINTENANCE_</u> e	_43d	37,755.	24,415.	8,565.	4,77
	_ <u>43e</u> 43f				
	43g				
94 Total functional expenses. Add lines 22a					
through 43g (Organizations completing	3				
columns (B)-(D), carry these totals to lines	. 44	3,470,270.	2,349,127.	737,949.	383,194
Joint Costs. Check ► If you are follo	owina SC	<u></u> )P 98-2.		<i></i>	
Are any joint costs from a combined education			tation reported in (B) Pro	gram services?	► Yes X N
f "Yes," enter (i) the aggregate amount of these		s \$	, (ii) the amount alloca	ted to Program services	، ری ۱۹۹ ر <u>م</u> ۹۷ \$
ii) the amount allocated to Management and g	•		, and (iv) the amount al		

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Form 990 (2006)

Form	n 990 (2006)	52-1071570	Page 3
Pa	t III Statement of Program Service Accomplishments (See the in	structions)	
Forr part on	n 990 is available for public inspection and, for some people, icular organization. How the public perceives an organization in ts return Therefore, please make sure the return is complete a grams and accomplishments	serves as the primary or sole source of such cases may be determined by the	information presented
Wha	at is the organization's primary exempt purpose? SEE STATEMEN	ντ 5	Program Service
	organizations must describe their exempt purpose achievements in a clear		Expenses (Required for 501(c)(3) and
	ients served, publications issued, etc. Discuss achievements that are nonizations and 4947(a)(1) nonexempt charitable trusts must also enter the a		(4) orgs , and 4947(a)(1) trusts, but optional for others )
Í j j	LITIGATION, LEGAL PUBLIC POLICY ANALYSIS, CLI INTERN PROGRAM, BRIEFS AND RESEARCH DOCUMENTS ISSUES, MONOGRAPH SERIES, EDUCATIONAL LEGAL S DIFFERENT PUBLICATION FORMATS, MEDIA BRIEFING SEMINARS.	, PUBLIC LEGAL TUDIES, SEVEN S AND WEB	
-	(Grants and allocations \$ ) If this amou	Int includes foreign grants, check here	1,872,234.
Ş	EDUCATIONAL_MATERIAL_DISTRIBUTED_THROUGHOUT_T STATES_AT_NO_CHARGE_TO_THE_GENERAL_PUBLICT MATERIALS_DISCUSS_BROAD_ISSUES_OF_INTEREST_TO	HE UNITED	1,012,231
с .	(Grants and allocations \$ ) If this amou	Int includes foreign grants, check here	476,893.
d	(Grants and allocations \$ ) If this amou	Int includes foreign grants, check here	
	Other program services (attach schedule)	Int includes foreign grants, check here	
f	Total of Program Service Expenses (should equal line 44, column (		2,349,127.
-			Form <b>990</b> (2006)

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Part IV			<b>-</b>	
Note:	Where required, attached schedules and amounts within the description column should be for end-of-year amounts only	(A) Beginning of year		(B) End of year
45	Cash - non-interest-bearing	712,360.	45	<u>738,98</u>
46	Savings and temporary cash investments	12,289,956.	46	13,620,893
	Accounts receivable			
b	Less: allowance for doubtful accounts 47b		47c	
	Pledges receivable			
b	Less allowance for doubtful accounts 48b		48c	
49	Grants receivable		49	
50a	Receivables from current and former officers, directors, trustees, and key employees (attach schedule).		50a	
b	Receivables from other disqualified persons (as defined under section			
51a	4958(f)(1)) and persons described in section 4958(c)(3)(B) (attach schedule) Other notes and loans receivable (attach		50b	
d b	schedule)   51a     Less allowance for doubtful accounts   51b			
ξ			51c	_
	Inventories for sale or use		52	6 4
53	Prepaid expenses and deferred charges	16,940.		6,74
	Investments - publicly-traded securities _ STMT_6. ► Cost X FMV	2,490,132.		2,777,73
	Investments - other securities (attach schedule) Cost FMV Investments - land, buildings, and		54b	
	equipment basis			
Ь	Less. accumulated depreciation (attach			
	schedule)		55c	
56	Investments - other (attach schedule)		56	
			30	
	Land, buildings, and equipment basis 57a 4,125,588. Less: accumulated depreciation (attach			
	schedule)	2 510 015	570	0 500 00
58	Other assets, including program-related investments	2,510,815.	370	2,532,904
30	(describe ► STMT 7 )	307,823.	58	399,80'
59	Total assets (must equal line 74) Add lines 45 through 58	18,328,026.		20,077,060
60	Accounts payable and accrued expenses	28,319.		87,81
61	Grants payable		61	
62	Deferred revenue		62	
63 64a	Loans from officers, directors, trustees, and key employees (attach		63	
640	schedule)	· · ·	64a	
5 04a	Mortgages and other notes payable (attach schedule)		64b	
		1 007 507	1 1	1 200 044
65	Other liabilities (describe > )	1,237,507.	65	1,328,940
66	Total liabilities. Add lines 60 through 65	1,265,826.	66	1,416,752
Orga	anizations that follow SFAS 117, check here > x and complete lines			
	67 through 69 and lines 73 and 74.			
မ္ဗိ 67	Unrestricted	16,980,131.	67	18,578,24
68	Temporarily restricted		68	
69	Permanently restricted	82,069.	69	82,06
50 67 68 69 69 0rga 0 0rga 70 71 71 72 73	anizations that do not follow SFAS 117, check here ► and complete lines 70 through 74			
5 70	Capital stock, trust principal, or current funds		70	
2 71	Paid-in or capital surplus, or land, building, and equipment fund		71	
2 72	Retained earnings, endowment, accumulated income, or other funds	<del></del>	72	
73	Total net assets or fund balances (add lines 67 through 69 or lines			
NG.	70 through 72. (Column (A) must equal line 19 and column (B) must			
	equal line 21)	17,062,200.	73	18,660,314
74	Total liabilities and net assets/fund balances. Add lines 66 and 73	18,328,026.		20,077,066
				Form <b>990</b> (2006

Form	n 990 (2006)		52-1	07157	0		Page 5
Pa	rt IV-A Reconciliation of Revenue per Audited-Fi instructions.)	nancial Statemen				n (See	e the
а	Total revenue, gains, and other support per audited finance	al statements				а	5,068,384.
b	Amounts included on line a but not on Part I, line 12:						
1	Net unrealized gains on investments		<u>b1</u>		<u>212,209.</u>		
2	Donated services and use of facilities		<u>b2</u>	·			
3	Recoveries of prior year grants						
4	Other (specify):		I. I.				
						b	212,209.
с	Add lines b1 through b4						4,856,175.
d	Amounts included on Part I, line 12, but not on line a:						
1	Investment expenses not included on Part I, line 6b		d1				
2	Other (specify):						
			ام ا		<u>.</u>		
	Add lines d1 and d2					d	
e	Total revenue (Part I, line 12). Add lines c and d		 		<u> </u>	e	4,856,175.
Pa	rt IV-B Reconciliation of Expenses per Audited F						2 (70 270
а	Total expenses and losses per audited financial statements	•••••				a	3,470,270.
b	Amounts included on line a but not on Part I, line 17:		b1				
1	Donated services and use of facilities		•••••••••••••••••••••••••••••••••••••••				
2	Prior year adjustments reported on Part I, line 20 Losses reported on Part I, line 20		$\cdots$				
3 4	Other (specify):						
•							
	Add lines b1 through b4					b	
с	Subtract line b from line a					C	3,470,270.
d	Amounts included on Part I, line 17, but not on line a:		امدا			1	
1	Investment expenses not included on Part I, line 6b		<mark>d1</mark>				
2	Other (specify)		1.10			-	
						d	
е	Add lines d1 and d2		· · · · · · ·			е	3,470,270.
Pa	art V-A Current Officers, Directors, Trustees, and						r, director, trustee,
	or key employee at any time during the year eve				i		
	(A) Name and address	(B) Title and average hours per	(C) Compe (If not paid	i, enter	(D) Contributions to benefit plans & d	eferred	(E) Expense account and other allowances
		week devoted to position	-0)		compensation	plans	<u> </u>
		-					+
<u>56</u>	E STATEMENT 9						
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Form 990 (2006)

Form 9	990 (2006)				52-	1071570			Page 6
Par	t V-A	Current Officers, D	Directors, Trustees,	and Key Emplo				Yes	No
75a	Enter meetii	the total number of on ngs	officers, directors, and	trustees permitte	ed to vote on orga	anization business at bo	ard		
b	emplo contra	oyees listed in Sche actors listed in Sche	dule A, Part I, or edule A, Part II-A o	highest compen or II-B, related to	sated professiona b each other thr	A, or highest compensa Il and other independ rough family or busin the relationship(s)	ent ess	X	
С	compo indepo organ	ensated employees I endent contractors I izations, whether tax	isted in Schedule sted in Schedule exempt or taxable,	A, Part Í, or hig A, Part II-A or II that are related t	hest compensate -B, receive comp o the organization	0, Part V-A, or high od professional and ot oensation from any ot ? See the instructions	her her for		x
	If "Yes Does	s," attach a statement the organization have	that includes the info a written conflict of in	rmation described	in the instructions.	<u></u> .	75d		x
	1 1 1 5	E 0/2					<b>•</b> • •	_	

Part V-B Former Officers, Directors, Trustees, and Key Employees That Received Compensation or Other Benefits (If any former officer, director, trustee, or key employee received compensation or other benefits (described below) during the year, list that person below and enter the amount of compensation or other benefits in the appropriate column See the instructions.)

	(A) Name and address	(B) Loans and Advances	(C) Compensation (if not paid, enter -0-)	(D) Contributions to employee benefit plans & deferred compensation plans	accou	) Expension ( Int and lowance)	other
		-0-	-0-	-0-	-0-		
					<u>_</u>		
			· ·				
Par	t VI Other Information (See the instructions.)		·	I <u></u>		Yes	No
76	Did the organization make a change in its activities or detailed statement of each change	methods of condu	cting activities?	If "Yes," attach a	76		Э <b>ж</b>
77	Were any changes made in the organizing or governing d				77		х
	If "Yes," attach a conformed copy of the changes.						
78a	Did the organization have unrelated business gross inclusion						
<b>b</b>	this return?				78a		X
					78b	N/	
79	Was there a liquidation, dissolution, termination, or sub a statement				79		х
80a	Is the organization related (other than by association v common membership, governing bodies, trustees, o	fficers, etc., to ar	ny other exemi	ot or nonexempt	-1-1 80a	v	
h	organization?						
5				ot or nonexempt			
	Enter direct and indirect political expenditures (See line 8	1 instructions )	81a				50002 25 4 4 4
b	Did the organization file Form 1120-POL for this year?		<u></u>		81b	N	А

Form 990 (2006)

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Par	t VI Other Information Intinued)		Yes	No
82 a	Did the organization receive donated services or the use of materials, equipment, or facilities at no charge			
	or at substantially less than fair rental value?	82a	х	
	If "Yes," you may indicate the value of these items here. Do not include this amount			
	as revenue in Part I or as an expense in Part II (See instructions in Part III)			
	Did the organization comply with the public inspection requirements for returns and exemption applications?	83a	х	
	Did the organization comply with the disclosure requirements relating to quid pro quo contributions?	83b	x	
	Did the organization solicit any contributions or gifts that were not tax deductible?	84a	N/	<u> </u>
	If "Yes," did the organization include with every solicitation an express statement that such contributions or			<u></u>
		84b	N/	a
	gifts were not tax deductible?	85a	N/	
	Did the organization make only in-house lobbying expenditures of \$2,000 or less?	85b	N/	
	If "Yes" was answered to either 85a or 85b, do not complete 85c through 85h below unless the organization	0.50	_11/	<u>n</u>
	received a waiver for proxy tax owed for the prior year			
	Dues, assessments, and similar amounts from members			
	Section 162(e) lobbying and political expenditures	-		
	Aggregate nondeductible amount of section 6033(e)(1)(A) dues notices	-		1
	Taxable amount of lobbying and political expenditures (line 85d less 85e)			
	Does the organization elect to pay the section 6033(e) tax on the amount on line 85f?	85g	<u>N/</u>	<u>A</u>
	If section 6033(e)(1)(A) dues notices were sent, does the organization agree to add the amount on line 85f			
	to its reasonable estimate of dues allocable to nondeductible lobbying and political expenditures for the following tax year?	85h	N/	<u>A</u>
	501(c)(7) orgs. Enter a Initiation fees and capital contributions included on line 12			1
	Gross receipts, included on line 12, for public use of club facilities			
	501(c)(12) orgs Enter a Gross income from members or shareholders			
	Gross income from other sources (Do not net amounts due or paid to other			
	sources against amounts due or received from them )			÷
88b	At any time during the year, did the organization own a 50% or greater interest in a taxable corporation or			r
	partnership, or an entity disregarded as separate from the organization under Regulations sections			
	301 7701-2 and 301 7701-3? If "Yes," complete Part IX	88a		X
	At any time during the year, did the organization, directly or indirectly, own a controlled entity within the			
	meaning of section 512(b)(13)? If "Yes," complete Part XI	88b		X
	501(c)(3) organizations Enter Amount of tax imposed on the organization during the year under			
	section 4911			
b	501(c)(3) and 501(c)(4) orgs Did the organization engage in any section 4958 excess benefit transaction			
	during the year or did it become aware of an excess benefit transaction from a prior year? If "Yes," attach			
	a statement explaining each transaction	89b		х
С	Enter Amount of tax imposed on the organization managers or disqualified persons during the year under			
	sections 4912, 4955, and 4958			1
d	Enter Amount of tax on line 89c, above, reimbursed by the organization			
е	All organizations. At any time during the tax year, was the organization a party to a prohibited tax shelter			
	transaction?	89e		x
	All organizations. Did the organization acquire a direct or indirect interest in any applicable insurance contract?	89f		x
	For supporting organizations and sponsoring organizations maintaining donor advised funds Did the			
-	supporting organization, or a fund maintained by a sponsoring organization, have excess business holdings			
	at any time during the year?	89g		 Х
90a	List the states with which a copy of this return is filed DC, FL, MN, NJ, NY, VA,	<u> </u>		_ 43
	Number of employees employed in the pay period that includes March 12, 2006 (See instructions )	90b	11	
	The books are in care of ► <u>CONSTANCE C. LARCHER</u> Telephone no ► (202)			
		00-0	502	
	Located at ► 2009 MASSACHUSSETTS AVE., N.W. WASHINGTON, DC ZIP +4 ► 20036			
L	At any time during the calendar year, did the procession have an interest in an element with a the without any	ſ	Yes	Ne
	At any time during the calendar year, did the organization have an interest in or a signature or other authority over		res	
	a financial account in a foreign country (such as a bank account, securities account, or other financial account)?	91b		<u>x</u>
	If "Yes," enter the name of the foreign country			
	See the instructions for exceptions and filing requirements for Form TD F 90-22.1, Report of Foreign Bank and Financial Accounts			
		Form	990	(2006)

Part VI Other Information (continue	ed)			1071570		Page Yes N
c At any time during the calendar year,		ization maintain an	office outside o	f the United States?	91c	x
If "Yes," enter the name of the foreign 92 Section 4947(a)(1) nonexempt charite		a Form 990 in liqu	f Eorm 1041 - (	Chack hara	<u> </u>	۰L
and enter the amount of tax-exempt in					•••••	.►∟ NC
Part VII Analysis of Income-Produc						
ote: Enter gross amounts unless otherwise	Unrelate	ed business income	Excluded by	section 512, 513, or 514	(E)	
dicated	(A)	(B)	(C)	(D)	Related o exempt fund	
93 Program service revenue	Business code	Amount	Exclusion code	Amount	income	
a			_			
b			_			
c						
d e						
ef Medicare/Medicaid payments						
g Fees and contracts from government agencies				·		_
94 Membership dues and assessments						
95 Interest on savings and temporary cash investments •			14	519,921.		
<b>96</b> Dividends and interest from securities			14			
97 Net rental income or (loss) from real estate	<u> </u>					-
a debt-financed property	<u>├</u>					
<b>b</b> not debt-financed property						
<ul><li>98 Net rental income or (loss) from personal property</li><li>99 Other investment income</li></ul>				·	· · -	
00 Gain or (loss) from sales of assets other than inventory			18	-9,422.		
01 Net income or (loss) from special events .						
02 Gross profit or (loss) from sales of inventory						
03 Other revenue a						
b	<b>├</b> ──- <b>├</b>					
c					· -	
d			-			
04 Subtotal (add columns (B), (D), and (E)).				529,746.		
05 Total (add line 104, columns (B), (D), and (B	E))				52	9,74
later Line 105 plus line to Dent - hand	ten and a set of a set to	ne 12 Part I				
lote: Line 105 plus line 1e, Part I, should equal t					<del></del>	
Part VIII Relationship of Activities	to the Accon	nplishment of Ex				
Part VIII         Relationship of Activities t           Line No.         Explain how each activity for which	to the Accon	nplishment of Ex orted in column (E) o	f Part VII contribu			
Part VIII Relationship of Activities	to the Accon	nplishment of Ex orted in column (E) o	f Part VII contribu			
Part VIII         Relationship of Activities t           Line No.         Explain how each activity for which	to the Accon	nplishment of Ex orted in column (E) o	f Part VII contribu			
Part VIII         Relationship of Activities t           Line No.         Explain how each activity for which	to the Accon	nplishment of Ex orted in column (E) o	f Part VII contribu			
Part VIII Relationship of Activities to Line No. ▼ of the organization's exempt purpos	to the Accon n income is repo ses (other than	nplishment of Ex orted in column (E) o by providing funds for	f Part VII contribu such purposes)	ted importantly to the accom		
Part VIII Relationship of Activities to Line No. ▼ of the organization's exempt purpose Part IX Information Regarding Taxa	to the Accon n income is repo ses (other than	nplishment of Ex orted in column (E) o by providing funds for aries and Disrega	f Part VII contribu such purposes) arded Entities	(See the instructions.)		
Part VIII Relationship of Activities ( Line No. ▼ of the organization's exempt purpor Part IX Information Regarding Taxa (A) Name, address, and EIN of corporation,	to the Accon n income is repo ses (other than able Subsidia	nplishment of Ex orted in column (E) o by providing funds for aries and Disrega (B) Percentage of Na	f Part VII contribu such purposes) arded Entities (C)	ted importantly to the accom	plishment	
Part VIII Relationship of Activities to Line No. ▼ of the organization's exempt purpos Part IX Information Regarding Taxa (A)	to the Accon n income is repo ses (other than able Subsidia	aries and Disrega (B) Percentage of wnership interest	f Part VII contribu such purposes) arded Entities	(See the instructions.)		ar
Part VIII Relationship of Activities ( Line No. ▼ of the organization's exempt purpor Part IX Information Regarding Taxa (A) Name, address, and EIN of corporation,	to the Accon n income is repo ses (other than able Subsidia	nplishment of Ex orted in column (E) o by providing funds for aries and Disrega (B) Percentage of Na	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII Relationship of Activities ( Line No. ▼ of the organization's exempt purpor Part IX Information Regarding Taxa (A) Name, address, and EIN of corporation,	to the Accon n income is repo ses (other than able Subsidia	aries and Disrega (B) Percentage of wnership interest	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII Relationship of Activities ( Line No. ▼ of the organization's exempt purpor Part IX Information Regarding Taxa (A) Name, address, and EIN of corporation,	to the Accon n income is repo ses (other than able Subsidia	aries and Disrega (B) Percentage of wnership interest	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII Relationship of Activities ( Line No. ▼ of the organization's exempt purpor Part IX Information Regarding Taxa (A) Name, address, and EIN of corporation,	to the Accon n income is repo ses (other than able Subsidia	nplishment of Ex orted in column (E) of by providing funds for aries and Disrega (B) Percentage of winership interest % of of of of of of of of of of of of of	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purpor         ▼       of the organization's exempt purpor         Part IX       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (a) Did the organization, during the year, receive a	to the Accon n income is repo ses (other than able Subsidia on nsfers Assoc	nplishment of Ex priced in column (E) of by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with priceity, to p	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purportion of the organization's exempt purportion.         ▼       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (         (a)       Did the organization, during the year, receive a         (b)       Did the organization, during the year	to the Accon n income is repo ses (other than able Subsidia able Subsidia or nsfers Assoc ny funds, directly or , pay premiur	nplishment of Ex prted in column (E) o by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with prindirectly, to p ms, directly	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purpor         ▼       of the organization's exempt purpor         Part IX       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (a) Did the organization, during the year, receive a	to the Accon n income is repo ses (other than able Subsidia able Subsidia or nsfers Assoc ny funds, directly or , pay premiur	nplishment of Ex prted in column (E) o by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with prindirectly, to p ms, directly	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purportion of the organization's exempt purportion.         ▼       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (         (a)       Did the organization, during the year, receive a         (b)       Did the organization, during the year	to the Accon n income is repo ses (other than able Subsidia able Subsidia or nsfers Assoc ny funds, directly or , pay premiur	nplishment of Ex prted in column (E) o by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with prindirectly, to p ms, directly	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purportion of the organization's exempt purportion.         ▼       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (         (a)       Did the organization, during the year, receive a         (b)       Did the organization, during the year	to the Accon n income is repo ses (other than able Subsidia able Subsidia or nsfers Assoc ny funds, directly or , pay premiur	nplishment of Ex prted in column (E) o by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with prindirectly, to p ms, directly	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purportion of the organization's exempt purportion.         ▼       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (         (a)       Did the organization, during the year, receive a         (b)       Did the organization, during the year	to the Accon n income is repo ses (other than able Subsidia able Subsidia or nsfers Assoc ny funds, directly or , pay premiur	nplishment of Ex prted in column (E) o by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with prindirectly, to p ms, directly	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar
Part VIII       Relationship of Activities (         Line No.       Explain how each activity for which of the organization's exempt purportion of the organization's exempt purportion.         ▼       Information Regarding Taxa (A)         Name, address, and EIN of corporation, partnership, or disregarded entity         Part X       Information Regarding Transition (         (a)       Did the organization, during the year, receive a         (b)       Did the organization, during the year	to the Accon n income is repo ses (other than able Subsidia able Subsidia or nsfers Assoc ny funds, directly or , pay premiur	nplishment of Ex prted in column (E) o by providing funds for aries and Disrega (B) Percentage of winership interest % ciated with prindirectly, to p ms, directly	f Part VII contribu such purposes) arded Entities (C)	(See the instructions.)	plishment	ar

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Form 990 (20	,		52-1071			Page <b>9</b>
Part XI	Information Regarding	Transfers To and From C ation as defined in section	Controlled Entities. Complet	e only if the organization		_
					Yes	No
106 D	id the reporting organizatio	n make any transfers to a c	ontrolled entity as defined in se	ction 512(b)(13) of	103	
		e the schedule below for each				x
	(A)	(B)	(C)	(D)		
	Name, address, of each controlled entity	Employer Identification	Description of	Amount of trans	sfer	
		Number	transfer			
a						
			<u></u>			
ь 						
c						
	Totals					
				l	Yes	No
107 D	id the reporting organizatio	n receive any transfers fron	a controlled entity as defined	in section		
5^		1 · · · · · · · · · · · · · · · · · · ·	e below for each controlled entity	/		x
	(A) Name, address, of each	(B) Employer Identification	(C) Description of	(D)		
	controlled entity	Number	transfer	Amount of trans	sfer	
	· <b>-</b>					
a						
	<u></u>					
b						
c						
	Totals		۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰			
<u> </u>						·
400 0			Karl an A. and A. 2000		Yes	No
	•	s described in question 107	ffect on August 17, 2006, cove above?	ring the interest,		x
	Under penalties of perjury, I o	leclare that I have examined this re	etum, including accompanying schedule			·
Please	and belief, it is true, correct,	and complete Declaration of prepa	arer (other than officer) is based on all info	rmation of which preparer has any kn	owledge	
Sign	Signature of officer	Carden	Date	1-14-07		
Here	Inals Taylor	1) Alottal Disting	IT + FKE CUTVE DI	loctal		
	Type or print name and ti		Date			
Paid	Preparer's	1772	Date Check if self-	Preparer's SSN or PTIN (See G	en Inst	X)
Preparer's		file Dem	1/14/07 employed ►			
Use Only	If self-employed)	BOND BEEBE		EIN 52-10441		
		4600 EAST-WEST HIGH	<u>IWAY SUITE 900</u> 20814-342		<u>.6000</u> 1 <b>990</b>	
		BETHESDA, MD	20014-342			(2000)

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### SCHEDULE A

(Form 990 or 990-EZ)

Department of the Treasury Internal Revenue Service Name of the organization



Organization Exempt Under Section 501(c)( (Except Private Foundation) and Section 501(e), 501(f), 501(k), 501(n), or 4947(a)(1)-Nonexempt Charitable-Trust

Supplementary Information - (See separate instructions.) MUST be completed by the above organizations and attached to their Form 990 or 990-EZ

OMB No 1545-0047

Employer identification number

WASHINGTON LEGAL FOUNDATION

52-1071570

Part I Compensation of the Five Highes (See page 2 of the instructions. List e	st Paid Employe ach one. If there a	es O re no	ther Than Off ne, enter "None	f <b>icers, Direc</b> e.")	tors, a	nd Trustees	
(a) Name and address of each employee paid more than \$50,000	(b) Title and average he per week devoted to po		(c) Compensation	(d) Contribution employee benefit deferred competition	t plans &	(e) Expense account and other allowances	
BINDU BALAN	DIRECTOR OF ADMIN				.		
2009 MASSACHUSETTS AVE., N.W.	45.00		57,917.	3,3	39.*	NONE	
PAUL D. KAMENAR	SENIOR EXEC. COUNS	3L					
2009 MASSACHUSETTS AVE., N.W.	45.00		135,000.	119,9	956.	NONE	
GLENN G. LAMMI	CHEIF COUNS./LEGAL						
2009 MASSACHUSETTS AVE., N.W.	45.00		143,000.	8,0	)65.*	NONE	
RICHARD A. SAMP	CHEIF COUNSEL						
2009 MASSACHUSETTS AVE., N.W.	45.00		153,333.	16,0	)56.*	NONE	
Total number of other employees paid over \$50,000 ►	NONE						
Part II-A Compensation of the Five Higher (See page 2 of the instructions. List e	each one (whether	<b>lent</b> indiv	Contractors f iduals or firms)	or Professi	onal Senone, e	e <b>rvices</b> nter "None.")	
(a) Name and address of each independent contractor paid	more than \$50,000		(b) Type of service		(0	) Compensation	
BOND BEEBE, P.C.							
BETHESDA, MD 20814-3423		ACCOUNTING			81,118.		
Total number of others receiving over \$50,000 for professional services	NONE						
Part II-B Compensation of the Five Highe (List each contractor who performed firms. If there are none, enter "None.	I services other tha	n pro	fessional servi				
(a) Name and address of each independent contractor paid	more than \$50,000		(b) Type of se	rvice	(0	) Compensation	
NONE							

	1		 (,,
NONE			
Total number of other contractors rece			· · · · · · · · · · · · · · ·
\$50,000 for other services	<u></u> <b>.</b> •	NONE	

For Paperwork Reduction Act Notice, see the Instructions for Form 990 and Form 990-EZ.

Schedule A (Form 990 or 990-EZ) 2006

\*These figures are not actual contributions made, but only actuarial projections for retirement plans based upon retirement age.

JSA 6E1210 2 000

Sche	adule A (Form 990 or 990-EZ) 52-1071570		F	age 2
Pa	Statements About Activities (See page 2 of the instructions.)		Yes	No
1	During the year, has the organization attempted to influence national, state, or local legislation, including any attempt to influence public opinion on a legislative matter or referendum? If "Yes," enter the total expenses paid or incurred in connection with the lobbying activities ► \$ (Must equal amounts on line 38, Part VI-A, or line i of Part VI-B).	1		x
	Organizations that made an election under section 501(h) by filing Form 5768 must complete Part VI-A Other organizations checking "Yes" must complete Part VI-B AND attach a statement giving a detailed description of the lobbying activities			
2	During the year, has the organization, either directly or indirectly, engaged in any of the following acts with any substantial contributors, trustees, directors, officers, creators, key employees, or members of their families, or with any taxable organization with which any such person is affiliated as an officer, director, trustee, majority owner, or principal beneficiary? (If the answer to any question is "Yes," attach a detailed statement explaining the transactions )			
а	Sale, exchange, or leasing of property?	2a		x
b	Lending of money or other extension of credit?	2b		x
с	Furnishing of goods, services, or facilities?	2c	<u>.</u>	x
d	Payment of compensation (or payment or reimbursement of expenses if more than \$1,000)?	2d	x	
e	Transfer of any part of its income or assets?	2e		x
3a	Did the organization make grants for scholarships, fellowships, student loans, etc? (If "Yes," attach an explanation of how the organization determines that recipients qualify to receive payments)	3a		<u>x</u>
b	Did the organization have a section 403(b) annuity plan for its employees?	3b	-	<u>x</u>
c	Did the organization receive or hold an easement for conservation purposes, including easements to preserve open space, the environment, historic land areas or historic structures? If "Yes," attach a detailed statement	3c		<u>x</u>
d	Did the organization provide credit counseling, debt management, credit repair, or debt negotiation services?	3d		<u>x</u>
4a	Did the organization maintain any donor advised funds? If "Yes," complete lines 4b through 4g If "No," complete			
b	lines 4f and 4g	4a 4b		X X
с	Did the organization make a distribution to a donor, donor advisor, or related person?	4c		x
d	Enter the total number or donor advised funds owned at the end of the tax year			
e	Enter the aggregate value of assets held in all donor advised funds owned at the end of the tax year			
f	Enter the total number of separate funds or accounts owned at the end of the tax year (excluding donor advised funds included on line 4d) where donors have the rights to provide advice on the distribution or investment of amounts in such funds or accounts		_	
g	Enter the aggregate value of assets held in all funds or accounts included on line 4f at the end of the tax year			

Schedule A (Form 990 or 990-EZ) 2006

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Schedule A (	Form 990 or 990-EZ) 2006			52-107157	0	Page 3		
Part IV	Reason for Reason For	undation Statu	<b>is</b> (See pages 4 thr	ough 7 of th	e instructions	.)		
certify that	t the organization is not a private foundati	ion because it is (Plea	ase check only ONE app	icable box.)				
5	A church, convention of churches, or ass	ociation of churches	Section 170(b)(1)(A)(i)					
6	6 A school Section 170(b)(1)(A)(II) (Also complete Part V)							
7	7 A hospital or a cooperative hospital service organization Section 170(b)(1)(A)(III).							
8	8 A federal, state, or local government or governmental unit Section 170(b)(1)(A)(v)							
	9 A medical research organization operated in conjunction with a hospital Section 170(b)(1)(A)(III) Enter the hospital's name, city, and state ▶							
	An organization operated for the benefit of Also complete the Support Schedule in F	-	rsity owned or operated I	by a governmen	tal unit Section 1	70(b)(1)(A)(ıv)		
	An organization that normally receives a 170(b)(1)(A)(vi) (Also complete the Supp			rnmental unit	or from the gene	eral public Section		
11b	A community trust Section 170(b)(1)(A)(	vi) (Also complete the	e Support Schedule in F	Part IV-A)				
12 An organization that normally receives (1) more than 33 1/3% of its support from contributions, membership fees, and gross receipts from activities related to its charitable, etc., functions - subject to certain exceptions, and (2) no more than 33 1/3% of its support from gross investment income and unrelated business taxable income (less section 511 tax) from businesses acquired by the by the organization after June 30, 1975 See section 509(a)(2) (Also complete the Support Schedule in Part IV-A.)								
	An organization that is not controlled the requirements of section 509(a)(3) Cl					otherwise meets		
[	Туре I Туре II	Type III - Fur	nctionally Integrated	Type III -	Other			
	Provide the following information	about the supported	organizations. (See pag	e 7 of the instru	uctions)			
(a) Name(s) of supported organization(s)		(b) Employer identification number (EIN)	(c) Type of organization (described in lines 5 through 12 above or IRC section)	ofIs the supportedationorganization listed inin linesthe supportinggh 12organization'sr IRCgoverning documents?		(e) Amount of support		
				Yes	No			
			· · · · · · · · · · · · · · · · · · ·		 			
Total · · ·				L	<u> </u>			
	n organization organized and operated to							

Schedule A (Form 990 or 990-EZ) 2006

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	edule A (Form 990 or 990-EZ) 2006			52-1071570		Page <b>4</b>
	rt IV-A Support Sched					ng.
	e: You may use the worksheet in the instruction	ns for converting fr	om the accrual to t	he cash method of	accounting.	
	endar year (or fiscal year beginning in)	(a) 2005	(b) 2004	(c) 2003	(d) 2002	(e) Total
15	Gifts, grants, and contributions received (Do					
40	not include unusual grants See line 28)	3,748,260.	4,779,110.	5,972,010.	4,349,270	. 18,848,650.
	Membership fees received				· · · · · · · · · · · · · · · · · · ·	
17	Gross receipts from admissions, merchandise					
	sold or services performed, or furnishing of					
	facilities in any activity that is related to the					
	organization's charitable, etc., purpose					
18	Gross income from interest, dividends,					
	amounts received from payments on securities					
	loans (section 512(a)(5)), rents, royalties, and					
	unrelated business taxable income (less					
	section 511 taxes) from businesses acquired					
	by the organization after June 30, 1975	364,549.	226,230.	226,231.	262,129	. 1,079,139.
19	Net income from unrelated business					
	activities not included in line 18					<u> </u>
20	Tax revenues levied for the organization's					
	benefit and either paid to it or expended on					
	its behalf					
21			:			
	the organization by a governmental unit		:			
	without charge Do not include the value of		1			
	services or facilities generally furnished to the					
	public without charge					
22	Other income Attach a schedule Do not	STMT 12				
	include gain or (loss) from sale of capital assets			5,989.	8,056	. 14,045.
23	Total of lines 15 through 22	4,112,809.	5,005,340.	6,204,230.	4,619,455	<u>. 19,941,834.</u>
24	Line 23 minus line 17	4,112,809.	5,005,340.	6,204,230.	4,619,455	. 19,941,834.
25	Enter 1% of line 23	41,128.	50,053.	62,042.	46,195	
		Enter 2% of amount				398,837.
Ł	Prepare a list for your records to show the i					
	governmental unit or publicly supported organi					
	amount shown in line 26a Do not file this li	•	n. Enter the total	of all these excess	amounts 🕨 261	
	Total support for section 509(a)(1) test Enter line 24				• 260	19,941,834.
c	Add Amounts from column (e) for lines 18					
						2,526,822.
e	Public support (line 26c minus line 26d total)				<b>▶</b> <u>26</u> €	17,415,012.
- f	Public support percentage (line 26e (numerator) of Organizations described on line 12: a For	livided by line 26c (de	enominator))	•••••	► 26f	87.3290 %
21	person," prepare a list for your records to sho	ow the name of, a	and total amounts	received in each	year from, each	"disqualified person "
	Do not file this list with your return. Enter the sum	of such amounts for	each year		-	
	NOT APPLICABLE					
	(2005) (2004)		(2003)		(2002)	
b	For any amount included in line 17 that was re-					
	show the name of, and amount received for each (Include in the list organizations described in line					
	the difference between the amount received an					
	amounts) for each year					
	(2005) (2004)		(2003)		(2002)	
С	Add Amounts from column (e) for lines         15           17         20		š		I	1
	17 20	2*		•••••••	···· ► 270	·
d	Add Line 27a total.	and line 27b total .	•	• • • • • • • • •	🕨 270	·
	Public support (line 27c total minus line 27d total).					
f	Total support for section 509(a)(2) test Enter amou Public support percentage (line 27e (numerator) of	nt from line 23, colum	n (e)	▶ <u>27f</u>		
g	Public support percentage (line 27e (numerator) of	livided by line 27f (de	enominator))		···· ► 27 g	<u>%</u>
h	Investment income percentage (line 18, column (	e) (numerator) divide	d by line 27f (denom	inator))	🕨 27t	N %
28	Unusual Grants: For an organization describe prepare a list for your records to show, for					
	description of the nature of the grant Do not file thi					• • • •
10.4					Cabadula A /E	m 000 or 000 E7) 2000

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Schedule A (Form 990 or 990-EZ) 2006

Sche	dule A (Form 990 or 990-EZ) 2006 52-1071570		F	Page 5
Par		ABLE	_	
29	Does the organization have a racially nondiscriminatory policy toward students by statement in its charter, bylaws,	ł	Yes	No
30	other governing instrument, or in a resolution of its governing body? Does the organization include a statement of its racially nondiscriminatory policy toward students in all its	29		
20	brochures, catalogues, and other written communications with the public dealing with student admissions,			
	programs, and scholarships?	30		
31	Has the organization publicized its racially nondiscriminatory policy through newspaper or broadcast media during			
	the period of solicitation for students, or during the registration period if it has no solicitation program, in a way			
	that makes the policy known to all parts of the general community it serves? If "Yes," please describe, if "No," please explain (If you need more space, attach a separate statement)	31		<u> </u>
32	Does the organization maintain the following			
	Records indicating the racial composition of the student body, faculty, and administrative staff?	32a	_	
	Records documenting that scholarships and other financial assistance are awarded on a racially nondiscriminatory basis?			
с	Copies of all catalogues, brochures, announcements, and other written communications to the public dealing	32b		
-	with student admissions, programs, and scholarships?	32c		
d	Copies of all material used by the organization or on its behalf to solicit contributions?	32d		
	If you answered "No" to any of the above, please explain. (If you need more space, attach a separate statement)			
33	Does the organization discriminate by race in any way with respect to			
а	Students' rights or privileges?	33a	-	
b	Admissions policies?	33b		
С	Employment of faculty or administrative staff?	33c		
	Scholarships or other financial assistance?	33d		
e	Educational policies?	33e		
f	Use of facilities?	33f		
g	Athletic programs?	33g		
h	Other extracurricular activities?	<u>33h</u>		
	If you answered "Yes" to any of the above, please explain (If you need more space, attach a separate statement.)			
34 a	Does the organization receive any financial aid or assistance from a governmental agency?	34a		
b	Has the organization's right to such aid ever been revoked or suspended?	34b		
35	Does the organization certify that it has complied with the applicable requirements of sections 4 01 through 4 05 of Rev. Proc. 75-50, 1975-2 C B 587, covering racial nondiscrimination? If "No," attach an explanation	35		

Schedule A (Form 990 or 990-EZ) 2006

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Sche	dule A (Form 990 or 990 006	52-10	71570	Page <b>o</b>
Par	t VI-A Lobbying Expenditures by Electing Public Charities (See page 1)	0 of th	ne instructions.)	
	(To be completed ONLY by an eligible organization that filed Form	n 5768	B) NOT APPLICA	BLE
Chec	k la a lif the organization belongs to an affiliated group Check b b lif you	checke	d "a" and "limited coi	ntrol" provisions apply.
	Limits on Lobbying Expenditures		(a) Affiliated group totals	(b) To be completed for all electing
	(The term "expenditures" means amounts paid or incurred )			organizations
36	Total lobbying expenditures to influence public opinion (grassroots lobbying) $\ldots$	36		
	Total lobbying expenditures to influence a legislative body (direct lobbying)	37		
38	Total lobbying expenditures (add lines 36 and 37)	38	<u> </u>	
39	Other exempt purpose expenditures	39		
40	Total exempt purpose expenditures (add lines 38 and 39)	40		
41	Lobbying nontaxable amount. Enter the amount from the following table -			
	If the amount on line 40 is - The lobbying nontaxable amount is -			
	Not over \$500,000			
	Over \$500,000 but not over \$1,000,000 \$100,000 plus 15% of the excess over \$500,000			
	Over \$1,000,000 but not over \$1,500,000 \$175,000 plus 10% of the excess over \$1,000,000	41		
	Over \$1,500,000 but not over \$17,000,000 \$225,000 plus 5% of the excess over \$1,500,000			
	Over \$17,000,000			
42	Grassroots nontaxable amount (enter 25% of line 41)	42		
43	Subtract line 42 from line 36 Enter -0- if line 42 is more than line 36	43	· · · · · · · · · · · · · · · · · · ·	
	Subtract line 41 from line 38. Enter -0- if line 41 is more than line 38	44		
		· ·		<u> </u>

Caution: If there is an amount on either line 43 or line 44, you must file Form 4720.

4-Year Averaging Period Under Section 501(h)

(Some organizations that made a section 501(h) election do not have to complete all of the five columns below. See the instructions for lines 45 through 50 on page 13 of the instructions )

		Lobbying Expenditures During 4-Year Averaging						
	Calendar year (or fiscal	(a)	(b)	(c)	(	d)		(e)
	year beginning in) 🕨	2006	2005	2004	20	03		Total
	Lobbying nontaxable		,					
<u>45</u>	amount							
	Lobbying ceiling amount							
46	(150% of line 45(e))							
47	Total lobbying expenditures							
	Grassroots nontaxable							
48	amount							
	Grassroots ceiling amount							
49	(150% of line 48(e))							
	Grassroots lobbying							
50	expenditures							
Pa			ing Public Charities ations that did not co				ICABI	
	ng the year, did the organ	•	· · · · · · · · · · · · · · · · · · ·	<b>.</b>	any	Yes	No	Amount
	mpt to influence public opi		-					
а	Volunteers					ļ		
b	Paid staff or managem	ient (Include compens	sation in expenses rep	orted on lines c throu	ughh)			-
С	Media advertisements							
d	Mailings to members,	legislators, or the pub	lic					· · ·
е	Publications, or publish	ned or broadcast state	ments					
f	Grants to other organiz	zations for lobbying pu	irposes					
g	Direct contact with legi	islators, their staffs, g	overnment officials, o	r a legislative body				
h	Rallies, demonstration							
i	Total lobbying expendi	tures (Add lines c thro	ough h )					
	If "Yes" to any of the a					livities		

JSA 6E1240 2 000

Schedule A (Form 990 or 990-EZ) 2006

Sch		m 990 or 990-EZ) 2006		52-1071570		Page 7
Pa		Information garding Exempt Organizations	Transfers To and Transactions and (See page 13 of the instructions.)	d Relationships With Charitabl	le	
<b>5</b> 1	Did the re	porting organization direc	tly or indirectly engage in any of the foll	owing with any other organization desc	ribed in s	ection
	501(c) of	the Code (other than sect	ion 501(c)(3) organizations) or in section	in 527, relating to political organizations	?	
а	Transfers	from the reporting organi	zation to a noncharitable exempt organiz	zation of	Y	es No
	(i) Cash	•••••••			51a(i)	X
	(ii) Othe	r assets			a(ii)	<u>x</u>
b	Other tran					
	(i) Sale	s or exchanges of assets	with a noncharitable exempt organization	n	_b(i)	<u> </u>
	(ii) Purc	hases of assets from a ne	oncharitable exempt organization		b(ii)	<u> </u>
	(iii) Rent	al of facilities, equipment,	or other assets		b(iii)	<u> </u>
	(iv) Rem	bursement arrangements			<u>b(iv)</u> b(v)	<u> </u>
	<ul> <li>(v) Loans or loan guarantees</li> <li>(vi) Performance of services or membership or fundraising solicitations</li> </ul>					<u> </u>
_	(VI) Perio	ormance of services or m	embership or fundraising solicitations		b(vi)	<u> </u>
			ling lists, other assets, or paid employee			x
a			s," complete the following schedule Column y the reporting organization If the organization		of the	
	-	-	by in column (d) the value of the goods, other			
	(a)	(b)	(c)	(d)		
	Line no	Amount involved	Name of noncharitable exempt organization	Description of transfers, transactions, and sha	anng arrange	ements
51	С		BUSINESS CIVIL	ONE FILE DRAWER OF ADMIN	ISTRA-	
			LIBERTIES, INC.	TIVE FILES LOCATED IN TH	E	
			(501(C)(4))	ADMINISTRATIVE OFFICE		
					· <u> </u>	

52a	Is the organization directly or indirectly affiliated with, or related to, one or more tax-exempt organizations		
	described in section 501(c) of the Code (other than section 501(c)(3)) or in section 527?	▶ 🔀 Yes	No

b If "Yes," complete the following schedule

(a) Name of organization	(b) Type of organization	(c) Description of relationship
BUSINESS CIVIL	ADVOCATE FOR	COMMON DIRECTORS
LIBERTIES, INC.	BUSINESS CIVIL	
(501(C)(4))	LIBERTIES	
· · · · · · · · ·		
	· · · · · · · · · · · · · · · · · · ·	
<u> </u>		

Schedule A (Form 990 or 990-EZ) 2006

- - - - - -

\_\_\_\_\_

FEDERAL FOOTNOTES

- -

\_\_\_\_

ATTACHMENT FORM 990, PART I, LINE 1

A SCHEDULE OF CONTRIBUTIONS, NOT OPEN TO PUBLIC INSPECTION, IS ATTACHED AS FORM 990, SCHEDULE B.

NO CONTRIBUTIONS WERE RAISED BY PROFESSIONAL FUNDRAISERS.

STATEMENT 1

4817 11/12/2007 12:25:22 V06-5.4 WA7820

FEDERAL FOOTNOTES =======================

> ATTACHMENT FORM 990, PART I, LINE 8(A)

THE FOUNDATION SOLD AND REDEEMED SHARES AND UNITS OF PUBLICLY TRADED SECURITIES AND U.S. GOVERNMENT OBLIGATIONS. AS SPECIFIED IN THE INSTRUCTIONS TO FORM 990, THE GROSS PROCEEDS, COST BASIS AND NET LOSS

ARE REPORTED AS LUMP-SUM FIGURES.

STATEMENT 2

4817 11/12/2007 12:25:22 V06-5.4 WA7820

# FORM 990, PART I - OTHER INCREASES IN FUND BALANCES

# DESCRIPTION

-

AMOUNT

## NET UNREALIZED GAINS ON INVESTMENTS

212,209.

212,209.

TOTAL

STATEMENT 3

4817 11/12/2007 12:25:22 V06-5.4 WA7820

## Washington Legal Foundation EIN: 52-1071570 Year Ended December 31, 2006

## Attachment Form 990, Part II, Line 42 Form 990, Part IV, Line 57

	Balance at 12/31/05	Additions	Deletions	Balance at 12/31/06
Furniture	236,908			236,908
Equipment	471,251	17,272		488,523
Building and Land	3,321,003	79,154	<u>.</u>	3,400,157
Totals	4,029,162	96,426	0	4,125,588
Accum Depr - Furniture	233,962	39,524		273,486
Accum Depr - Equipment	306,617	22,778		329,395
Accum Depr - Building	977,768	12,033		989,801
	1,518,347	74,335	0	1,592,682
	2,510,815		=	2,532,906

FORM 990, PART III - ORGANIZATION'S PRIMARY EXEMPT PURPOSE

THE FOUNDATION SERVES THE PUBLIC INTEREST THROUGH LITIGATION AND REPRESENTATION, LEGAL PUBLIC POLICY ANALYSIS, INTERN PROGRAMS, RESEARCH AND BRIEFS, MONOGRAPHS, EDUCATIONAL MATERIALS, MEDIA BRIEFINGS AND WEB SEMINARS.

STATEMENT 5

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# WASHINGTON LEGAL FOUNDATION

52-1071570

FORM 990, PART IV - INVESTMENTS - PUBLICLY TRADED SECURITIES

	ENDING
DESCRIPTION	BOOK VALUE
	~ <b></b> -
PUBLICLY TRADED SECURITIES CORPORATE BONDS CORPORATE STOCK (<5% OWNER) FOREIGN BONDS MUTUAL FUNDS U.S. GOVERNMENT OBLIGATIONS	298,993. 1,448,540. 31,185. 599,019. 400,000.
TOTALS	2,777,737.
	=======================================

STATEMENT 6

4817 11/12/2007 12:25:22 V06-5.4 WA7820

## WASHINGTON LEGAL COUNDATION

FORM 990, PART IV - OTHER ASSETS

#### DESCRIPTION

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\_\_\_\_\_

ACCRUED INTEREST RECEIVABLE CASH SURRENDER VALUE OF LIFE INSURANCE

TOTALS

52-1071570

ENDING BOOK VALUE

\_\_\_\_

106,118.

293,689.

399,807.

\_\_\_\_

STATEMENT 7

4817 11/12/2007 12:25:22 V06-5.4 WA7820

## WASHINGTON LEGAL FOUNDATION

FORM 990, PART IV - OTHER LIABILITIES

#### DESCRIPTION

-

\_\_\_\_\_

ACCRUED EMPLOYEE BENEFITS ACCRUED PENSION LIABILITY

TOTALS

52-1071570

ENDING BOOK VALUE

410,860.

918,080.

1,328,940.

STATEMENT 8

4817 11/12/2007 12:25:22 V06-5.4 WA7820

#### WASHINGTON LEGAL FOUNDATION

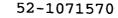
#### 52-1071570

# FORM 990, PART V-A - CURRENT OFFICERS, DIRECTORS, AND TRUSTEES

			CONTRIBUTIONS	EXPENSE ACCT
	TITLE AND TIME		TO EMPLOYEE	AND OTHER
NAME AND ADDRESS	DEVOTED TO POSITION	COMPENSATION	BENEFIT PLANS	ALLOWANCES

SEE ATTACHED SCHEDULE

\_



FORM 990, PART VI - NAMES OF RELATED ORGANIZATIONS

-

RELATED	ORGANIZATION NAME:	AMERICAN LEGAL FOUNDATION
EXEMPT:	X NONEXEMPT:	
RELATED	ORGANIZATION NAME:	BUSINESS CIVIL LIBERTIES
EXEMPT:	X NONEXEMPT:	
RELATED	ORGANIZATION NAME:	UNITED STATES LEGAL FOUNDATION
EXEMPT:	X NONEXEMPT:	

STATEMENT 10

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SCHEDULE A, PART III - EXPLANATION FOR LINE 2D

SEE FORM 990, PART V. THE FOUNDATION REIMBURSED FULLY-ACCOUNTED EXPENSES FOR ORDINARY AND NECESSARY OPERATIONAL PURPOSES. THE FOUNDATION DID NOT PROVIDE A NONACCOUNTABLE EXPENSE ACCOUNT OR ALLOWANCE TO ANY DISQUALIFIED PERSON.

STATEMENT 11

4817 11/12/2007 12:25:22 V06-5.4 WA7820

52-1071570

# SCHEDULE A, PART IV-A - OTHER INCOME

DESCRIPTION	2005	2004	2003	2002	TOTAL
					'
OTHER INCOME			5,989.	8,056.	14,045.
TOTALS			5,989.	8,056.	14,045.
		=======================================		============	

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FEDERAL FOOTNOTES

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ATTACHMENT FORM 990, PART VI, LINE 82

THE FOUNDATION RECEIVED DONATED SERVICES VALUED AT HUNDREDS OF THOUSANDS OF DOLLARS.

STATEMENT 3

4817 11/12/2007 12:25:22 V06-5.4 WA7820

FEDERAL FOOTNOTES

#### ATTACHMENT

-

FORM 990, PART V-A, LINE 75B

TWO OF THE DIRECTORS LISTED UNDER PART V, DANIEL J. POPEO AND JOHN POPEO ARE RELATED.

#### STATEMENT 4

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WASHINGTON LEGAL FOUNDATION 52-1071570

### ATTACHMENT FORM 990, PART V

Name and address	Title and average hours per week devoted to position	Compensation	Contributions to employee benefit plans	Expense account and other allowances
DANIEL J. POPEO 2009 MASSACHUSETTS AVENUE, NW WASHINTON, DC 20036	CHAIRMAN/ DIRECTOR 45 HOURS	332,698	148,922 *	NONE
CONSTANCE C. LARCHER 2009 MASSACHUSETTS AVENUE, NW WASHINTON, DC 20036	PRESTREAS. DIRECTOR 45 HOURS	291,365	181,531 *	NONE
JOHN POPEO 2009 MASSACHUSETTS AVENUE, NW WASHINTON, DC 20036	DIRECTOR 3 HOURS	NONE	NONE	NONE

\* THESE FIGURES ARE NOT ACTUAL CONTRIBUTIONS MADE, BUT ONLY ACTUARIAL PROJECTIONS FOR RETIREMENT PLANS BASED UPON RETIREMENT AGE.

NO COMPENSATION IS PAID TO ANY DIRECTOR FOR THEIR SERVICES AS A DIRECTOR.

January 17, 2007

# YEARLY ACTIVITIES REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

The ideals upon which America was founded - individual freedom, limited government, free market economy, and a strong national security and defense - are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. WLF's overriding mission is to defend and promote freedom and justice. WLF engaged in the following activities in support of this mission during 2006.

# **COURT PROCEEDINGS**

NATIONAL SECURITY -- INTERCEPTING ELECTRONIC COMMUNICATIONS. ACLU v. National Security Agency; Center for Constitutional Rights v. Bush. On October 24, 2006, WLF filed its appellate brief in this important counter-terrorism case. On August 21, 2006, Judge Anna Diggs Taylor of the United States District Court for the Eastern District of Michigan agreed with the ACLU and struck down the National Security Agency's (NSA) electronic Terrorist Surveillance Program (TSP). Under TSP, certain international electronic communications where one of the parties to the communication is a suspected al Qaeda agent or affiliate could be intercepted without a court order. In doing so, Judge Taylor became the first and only federal judge to order a president to stop a wartime foreign intelligence gathering operation. The ruling, however, has been temporarily stayed while the case is heard in the court of appeals. On May 30, 2006, WLF filed a brief before Judge Taylor opposing the ACLU suit. On June 6, 2006, WLF filed a similar brief in New York federal court in a related case filed by the Center for Constitutional Rights (CCR). In ACLU v. NSA and CCR v. Bush, the activist groups claim that the recently revealed NSA surveillance program where international calls and emails are monitored violates the Foreign Intelligence Surveillance Act of 1978 (FISA), which requires approval by a special FISA court confirming that there is probable cause to believe that the person targeted for electronic surveillance is an agent of a foreign power. WLF argued forcefully in its brief that it is FISA that violates the separation of powers to the extent it impairs the President's ability to carry out his constitutional responsibilities to defend the country from further attack and to collect foreign intelligence. The Justice Department took the position that the courts cannot reach the merits of the case, asserting military and state secrets privilege, and requested that these and similar cases be transferred to a single federal court. WLF's brief was drafted

WASHINGTON LEGAL FOUNDATION 2009 MASSACHUSETTS AVENUE, N.W. WASHINGTON, DC 20038

02-588-0302

with the pro bono help of Bryan Cunningham of Morgan & Cunningham in Denver, CO.

Status: Loss in district court. Appellate argument scheduled for January 31, 2007.

NATIONAL SECURITY -- DETERRING TERRORIST ATTACKS. MacWade v. Kelly. On August 11, 2006, WLF scored a major victory when the U.S. Court of Appeals for the Second Circuit upheld a lower court ruling that rejected a constitutional challenge by the New York Civil Liberties Union (NYCLU) to New York City's subway bag inspection program designed to detect and deter terrorist attacks. On April 4, 2006, WLF filed its brief in the court of appeals to preserve its victory in the district court on behalf of its clients, U.S. Representative Peter T. King of New York and Chairman of the House Committee on Homeland Security and U.S. Representative Ginny Brown-Waite of Florida and a member of the committee; Families of September 11, Inc. and the Allied Educational Foundation; New York State Senator Martin J. Golden; New York Assemblymen Vincent M. Ignizio and Matthew Mirones; New York City Council Member James S. Oddo; and Stephen M. Flatow of New Jersey, whose daughter, Alisa Flatow, was killed by the Palestinian Islamic Jihad in a bus bombing while studying in Israel. WLF's district court victory came on December 2, 2005, when U.S. District Judge Richard Berman in Manhattan issued a 41-page ruling upholding the constitutionality of New York City's subway bag inspection implemented shortly after the London terrorist subway bombings in the summer of 2005. In the district court, WLF filed two briefs, the second one following the two-day trial that began on October 31, 2005, at the specific request of the presiding judge and over the objections of WLF's brief was drafted with the pro bono assistance of Andrew T. Frankel, the NYCLU. partner in the New York office of Simpson Thacher & Bartlett LLP, and associates Bryce L. Friedman and Seth M. Kruglak.

Status: Victory.

NATIONAL SECURITY -- DETERRING TERRORIST ATTACKS. Johnston v. Tampa Sports Authority. On November 17, 2006, WLF filed a brief in the U.S. Court of Appeals for the Eleventh Circuit, urging it to reject a challenge to an NFL policy that entails brief searches of all patrons entering NFL stadiums. WLF argued that the searches are "reasonable" within the meaning of the Fourth Amendment and in any event are not subject to the Fourth Amendment because they are being carried out at the direction of-private entities. The case is on appeal from a district court injunction against such searches at home games being played by the Tampa Bay Buccaneers, an NFL team. Pursuant to a league-wide policy, the Buccaneers required that all patrons entering their stadium submit to a brief, nonintrusive pat-down search to determine whether they are carrying explosives. WLF argued that the searches are minimally intrusive and are more than justified by the very real possibility that terrorist groups will attempt to kill large numbers of civilians by planting a bomb in a football stadium.

Status: Awaiting oral argument.

NATIONAL SECURITY -- SUPPORT FOR TERRORIST GROUPS. Humanitarian Law Project v. Gonzales. On April 13, 2006, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, urging it to uphold a portion of the USA PATRIOT Act that makes it a crime to provide "material support" to any group that has been designated by the Attorney General as a "foreign terrorist organization." WLF argued that the statute is not impermissibly vague and does not violate the First Amendment rights of those who wish to support humanitarian work conducted by terrorist groups. WLF argued that the First Amendment does not prevent Congress from barring actions taken to aid terrorist groups simply because the actions may have an expressive component. WLF argued that material support provided to a terrorist organization - even material support intended to further the organization's humanitarian activities - can be prohibited because material support used to provide humanitarian activities frees up other resources and thereby permits the organization to divert those other resources to terrorism. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Awaiting oral argument.

ILLEGAL ALIENS -- DRIVER'S LICENSES. Cubas v. Martinez. On July 6, 2006, the Appellate Division of the New York Supreme Court upheld new regulations adopted by the State of New York that make it extremely difficult for illegal aliens to obtain driver's licenses. The decision was a victory for WLF, which filed a brief urging the court to uphold the regulations. WLF argued that the restrictions are needed to ensure that terrorists and criminals do not obtain fake identification documents that can facilitate their activities. The Appellate Division agreed and held that those interests outweigh any interests that illegal aliens may have in obtaining driver's licenses. The appeals court overturned a trial court's preliminary injunction against the new regulations. Among other changes, the new Department of Motor Vehicles (DMV) regulations prohibit use of foreign-source documents (such as foreign passports) to establish identity, because their authenticity cannot easily be verified. The result is that illegal aliens rarely qualify to obtain new or renewed driver's licenses, because they rarely possess verifiable U.S.-source documents (e.g., birth certificates or immigration papers) that establish their identity. The appeals court agreed with WLF's argument that DMV's authority to demand proof of "identity" includes the right to adopt any reasonable rule designed to ensure that the driver's license applicant is who he says he is. The regulations are not rendered invalid simply because they have the effect of preventing illegal aliens from obtaining licenses, the appeals court agreed. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Victory.

CRIMINALIZATION OF FREE ENTERPRISE -- U.S. SENTENCING GUIDELINES. Claiborne v. U.S.; Rita v. U.S. On December 18, 2006, WLF filed a brief in the U.S. Supreme Court in a pair of related cases that will decide what weight the U.S. Sentencing Guidelines should be given by federal judges in determining the appropriate sentence in a particular criminal case. The outcome of the case will have significant impact on federal

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sentencing practices that affect business owners and executives, particularly with respect to regulatory offenses where the current Guidelines call for excessive prison terms for minor infractions. In *Claiborne v. U.S.* and *Rita v. U.S.*, WLF argued that Congress intended that punishments should fit the crime and the offender, but that the Sentencing Guidelines do neither. For almost 20 years, the Guidelines dictated mandatory sentences that regularly called for severe prison sentences, some from three to nine years or even more, for minor regulatory infractions, including environmental offenses where no harm occurred. In early 2005, the Supreme Court in *Booker v. United States* struck down the mandatory feature of the Guidelines as unconstitutional under the Sixth Amendment right to jury trial. Since that decision, however, many courts of appeals have reversed sentences imposed by district court judges below the Guideline level as unreasonable. In doing so, they ruled that the Guidelines should be given a presumption of reasonableness and special weight. WLF's brief was filed on behalf of itself and the Allied Educational Foundation.

Status: Oral argument scheduled for February 20, 2007.

ENVIRONMENTAL REGULATION -- JURISDICTION OVER WETLANDS. Rapanos v. United States. On June 19, 2006, the Supreme Court ruled that the U.S. Army Corps of Engineers could not assert federal jurisdiction over certain wetlands that had only a tenuous hydrological connection to navigable waterways. However, because the decision was supported by only four justices, with a separate decision and rationale for reversal written by Justice Kennedy who provided the fifth vote, the ramifications of the decision will be litigated in future cases. On December 2, 2005, WLF filed a brief in the United States Supreme Court urging it to reject the federal government's claim that it has regulatory authority under the Clean Water Act over isolated "wetlands" located over 20 miles away from any navigable waterway. Federal regulators who have seemingly ignored the Court's ruling four years ago that Congress intended the Clean Water Act's jurisdiction to extend only over wetlands that are adjacent to waterways that are navigable, and not over isolated wetlands that are otherwise subject to local control. In Rapanos v. United States, the U.S. Army Corps of Engineers and prosecutors have spent the last decade relentlessly pursuing civil and criminal charges against John Rapanos, a small developer, for placing sand on his own property that the Corps deems to be federally regulated wetlands. The linchpin for the Corp's jurisdiction over the property was the fiction that the property was "adjacent" to a river over 20 miles away. WLF clients include the Allied Educational Foundation and two environmental scientists, Laurence A. Peterson and Edmond C. Packee, Jr., of Travis/Peterson Environmental Consulting, Inc., of Alaska. WLF's brief was drafted pro bono by Mark A. Perry, a partner with Gibson, Dunn & Crutcher, LLP, in Washington, D.C.

Status: Victory.

GLOBAL WARMING -- EPA RULEMAKING AUTHORITY. Massachusetts v. EPA. On November 29, 2006, the Supreme Court heard oral argument in this important global warming case. On October 24, 2006, WLF filed a brief in the Court seeking to uphold its

victory below in this important global warming case. On July 15, 2005, WLF's victory came when the United States Court of Appeals for the District of Columbia Circuit rejected an effort by several states and environmental groups to require that the Environmental Protection Agency (EPA) regulate carbon dioxide as a pollutant under the Clean Air Act. If the court had ruled in favor of the petitioners, the EPA would be required to regulate socalled "greenhouse gases" produced by automobiles, manufacturing facilities, and other sources of carbon dioxide that petitioners claim are causing global warming. Such a ruling would, in effect, implement the unratified Kyoto Treaty regulating greenhouse gases. In its brief, WLF argued that the issue of global climate change and its causes has been the most prominent energy and environmental issue of recent years. WLF referred the court to comments WLF filed in 1999 as part of the Working Group to Oppose Expanded EPA Authority urging the agency to reject the petition filed by the International Center for Technology Assessment (ICTA). WLF argued that Congress would certainly have been clear and explicit when it enacted the Clean Air Act if it wanted to give the EPA authority to initiate a massive regulatory program for greenhouse gases. Accordingly, under basic principles of statutory interpretation and administrative law, the EPA was not authorized by Congress to venture into this highly controversial area. WLF's brief was filed with the pro bono assistance of Peter Glaser of the Washington, D.C., law firm of Troutman Sanders, LLP.

### Status: Awaiting decision.

FDA REFORM -- ACCESS TO LIFESAVING MEDICINES. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach. On December 29, 2006, WLF filed a brief in the U.S. Court of Appeals for the District of Columbia Circuit (sitting en banc), urging it to affirm its earlier ruling in favor of WLF that granted terminally ill patients a constitutionally-based right of access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA). WLF argued that throughout American history the judiciary has recognized the right of individuals to engage in selfdefense -- regardless whether the attacker is another person, an animal, or a disease. WLF argued that, based on that traditional self-defense right, the appeals court should recognize a constitutional right of terminally ill patients who lack effective treatment options to take experimental drugs, without interference from FDA. WLF argued that the decision to take such drugs should be left up to the patient, his or her doctor, and the drug's manufacturer. In a historic decision last May, a three-judge D.C. Circuit panel ruled in WLF's favor on the issue. The D.C. Circuit granted FDA's rehearing petition in November and called for a new round of briefs from the parties (beginning with WLF's December 29 brief). WLF will argue its case before the en banc court (that is, before all ten judges on the court) on March 1, 2007. WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group. WLF has received invaluable pro bono legal assistance from Scott Ballenger, a partner in the Washington office of Latham & Watkins.

Status: Oral argument scheduled for March 1, 2007.

IMMIGRATION -- VOTING INTEGRITY. Gonzalez v. State of Arizona. WLF continues to battle efforts by activists to strike down Proposition 200, an immigration-control initiative adopted in November 2004 by Arizona voters. On September 11, 2006, the U.S. District Court for the District of Arizona rejected a challenge to those portions of Prop 200 designed to prevent aliens from voting. The appeals court issued an injunction pending appeal, but the U.S. Supreme Court overturned that injunction on October 20, 2006 -- in time for the November elections. The district court and Supreme Court decisions were victories for WLF, which filed a brief urging denial of a preliminary injunction request. WLF argued that Arizona voters were well within their rights in adopting measures designed to prevent election fraud -- including a requirement that those seeking to register to vote must provide documentary proof of citizenship and a requirement that voters provide a picture ID when they come to the polls. The court agreed with WLF that these measures violated neither the U.S. Constitution nor the National Voting Rights Act of 1993 (also known as the "motorvoter" law), which requires all States to permit mail-in voter registration. WLF is representing Protect Arizona NOW (PAN); the group that spearheaded adoption of Prop 200. WLF also represented PAN in prior litigation challenging other portions of Prop 200 that seek to prevent illegal aliens from collecting welfare benefits. WLF prevailed in the prior litigation, and the welfare-related provisions are not at issue in the latest round of lawsuits.

Status: Victory. WLF to file new brief in appeals court in January 2007.

NATIONAL SECURITY -- DETENTION OF ENEMY COMBATANT. Padilla v. Hanft. On April 3, 2006, the U.S. Supreme Court declined to review a lower court decision upholding the federal government's detention of Jose Padilla, the "dirty bomber" accused of being an al Qaeda operative. The decision was a victory for WLF, which filed a brief (on behalf of itself and the Allied Educational Foundation) urging the Court not to hear the case. The Supreme Court neither declared the case moot nor vacated the lower court decision on mootness grounds, even though Padilla, a U.S. citizen, is no longer being held as an "enemy combatant" - Padilla was recently released from military custody and turned over to civilian authorities to face trial in connection with largely unrelated charges that he conspired to aid overseas terrorist organizations. As a result of the Supreme Court not taking any action to declare the case moot, the September 2005 appeals court decision in the government's favor remains standing and can serve as a precedent in future enemy combatant cases. WLF filed a total of four briefs in support of the government as Padilla's case wound its way through the federal courts over the past four years. On September 9, 2005, the U.S. Court of Appeals for the Fourth Circuit in Richmond upheld the federal government's detention of Padilla. As a result of decisions in this case, the courts have now clearly established that the government is entitled to detain without trial American citizens discovered fighting for enemy forces, just as it is entitled to detain any enemy soldier captured in time of war. The courts also agreed with WLF that the right to detain Padilla was not diminished simply because he was captured in Chicago rather than on some overseas battlefield. The government alleges that Padilla fought with al Qaeda/Taliban forces in Afghanistan against the United States.

Status: Victory.

LEGAL REFORM -- PUNITIVE DAMAGES. *Philip Morris USA v. Williams*. On October 31, 2006, the Supreme Court heard oral argument in this important punitive damages case. On July 28, 2006, WLF filed a brief with the Court urging it to reverse an Oregon Supreme Court decision that upheld an excessive \$79.5 million punitive damages award to a lifelong smoker who died of lung cancer after smoking for over 45 years. WLF argued that in light of the compensatory damage award of approximately \$800,000 and the jury's finding that the smoker was equally responsible for his medical injuries, the punitive damages award of approximately 100 times the amount of compensatory damages was grossly excessive and violated the company's due process rights. The outcome of the case will have a major impact on the assessment of punitive damages against other industries in future cases. WLF argued in its brief filed on behalf of itself and the Allied Education Foundation that under recent U.S. Supreme Court decisions, the jury should have been instructed to ignore alleged harms to other persons for the conduct of the defendant; otherwise, the case would effectively be transformed into a class action without any of the procedural protections afforded defendants in those cases.

Status: Awaiting decision.

SECURITIES CLASS ACTIONS -- PREEMPTION. Merrill Lynch v. Dabit. On March 21, 2006, the U.S. Supreme Court reversed a lower court's restrictive interpretation of the Securities Litigation Uniform Standards Act of 1998, or "SLUSA." In that statute, Congress acted to curb abusive class action claims in state court for securities fraud. The appeals court in this case read a restriction into the statute's preemption provision, holding that it allows suits to proceed in state court on behalf of persons who merely hold, rather than purchase or sell, securities. In its brief filed in the Supreme Court on November 14, 2005, WLF argued that SLUSA's language preempts "holder" claims as well as purchaser and seller claims. WLF noted that SLUSA was intended to protect the federal policy of encouraging efficient securities markets by preventing circumvention of Securities Litigation Reform Act of 1995. WLF's brief also argued that a broad reading of SLUSA is consistent with principles of federalism. WLF was represented in the case on a *pro bono* basis by Donald B. Verrilli, Jr., of the Washington, D.C. office of Jenner & Block LLP.

Status: Victory.

ANTITRUST -- INTELLECTUAL PROPERTY. Illinois Tools Works, Inc. v. Independent Ink, Inc. The U.S. Supreme Court issued a ruling on March 1, 2006, limiting antitrust actions against intellectual property owners by rejecting a presumption that the owner of a copyright or patent possesses market power under the antitrust laws. WLF filed a brief in the case on August 4, 2005, urging the Court to reject that presumption. In its brief, WLF argued that intellectual property has no inherent characteristics that justify shifting the burden of proof in antitrust cases onto the owners of that property. WLF noted that the Federal Circuit's rule would encourage frivolous nuisance suits by rendering it much easier for a suit to survive a motion to dismiss, even where the patent or copyright owner possesses no market power whatsoever. WLF also argued that the rule would encourage defendants in patent infringement actions to bring antitrust counterclaims, thus bypassing the requirements of the patent misuse defense created by Congress. WLF's brief was drafted on a *pro bono* basis by William C. MacLeod, a member of Collier Shannon Scott specializing in antitrust, and by Samuel M. Collings, an associate at the firm.

#### Status: Victory.

ANTITRUST -- COMPETITIVE BIDDING. Volvo Trucks North America v. Reeder-Simco GMC. On January 10, 2006, the U.S. Supreme Court issued a decision rejecting a broad interpretation of the Robinson-Patman Act. This antitrust statute prohibits certain forms of price discrimination in commercial transactions (such as transactions between manufacturers and retail sellers). The Justices accepted WLF's position that a manufacturer is liable under the Act for alleged favoritism among dealers only if the dealers were in competition with one another. WLF filed its brief on the merits in the case on May 20, 2005, noting that the appeals court's interpretation of the Act would have banned pricing practices that are common and legitimate in competitive bidding situations. WLF also filed a brief in February 2005 urging the Supreme Court to review the case.

### Status: Victory.

ANTITRUST -- JOINT VENTURES. Texaco, Inc. v. Dagher. The U.S. Supreme Court issued a decision on February 28, 2006, reversing an appeals court decision that expanded the reach of the price-fixing laws with respect to joint ventures. WLF had filed a brief on September 12, 2005, asking the Justices to reverse the appeals court decision. The litigation involves two joint ventures formed by Texaco and Shell Oil to take over the gasoline wholesaling and retailing operations of those companies in the United States. The "Texaco" and "Shell" names continue to exist as separate brands under the joint ventures. The court below, the U.S. Court of Appeals for the Ninth Circuit, ruled that the companies could be held liable for price-fixing because the joint ventures priced Texaco and Shell gasoline the same. The case was important to the business community because the Ninth Circuit's decision, by treating a bona fide joint venture as a cartel, created the potential for antitrust liability for joint ventures in a variety of contexts. WLF's brief was drafted on a *pro bono* basis by William J. Kolasky and Ali M. Stoeppelwerth of the Washington, D.C. office of Wilmer Cutler Hale and Dorr LLP and by Steven P. Lehotsky of the firm's Boston office. WLF previously filed a brief on January 13, 2005, urging the Court to hear the case.

### Status: Victory.

LAND USE -- BALLOT INITIATIVE. MacPherson v. Dep't of Admin. Svcs. On February 21, 2006, the Oregon Supreme Court issued a decision upholding the legality of a ballot measure adopted by the voters for the protection of landowners' rights. The decision reversed a trial court ruling that found the ballot measure to be a violation of the Oregon Constitution. WLF had filed a brief in the state Supreme Court supporting the ballot measure on December 5, 2005. The case was a challenge to the constitutionality of Ballot Measure 37, an Oregon

ballot measure protecting landowners who suffer a loss in the value of their property on account of land use regulations. After the passage of the measure in 1994, a state trial court held it invalid under various provisions of the Oregon Constitution. In its brief, WLF argued that the trail court had erred in its ruling under the Equal Privileges and Immunities Clause of the Oregon Constitution; the state Supreme Court agreed. Dorothy S. Cofield of the Cofield Law Office in Lake Oswego, Oregon represented WLF as local counsel on a *pro bono* basis.

Status: Victory.

OIL AND GAS DEVELOPMENT -- ENVIRONMENTAL RESTRICTIONS. Northern Alaska Environmental Center, et al. v. Norton. On July 25, 2006, the U.S. Court of Appeals for the Ninth Circuit upheld a lower court decision that rejected a challenge by environmental groups to the preliminary plans by the Department of Interior to offer certain oil and gas leases in a particular area of Alaska. On July 11, 2005, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, urging the court to affirm a lower court ruling that upheld the Final Environmental Impact Statement (FEIS) for the oil and gas leasing program for the Northwest Planning Area of the National Petroleum Reserve in Alaska (NPR-A). Oral argument was held September 15, 2005. WLF argued that the FEIS was more than sufficient to satisfy environmental laws, including the Endangered Species Act (ESA). Environmental groups, including the Sierra Club, Audubon Society, and Center for Biological Diversity, are trying to stop oil leases from being issued. WLF argued that any oil and gas production, which is at least ten years away, would disturb less than 1,900 acres of the surface area of the Northwest Planning Area, or 0.02 percent of the 8.8 million acre oil reserve. Furthermore, significant measures would also be taken to mitigate any harm to wildlife and the environment.

Status: Victory.

TORT REFORM -- FIRST AMENDMENT. *Physicians Committee for Responsible Medicine v. General Mills.* On November 30, 2006, the U.S. District Court for the Eastern District of Virginia dismissed a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. The decision was a victory for WLF, which filed a brief urging dismissal of the suit. The court agreed with WLF that Virginia law does not permit private citizens to seek injunctions against advertisements with which they disagree. WLF had also argued that the suit threatened to undermine manufacturers' commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled. WLF argued that the plaintiffs' real objection was not to the ads, but to what they view as inhumane treatment of cows. WLF argued that the courts should not allow the judicial process to be abused in this manner.

Status: Victory.

PATENTS -- INHERENT ANTICIPATION. SmithKline Beecham Corp. v. Apotex Corp. On June 19, 2006, the U.S. Supreme Court issued an order declining to review an appeals court decision that invalidated a significant pharmaceutical patent based on a finding that the drug was not "novel" when the patent application was filed in 1986 - even though it is undisputed that if the drug existed before then, it was in such minute quantities as to be undetectable. The order, issued without comment, was a setback for WLF, which filed a brief urging that review be granted. WLF argued that if allowed to stand, the decision of the U.S. Court of Appeals for the Federal Circuit would undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights. WLF argued that under the doctrine of "accidental prior use," an invention should not be deemed to have been "anticipated" by the prior art if the prior art's disclosure of the claimed invention is accidental or unwitting and no one - not even experts in the field - would have recognized the existence of the disclosure. WLF argued that the challenged patent should have been upheld under the "accidental prior use" doctrine. WLF also filed briefs in the case supporting the validity of the underlying patent - in the Federal Circuit in 2004 and 2005.

Status: Supreme Court review denied.

GOVERNMENT ACCOUNTABILITY -- UNITED STATES POSTAL SERVICE. Dolan v. U.S. Postal Service. On February 22, 2006, the U.S. Supreme Court ruled that the United States Postal Service (USPS) is not immune from lawsuits under the Federal Tort Claims Act (FTCA) where postal employees' negligence causes physical injuries and property damage to the public. The Court agreed with WLF's argument that Congress did not provide USPS with such special immunity and thus, it should be held liable just as private carriers would be held liable for similar negligent conduct. On July 18, 2005, WLF filed a brief in the Court on behalf of itself and the Allied Educational Foundation urging the Court to reverse a lower court decision and hold that the USPS is not immune from lawsuits under the FTCA where postal employees' negligence causes physical injuries and property damage to the public. In doing so, WLF stressed in its brief that the USPS should not be given special immunity in that regard, but should be held liable just as private carriers would be held liable for similar conduct. In Dolan v. USPS, the postal carrier delivered postal matter to Mrs. Dolan's home and negligently piled the mail and magazines on the porch by the door where a person leaving the home would likely step. Mrs. Dolan slipped on the mail and was severely injured. WLF argued that Congress only intended immunity for damage, loss, or delay of the mail itself, not for physical injuries due to negligence of postal employees. Such a broad reading would immunize USPS for accidents caused by postal vehicles transporting the mail, a result which Congress most certainly did not intend.

### Status: Victory.

FIRST AMENDMENT -- COMPELLED SPEECH. R.J. Reynolds Tobacco Co. v. Shewry. On February 21, 2006, the U.S. Supreme Court declined to review an appeals court decision that rejected a First Amendment challenge to an advertising campaign conducted by the State of California. The Court's action, made without comment, was a setback for WLF, which filed a brief urging the Court to review the appeals court ruling. WLF argued that the First Amendment prohibits a state from forcing a company to pay for advertisements that vilify the company. California imposes a special fee on the tobacco industry and then uses it to finance a \$25 million per-year ad campaign designed to prevent smoking by vilifying the tobacco industry. The advertisements repeatedly have called the tobacco industry "deceptive," a "dangerous enemy," and indifferent to the health of its customers, and have routinely accused the industry of lying to the public. WLF argued that the First Amendment protection against compelled financial support of speech to which one objects has been recognized repeatedly by the courts and applies just as strongly when the speaker is the government as it does when the speaker is a private party. WLF also filed briefs in the case when it was before the appeals court.

Status: Review denied.

TORT REFORM -- "JUNK SCIENCE." Zito v. Zabarsky. On May 16, 2006, the Appellate Division of the New York Supreme Court issued an order declining to reconsider a decision that permits expert testimony to be introduced in a medical malpractice case. The decision was a setback for WLF, which filed a brief urging reconsideration. WLF's brief argued that expert medical testimony must be excluded from court proceedings when it is based on "junk science." WLF argued that the testimony should have been excluded because the medical conclusions reached by the "experts" lacked support in the medical literature. The American Medical Association also urged the appeals court to reconsider its decision. WLF argued that allowing the "expert" testimony in this case was particularly inappropriate because it consisted of a claim that an FDA-drug had caused the plaintiff's disease, yet the drug in question has been marketed for decades without any indication in the medical literature that the drug can trigger that disease.

Status: Review denied.

ILLEGAL IMMIGRANTS -- TORT DAMAGES. Paramount Citrus v. Superior Court. On January 5, 2006, the California Supreme Court declined to review a trial court decision that allows illegal aliens who file tort actions to seek recovery for damages not yet incurred, and to base those damage claims on an assumption that they will remain in the United States for the remainder of their lives. The decision was a setback for WLF, which filed a brief urging the court to grant review. WLF argued that, because illegal aliens have no right to remain in this country, such damage claims should be limited to the amount of damages that would be incurred if the illegal alien returned to his native country. The case involves an illegal alien who was permanently disabled in a car accident. He seeks recovery of the cost of providing him "life care" for the next 50 years. The present value of such care is \$5.3 million if he remains in the United States, but only \$1.8 million if he returns to his native Mexico. WLF argued that because the plaintiff has no right to remain in this country, he has no right to recover damages computed based on an assumption that he will remain here. WLF also argued that granting the plaintiffs' damage claims would undermine federal immigration policy.

Status: Review denied; case now goes to trial.

SECURITIES CLASS ACTION ABUSE -- SHORT-SELLING PRACTICES. WLF v. SEC On April 28, 2006, WLF settled this Freedom of Information Act case with the Securities and Exchange Commission (SEC). On June 30, 2005, WLF filed a lawsuit in U.S. District Court for the District of Columbia against the SEC for failing to provide certain documents WLF sought under the Freedom of Information Act (FOIA) relating to abusive class action and short-selling practices. As part of WLF's INVESTOR PROTECTION PROGRAM, WLF filed several complaints with the SEC requesting an investigation into the questionable relationship between short-sellers of stock (those who profit when the price of a stock drops) and class action attorneys who later sue the targeted company. Such suits usually cause the stock price to drop, and short-sellers profit at the expense of other stockholders. One complaint filed with the SEC by WLF in 2003 involved the short-selling of stock in J.C. Penney Co. that occurred shortly before and after the filing of a class action lawsuit against Eckerd Drug Store, which was then owned by J.C. Penney Co. WLF's SEC complaint requested that the SEC investigate whether there may have been a violation of the securities laws and regulations with respect to the timing of the lawsuit and the communications between the short-sellers of the company's stock and class counsel suing the company. The SEC agreed with WLF that it did not conduct a proper search for the documents and are providing WLF with certain documents, and provided WLF with certain documents in March and April 2006.

Status: Case settled.

FALSE CLAIMS ACT -- ABUSIVE USE OF RELATOR PROVISION. Rockwell Int'l Corp. v. United States ex rel. Stone On December 5, 2006, oral argument was held before the Supreme Court in this important False Claims Act case. On October 25, 2006, WLF had filed a brief with the on behalf of itself and the Allied Educational Foundation, urging it to reverse a court of appeals decision that, if left intact, would greatly expand the ability of socalled relators and their attorneys to file abusive False Claims Act (FCA) cases against government contractors, contrary to the intent of Congress. The FCA forbids government contractors from submitting claims for payment to the federal government for goods or services where the work performed did not fully meet government requirements as specified in the contract. The FCA also has a very narrowly drafted "qui tam" provision that allows certain insiders or whistleblowers to file suit on behalf of the government if they are an original source of the information showing the claims were false. If they prevail at trial, the court may award them a "bounty" between 15 and 30 percent of the recovery from the contractor. WLF's brief was filed with the pro bono assistance of Alan I. Horowitz, Robert K. Hoffman, Peter B. Hutt, II, and R. Weston Donehower of the Washington, D.C., law firm of Miller & Chevalier.

Status: Awaiting decision.

FALSE CLAIMS ACT -- LIABILITY FOR AMBIGUOUS REGULATIONS. **R&F** Properties of Lake County, Inc. v. U.S. ex rel. Walker. On October 2, 2006, WLF filed a brief in the U.S. Supreme Court urging the Court to review and reverse a court of appeals decision that ruled that a company can be subject to substantial penalties under the False Claims Act, even though its billing practices were based on a reasonable interpretation of ambiguous agency regulations and contractual provisions. Unless the High Court reviews and reverses the decision, companies doing business with the federal government will be subject to unfair and ruinous civil suits by so-called private "relators" and their attorneys who stand to get a substantial "bounty" for bringing the suit, even though the government does not believe the case is worth its attention. WLF's brief was filed with the pro bono assistance of Woody N. Peterson and Andrew Jackson, partners in the Washington, D.C., office of Dickstein Shapiro LLP, and associate Justin A. Chiarodo.

Status: Review denied on November 6, 2006.

TORT REFORM -- FAIR CREDIT REPORTING ACT. Safeco Insurance Co. of America v. Burr. On November 13, 2006, WLF filed a brief in the U.S. Supreme Court, urging it to crack down on frivolous lawsuits filed by plaintiffs' attorneys against the insurance industry. Such suits allege technical violations of the Fair Credit Reporting Act (FCRA) yet seek billions of dollars in damages. WLF argued that the plaintiffs' lawyers do not claim that their clients suffered any real damages for alleged FCRA violations, and are simply trying to extort settlements from deep-pocketed defendants. WLF argued that the plaintiffs cannot show that any alleged violations were committed "willfully" and that the suits must be dismissed in the absence of such a showing. WLF also argued that no violations of the FCRA were committed. The suits, filed on behalf of large classes of consumers who each seek \$100 in damages, claim that insurance companies violated the FCRA by failing to notify consumers that they had taken "adverse action" by declining to offer their lowest rates.

Status: Oral argument scheduled for January 16, 2007.

HEALTH CARE -- FIRST AMENDMENT. *IMS Health Inc. v. Ayotte.* On November 30, 2006, WLF filed a brief in the U.S. District Court for the District of New Hampshire, urging it to protect First Amendment rights by striking down a New Hampshire law that blocks access to critical healthcare information. The law, which is unique to New Hampshire, criminalizes the collection and disclosure of information about the prescribing practices of physicians. WLF argued that the law violates the First Amendment by prohibiting disclosures of truthful information, even disclosures arising outside the context of advertising. WLF argued that such prohibitions are only rarely permissible and only then when based on showings of the most compelling of government needs. WLF argued that the information that New Hampshire is trying to ban plays a vital healthcare role; it is used to monitor the safety of medications, implement drug recalls, and rapidly communicate information to doctors about innovative new treatments.

Status: Awaiting trial in January 2007.

TORT REFORM -- FIRST AMENDMENT. Raytheon Technical Services Co. v. Hyland. On November 6, 2006, WLF filed a brief in the Virginia Supreme Court, urging it to protect First Amendment rights by imposing strict limits on the ability of disgruntled employees to file defamation actions against their employers based on unhappiness over statements made in annual performance evaluations. WLF argued that allowing employees to sue every time they disagree with a performance evaluation will cause corporations -- wary of the prospect of large jury verdicts -- to cease providing candid evaluations. WLF argued that by its very nature, a performance evaluation constitutes a supervisor's subjective judgment regarding how well an employee is performing and as such constitutes a nonactionable statement of opinion. WLF argued that statements in a performance evaluation (e.g., that an employee is incompetent or talks too much) should not be the subject of a defamation suit because they are virtually never provably true or false. The case is on appeal from a \$3.5 million jury verdict in favor of an employee who was upset about her supervisor's subjective evaluation of her job performance.

Status: Oral argument scheduled for January 9, 2007.

HEALTH CARE -- PRICE CONTROLS. Biotechnology Industry Organization v. District of Columbia. On December 29, 2006, WLF filed a brief in the U.S. Court of Appeals for the Federal Circuit, urging it to protect critical pharmaceutical research and development by striking down a District of Columbia law that imposes strict price controls on prescription drugs still covered by a patent. WLF argued that the law is preempted by federal patent laws because it interferes with the objective Congress sought to achieve in adopting the patent laws - namely, to encourage innovation by rewarding those who expend the resources necessary to develop new products. WLF argued that the law (the "D.C. Act") stands as an obstacle to Congress's objectives because, by depressing prices, it prevents drug patent holders from reaping the rewards Congress intended to bestow. WLF filed its brief on behalf of itself; the Kidney Cancer Association, a group that advocates on behalf of patients suffering from kidney cancer; and the 60 Plus Association, a group that advocates on behalf of senior citizens. WLF also argued that the D.C. Act, if allowed to take effect, will have devastating long-term adverse effects on health care in this country. WLF argued that price controls on drugs stifle pharmaceutical research, with the inevitable result that fewer lifesaving drugs will be developed. WLF noted that, on average, it takes anywhere from \$800 million to \$1.7 billion in research and development costs to get a drug approved for use in the U.S. Drug companies will be unwilling to invest such massive sums if State drug price controls deprive them of any assurance that they can recover those costs by utilizing the market advantages provided them under the patent system, WLF argued.

Status: Awaiting oral argument.

FIRST AMENDMENT -- HEALTH CARE DELIVERY. Washington Legal Foundation v. Leavitt. On August 24, 2006, WLF filed suit in U.S. District Court for the District of Columbia against CMS (the federal Centers for Medicare and Medicaid Services), alleging that CMS is trampling on First Amendment rights in seeking to suppress truthful speech regarding insurance coverage available to senior citizens under Medicare Part D. Part D is the recently enacted Medicare program that offers insurance for the cost of prescription drugs. WLF filed suit on behalf of members who, as a result of CMS's actions, are unable to obtain accurate information about competing insurance providers. The suit seeks an injunction against continuation of CMS's policy. Ironically, the groups that CMS bars from providing truthful information – including nursing homes and pharmacies – are often the very groups that have the most knowledge regarding the health-care needs of Medicare recipients, WLF charged. WLF charged that CMS's rationales for its speech-suppression policies – including a concern that health care providers might accept kick-backs in return for recommending a particular insurance plan – do not justify its infringement on free speech rights. WLF noted that CMS may enforce anti-kickback statutes without suppressing speech. WLF asked the Court to enjoin CMS from continuing to bar providers from providing truthful information.

Status: WLF to file motion for preliminary injunction in January 2007.

DEPORTATION -- ALIEN FELONS. Lopez v. Gonzales. On December 5, 2006, the U.S. Supreme Court ruled that the federal government is not required to deport all aliens convicted of drug-related felonies. Rather, the Court held, a *state-court* drug-related felony conviction should not lead to *automatic* deportation unless the crime for which the alien was convicted would also have been deemed a felony under *federal* drug laws. The 8-1 decision was a setback for WLF, which had filed a brief urging the Court to permit the U.S. government to deport all aliens who commit felonies that are drug-related. WLF urged the Court to rule that such crimes are "aggravated felonies," which bar the alien from pleading extenuating circumstances as a reason to avoid deportation. Because his deportation is no longer deemed automatic, the alien is now permitted to apply for "cancellation of removal" and plead that extenuating circumstances should permit him to avoid deportation. The case before the Court involves Jose Lopez, a Mexican citizen who sneaked into the country illegally in the 1980's. Lopez was later convicted on felony cocaine charges and sentenced to five years imprisonment, but he is seeking to avoid deportation on the grounds that he has developed strong ties to this country and has only one felony conviction.

Status: Loss.

CRIMINALIZATION OF FREE ENTERPRISE -- NON-PROSECUTION AGREEMENTS. Stolt-Nielsen S.A. v. United States. On October 30, 2006, the U.S. Supreme Court declined to hear this challenge to the government's efforts to back out of a nonprosecution agreement. On September 20, 2006, WLF filed a brief in the U.S. Supreme Court, urging the Court to permit companies and individuals threatened with criminal prosecution to seek immediate judicial review of claims that nonprosecution agreements signed by the government render them immune from prosecution. WLF urged the Court to hear the case of a company whose nonprosecution agreement the federal government is refusing to honor. WLF argued that the hope of cutting an immunity deal is a principal reason that companies come forward with evidence, and that they will be far less willing to do so if they lack any effective means of enforcing their deals. WLF argued that when a company bargains for immunity from indictment, the right to file a motion to dismiss a later indictment does not adequately remedy the government's breach. Rather, companies must be permitted to seek an injunction the moment that an indictment is threatened; otherwise, they are denied the benefit of their bargain. WLF filed its brief on behalf of itself, the National Association of Manufacturers, and the National Association of Criminal Defense Lawyers.

#### Status: Review denied.

ENVIRONMENTAL REGULATION -- CLEAN AIR ACT. Environmental Defense v. Duke Energy Corp. On November 1, 2006, oral argument was heard by the Supreme Court in this important case. On September 15, 2006, WLF filed a brief with the Court urging it to reject an attempt by several environmental groups and the Environmental Protection Agency (EPA) to overturn a court of appeals ruling in favor of Duke Energy Corporation regarding EPA's controversial interpretation of one of its major Clean Air Act regulations. EPA filed an enforcement action against Duke Energy in 1999 in federal court in North Carolina claiming that the power company violated EPA's 1980 Prevention of Significant Deterioration (PSD) rule by failing to get a permit when it modified its power plants. At issue is the EPA's recent interpretation of its 1980 PSD Rule that would require power companies to comply with the rule and incur huge costs, even though the modification would result in less emissions from its power plant. In its brief, WLF forcefully argued that the lower courts had jurisdiction to adjudicate Duke Energy's valid defense to the enforcement action brought by the EPA. WLF contended that Duke Energy was not challenging the 1980 PSD Rule itself, but EPA's more recent and inconsistent interpretation of that rule in the enforcement action. To rule otherwise would unfairly enable the EPA to escape any judicial review of its enforcement actions when it misinterprets the underlying statute and the language of the original rule itself.

Status: Awaiting decision.

SEPARATION OF POWERS --CONSTITUTIONALITY OF SARBANES-OXLEY. Free Enterprise Fund v. PCAOB On December 21, 2006, oral argument was heard in this important separation of powers case. On August 22, 2006, WLF filed a brief in the U.S. District Court for the District of Columbia urging the Court to strike down, as unconstitutional, the Public Company Accounting Oversight Board (PCAOB) established by Congress under the Sarbanes-Oxley Act of 2002. Congress gave the PCAOB massive and unchecked powers to regulate the auditing of publicly traded companies by public accounting firms, including the power to tax the firms and establish criminal penalties. Congress established the PCAOB as a private organization whose members are appointed by the Securities and Exchange Commission (SEC) rather than by the President as required by the Appointments Clause of Article II, and who are otherwise immune from control or removal by the President in violation of the separation of powers. More troubling, as WLF emphasized in its 20-page brief, Congress unconstitutionally delegated core legislative powers to the PCAOB. WLF's brief was drafted with the *pro bono* assistance of Kathryn Comerford Todd, partner in the Washington, D.C. firm of Wiley, Rein & Fielding, LLP, and associates Thomas R. McCarthy and William S. Consovoy.

Status: Case pending.

CLASS ACTIONS -- EXCESSIVE ATTORNEYS' FEES. Benney v. Sprint Corp. On November 8, 2006, the court approved the settlement of this class action lawsuit. On July 12, 2006, WLF filed formal objections in the District Court of Wyandotte, Kansas to the proposed award of \$5 million in attorneys' fees to plaintiffs' counsel and \$10,000 to each of their five clients who are lead plaintiffs in a class action lawsuit. The suit was brought on behalf of current and former Sprint wireless customers, many of whom will receive only prepaid phone cards of nominal value as part of this nationwide class action settlement. WLF filed the objections on behalf of a former Sprint customer as part of its legal reform efforts to curtail abusive class action cases where absent class members often receive little or no compensation or worthless coupons, while class action attorneys reap millions of dollars. WLF argued in its objections that the phone card is of little value and utility, and that class counsel's requested fee of \$5 million is excessive in light of the meager results obtained in the case. WLF further argued that the court should defer ruling on the fee request until class counsel files a detailed report on the number and value of claims submitted, and provides full documentation for their fee request. In any event, WLF argued that the fee should be substantially reduced and reserved the right to file further objections after the plaintiffs' attorneys file their motions justifying the settlement and their fee request. WLF also argued that the \$10,000 cash award to each of the lead plaintiffs should be denied.

Status: Settlement approved; appeal pending.

FIRST AMENDMENT -- CALIFORNIA "UNFAIR COMPETITION" LAW. Doe v. Wal-Mart Stores, Inc. On December 5, 2006, oral argument was held in this important First Amendment case. On May 5, 2006, WLF filed a brief in U.S. District Court in Los Angeles, urging the Court to dismiss a lawsuit brought against Wal-Mart by activists who are critical of Wal-Mart's overseas labor practices. In response to such criticisms, Wal-Mart issued statements denying that it purchases products manufactured overseas under "sweat shop" conditions. The activists responded by filing suit against Wal-Mart under California's infamous "unfair competition" law, claiming that Wal-Mart's denials are false and constitute unfair competition. WLF's brief urged dismissal on the ground that the First Amendment fully protects Wal-Mart's right to speak out on issues of public importance, such as international labor conditions. WLF also urged dismissal of the plaintiffs' claims that overseas labor practices used by Wal-Mart's suppliers violate international human rights laws because they constitute "slavery."

Status: Awaiting decision.

TORT REFORM -- UNETHICAL ATTORNEY CONDUCT. In re Congoleum Corp. On June 9, 2006, WLF filed a brief in the U.S. District Court for the District of New Jersey,

urging it to uphold a \$9 million sanction imposed by a bankruptcy judge on a Washington, D.C., law firm for its unethical behavior while representing a company that filed for bankruptcy in the face of massive asbestos liability litigation. WLF argued that the law firm of Gilbert Heintz & Randolph (GHR) should be required to disgorge all legal fees it was paid during the course of bankruptcy proceedings. WLF noted that last year the U.S. Court of Appeals for the Third Circuit removed GHR from the case because of the firm's unethical conduct. WLF argued that GHR had done tremendous damage to the bankruptcy system by undermining public confidence in the integrity of that system, particularly with respect to asbestos-related bankruptcies. WLF argued that disgorgement of fees is an appropriate remedy in that it will provide at least partial compensation for the losses caused by GHR.

Status: Awaiting decision.

TORT REFORM -- ALIEN TORT STATUTE. Abdullahi v. Pfizer. On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging it to dismiss claims that a drug company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits asserting that doctors violated international law by allegedly treating patients without first obtaining the patients' informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a law that lay dormant for nearly 200 years before activists recently began seeking to invoke it. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF argued that it has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations.

Status: Awaiting oral argument.

COMMERCE CLAUSE -- STATE TAXATION. McLane Western, Inc. v. Department of Revenue. On October 2, 2006, the U.S. Supreme Court declined to hear a Commerce Clause challenge to a Colorado tax. On June 12, 2006, WLF had filed a brief urging the Court to review (and ultimately overturn) a court decision upholding a Colorado excise tax that imposes higher taxes on out-of-state companies than on Colorado companies. WLF argued that taxes, such as the Colorado tax at issue here, that discriminate against interstate commerce violate the Constitution's Commerce Clause. WLF also argued that such taxes interfere with the unrestricted flow of commerce and can damage the national economy. The petitioner in this case purchases the products subject to the tax fairly late in the distribution chain, from an out-of-state distributor. The "tax base" used in computing the excise tax is the purchase price paid by whichever distributor first brings the products into Colorado. Thus the petitioner pays a higher tax than when the same products are brought into the state at an earlier stage of the distribution chain (before all distribution mark-ups have been added to the price).

Status: Review denied.

ANTITRUST LAW -- PLEADINGS STANDARDS. Bell Atlantic v. Twombly. On November 27, 2006, oral argument was held in this important antitrust case, which will provide the U.S. Supreme Court with an opportunity to crack down on frivolous antitrust lawsuits by making it easier for defendants to win dismissal of such suits before being forced to incur the huge expense of discovery. In its brief urging the Court to review the case, WLF argued that unless antitrust defendants are provided a fair opportunity to win early dismissal, they will often end up agreeing to pay plaintiffs to settle meritless claims. The case involves an antitrust suit against the four principal companies that maintain local telephone networks in this country. The plaintiffs claim that the companies conspired to suppress competition for local telephone service, but they have provided no evidence to support that claim. WLF argued that in the absence of such evidence, the lower courts should have granted the defendants' motion to dismiss the case prior to discovery.

Status: Awaiting decision.

CLASS ACTIONS -- EXCESSIVE ATTORNEYS' FEES. Chance v. United States Tobacco, Co. On April 3, 2006, WLF filed a brief in the District Court of Seward County, Kansas, opposing a fee request by plaintiffs' attorneys for \$22.5 million for settling a class action lawsuit where users of smokeless tobacco products will receive only coupons toward the purchase of future products. WLF argued that the coupon settlement was highly inflated, and that the court should base any fee on the hourly rate which plaintiffs estimate to be \$4.6 million, and which defendants estimate to be more like \$3.6 million. WLF cited cases where coupon redemption rates were only in the 3 to 6 percent range, and where part of the attorneys' fees were ordered to be paid in coupons. The recent federal Class Action Fairness Act as well as the law in Texas, provides that fees should be based on the amount of coupons actually redeemed.

Status: Awaiting decision.

SECURITIES CLASS ACTIONS -- PRIVATE RIGHT OF ACTION. Neer v. Pelino. On May 17, 2006, WLF filed a brief with the U.S. Court of Appeals for the Third Circuit in Philadelphia urging the court to affirm a lower court decision that a private litigant does not have the right under Section 304 of the Sarbanes-Oxley Act (SOX) to sue officers and directors of a publicly traded company to disgorge bonuses and profits for alleged errors in the company's accounting statements filed with the Securities and Exchange Commission (SEC). Instead, WLF argued that Congress intended for only the SEC to have the authority to enforce the penalty provision. WLF argued that Congress did not manifest any intent to allow private litigants to enforce the penalty provision and that to permit such suits would be contrary to sound public policy. In particular, enforcement of Section 304 would not be uniform and may cause officers to unfairly disgorge profits when their conduct was not blameworthy to avoid expensive lawsuits. In addition, since the disgorgement is required to be returned to the company and its shareholders, plaintiffs' attorney fees would be siphoned from the penalty imposed, whereas all the funds would be returned if the SEC imposed the penalty.

Status: Oral argument scheduled for February 26, 2007.

CRIMINALIZATION -- U.S. SENTENCING GUIDELINES. Thurston v. United States. On July 26, 2006, the U.S. Court of Appeals for the First Circuit in Boston reversed a threemonth prison sentence that was imposed by two different district court judges on two separate occasions, and ordered that the defendant be resentenced for a third time to a sentence of at least three years. On March 20, 2006, WLF filed a brief in the court of appeals opposing an appeal by the Justice Department seeking to have a businessman resentenced to five years in prison despite the fact that prosecutors plea bargained with a more culpable co-defendant to receive only probation for pleading nolo contendere. In effect, the Justice Department took the extreme position that even though the Sentencing Guidelines were ruled unconstitutional by the U.S. Supreme Court last year and are no longer mandatory, the trial court should have treated the voluntary guidelines as if they were mandatory, and that Mr. Thurston should have received the maximum statutory sentence. WLF previously filed a brief in the case in late 2004 in the Supreme Court urging the Court to review and reverse the court of appeals decision, and successfully argued that the courts should be allowed to depart from the draconian sentences dictated by the Guidelines, particularly in those cases where imposing the Guidelines would result in gross disparities of sentences with co-defendants. The entire purpose of the Guidelines was to reduce sentence disparity. Thurston filed a petition for writ of certiorari to the Supreme Court in September.

Status: Loss. Petition for Supreme Court review pending.

TORT REFORM -- STATUTE OF LIMITATIONS. Grisham v. Philip Morris USA, Inc. Oral argument was held on December 6, 2006 in this important tort reform case. On March 9, 2006, WLF had filed a brief in the California Supreme Court, urging it to uphold the dismissal of tort claims filed against cigarette companies based on allegations that the companies wrongfully addicted the plaintiffs to tobacco. WLF argued that such claims by long-time smokers are barred by the statute of limitations because the plaintiffs knew (or should have known) for decades that they were addicted to cigarettes, yet they waited until 2002 to file suit. WLF urged the court to reject the plaintiffs' contentions that their addiction to tobacco rendered them incapable of recognizing their addiction. The public has known for decades that tobacco is addictive, WLF argued; if there were any doubt on that score, it was eliminated in 1988 when the Surgeon General confirmed that tobacco is addictive. In light of that knowledge, individuals who sue based on claims that they were wrongfully addicted should not be permitted to wait for decades before filing suit, WLF argued.

Status: Awaiting decision.

GOVERNMENT CONTRACTOR DEFENSE -- INTERNATIONAL LAW CLAIMS. Vietnam Assoc. for Victims of Agent Orange v. Dow Chemical Co. On February 13, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit urging the court to reject a class action lawsuit brought on behalf of Vietnamese nationals, including former North Vietnamese and Viet Cong fighters, against a group of American chemical companies for their role in producing Agent Orange during the Vietnam War. The plaintiffs, the Vietnam Association for Victims of Agent Orange/Dioxin ("VAVAO") and various Vietnamese nationals, claim that the U.S. military's herbicide spraying program during the war was illegal under international law. In its brief, WLF focused on the applicability of the government contractor defense to international law claims, arguing that the defense does apply to such claims. WLF noted that allowing tort suits against defense contractors based on alleged violations of the laws of war by U.S. forces would be inequitable and would have serious deleterious effects on military procurement.

Status: Awaiting oral argument.

GLOBAL WARMING -- ENVIRONMENTAL REGULATION. Connecticut v. American Electric Power Company. On June 7, 2006, oral argument was held in this important global warming case. On March 2, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit in New York on behalf of itself and its client, U.S. Senator James M. Inhofe, Chairman of the Senate Environment and Public Works Committee, urging the court to reject an appeal filed by several states and environmental groups claiming that global warming is a public nuisance, and that the courts should order the major power companies to restrict their carbon dioxide emissions. The States of Connecticut, New York, California, Iowa, New Jersey, Rhode Island, Vermont, and Wisconsin sued American Electric Power Company. Southern Company, XCel Energy, Inc., Cinergy Corp., and the Tennessee Valley Authority (TVA) in federal court in New York City claiming that global warming constitutes a legal and actionable public nuisance under federal common law. A related lawsuit was filed against the same power companies by the Open Space Institute, the Open Space Conservancy, and the Audubon Society of New Hampshire. WLF argued in its brief that the district court was correct in dismissing the case on political question grounds because the policy issues involved in the case should be resolved by the political branches rather than by a federal court. WLF argued that the Congress has repeatedly rejected proposed legislation and the Kyoto Treaty that would impose unfair mandatory caps on carbon dioxide emissions on U.S. power companies while leaving countries such as China and India free from any constraints.

#### Status: Awaiting decision.

LEGAL REFORM -- ASBESTOS LIABILITY. Rehm v. Navistar. On January 6, 2006, WLF, along with a dozen leading industry and insurance trade organizations, urged the Kentucky Supreme Court to affirm a lower court ruling rejecting attempts to circumvent Kentucky workers' compensation program. In Rehm v. Navistar, the plaintiff was an employee of a company that installs industrial conveyor systems and machinery. That company was hired as a subcontractor over the years by some 15 different companies to install such equipment at their facilities. The plaintiff claims he was exposed to asbestos at those premises and contracted malignant mesothelioma. Under Kentucky law, a contractor becomes a statutory employer, and thus is immune from tort liability, if the work it subcontracted is a "regular or recurrent" part of the work or trade of the contractor. In that circumstance, injured employees are compensated under the state's workers' compensation program and cannot sue the companies separately under tort liability.

Status: Awaiting decision.

ANTITRUST -- PREDATORY BUYING. Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co. On November 28, 2006, oral argument was held before the U.S. Supreme Court in this important antitrust case that could impose substantial antitrust liability on a large company for engaging in "predatory buying" (*i.e.*, buying supplies at too high a price), even though the uncontested evidence demonstrated that the company at all times sold its products at prices that exceeded its costs. In its brief successfully urging the Court to review the case, WLF argued that consumers, as well as the economy as a whole, benefit when companies bid up the prices of goods they seek and that companies should not be punished for engaging in buying competition that is good for consumers. WLF argued that the lower court decision, unless reversed on appeal, will chill pro-consumer activity by companies that seek to avoid potential antitrust liability.

Status: Awaiting decision.

ILLEGAL ALIENS -- COLLEGE TUITION RATES. Day v. Bond. Oral argument was held on September 27, 2006 in this important immigration case. On October 25, 2005, WLF had filed a brief in the U.S. Court of Appeals for the Tenth Circuit in Denver, urging the court to reinstate a challenge to a Kansas statute that, WLF charges, violates the civil rights of U.S. citizens who live outside the state. The statute grants illegal aliens the right to attend Kansas universities at in-state rates but denies that same right to U.S. citizens who live outside of Kansas. WLF argued that the Kansas law violates a 1996 federal statute that prohibits states from granting more favorable tuition rates to illegal aliens than they grant to citizens. A federal district court dismissed the suit earlier this year on procedural grounds; WLF urged the appeals court to overturn that dismissal. WLF filed its brief on behalf of Brigette Brennan, who attended and graduated from a Kansas high school and has been living for the past four years in Kansas while attending the University of Kansas. But Kansas has refused to offer her in-state tuition rates because she lived in Kansas City, Missouri, while attending high school. The result is that she is paying considerably higher tuition than do illegal aliens who lived in Kansas illegally while attending high school and whose presence in this country continues to be illegal. WLF also filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Awaiting decision.

EXPERT TESTIMONY -- CHEMICAL EXPOSURE. Aguilar v. ExxonMobil Corp. (Lockheed Litigation Cases). On October 10, 2005, WLF filed a brief in the California Supreme Court asking the Court to affirm an appeals court ruling that recognized the need for California trial judges to assess the testimony of expert witnesses for validity. The proceeding involves claims by former workers at a Lockheed aerospace plant that their exposure to five solvent chemicals in the workplace caused them to become sick with cancer. The plaintiffs seek to present an expert witness to testify that their cancer was, in fact, caused by those chemicals. The issue before the California Supreme Court is the admissibility of the testimony of that witness where none of the articles and other materials on which he relies demonstrates a link between the chemicals involved and cancer in humans. In its brief, WLF argued that the decisions of the trial court and the Court of Appeal to exclude this testimony were proper.

Status: Awaiting oral argument.

TORT REFORM -- FIRST AMENDMENT. In re Tobacco Cases II. On September 14, 2005, WLF filed a brief in the California Supreme Court, urging the court to uphold the dismissal of tort claims filed against tobacco companies for having run truthful advertising that allegedly overglamorized smoking. WLF argued that such claims are barred both by the First Amendment and by federal law -- regardless of the plaintiffs' claim that glamorous advertisements induce minors to buy cigarettes in violation of California law. WLF argued that cigarette advertising is already heavily regulated at the federal level (by the Federal Cigarette Labeling and Advertising Act and by oversight conducted by the Federal Trade Commission), and at the state level by state regulators (by virtue of the Master Settlement Agreement entered into between tobacco companies and state attorneys general). WLF argued that there is no reason to permit an additional level of advertising regulation, in the form of tort suits filed under state law. WLF also noted that the plaintiffs seeking recovery are all admitted lawbreakers (they purchased cigarettes while under age 18) and argued that they should not be rewarded for their misconduct.

Status: Awaiting oral argument.

FEDERAL REGULATION -- EXCESSIVE PUNISHMENT. United States v. RxDepot, Inc. On February 22, 2006, the U.S. Court of Appeals for the Tenth Circuit in Denver declined an opportunity to prevent FDA from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, affirming FDA's authority to seek a massive damage award against an internet pharmaceutical distributor, was a setback for WLF, which had filed a brief urging the court to deny FDA that authority. In its brief, WLF argued that FDA has no power to seek disgorgement or restitution from companies alleged to have violated federal drug laws. WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that disgorgement and restitution are not among them. WLF argued that FDA, throughout most of its history, never asserted a right to seek disgorgement; WLF charged that FDA only recently began asserting that power in order to have a big club with which to intimidate manufacturers who might otherwise seek to challenge FDA. The Tenth Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief.

Status: Loss. Petition for Supreme Court denied October 2, 2006.

NATIONAL SECURITY -- DETENTION OF ALIEN ENEMY COMBATANTS. Al Odah v. United States. On March 22, 2006, oral argument was held in this important national security case. WLF continues its long running support of Bush Administration policy in this challenge to the detention of suspected al Qaeda terrorists at Guantanamo Bay, Cuba. During the nearly five years that the consolidated challenges have been pending in federal courts in the District of Columbia, Congress has passed a series of laws that have restricted the courts' jurisdiction to hear such cases. The most recent federal law, the Military Commissions Act of 2006, declares that federal courts have no habeas corpus jurisdiction over Guantanamo Bay detainee suits. WLF has filed numerous briefs in the case. Its most recent brief urged the U.S. Court of Appeals for the District of Columbia Circuit to rule that Congress acted constitutionally in withdrawing jurisdiction. WLF also filed a brief in April 2005, contesting the merits of the detainees' claims. WLF argued that the U.S. Constitution does not extend protections to aliens not living in the United States. WLF argued that the protections of the Constitution are reserved for U.S. citizens and others, such as resident aliens, who have contributed to American society and thus have a legitimate basis for invoking constitutional protections. WLF also argued that even if detainees were entitled to Due Process Clause protections, they have already received all the process that could possibly be due them under the Constitution, noting that the military has established review tribunals to hear claims of innocence. All of those still being detained at Guantanamo Bay have been determined by a tribunal to be enemy combatants who took up arms against the United States or its allies. WLF argued that the tribunal system satisfies the detainees' due process concerns, because it ensures that all detainees have a fair opportunity to contest their detention. WLF filed its briefs on behalf of itself and the Allied Educational Foundation.

### Status: Awaiting decision.

ENVIRONMENTAL LAW -- MERCURY EMISSIONS LEVELS. New Jersey v. EPA. On June 29, 2005, the U.S. Court of Appeals for the District of Columbia granted WLF's motion to file a brief in this important Clean Air Act case. The EPA revised and reversed its December 2000 finding that it was "appropriate and necessary" to regulate coal- and oilfired electric utility steam generating units ("Utility Units") under Section 112(n)(1)(A) of the Clean Air Act (CAA). Based on that action, EPA removed Utility Units from the CAA § 112(c) source category list. EPA determined that it was not "appropriate and necessary" to regulate mercury emissions from Utility Units based, in part, on a review of scientific evidence concerning asserted adverse human health effects of mercury emissions. Instead, the EPA proposes to regulate mercury emissions under the New Source Performance Standards (NSPS) of Section 111 of the Clean Air Act. In its amicus brief to be filed, WLF will review the scientific evidence in the record and demonstrate that it is not "appropriate and necessary" to regulate mercury emissions from Utility Units because such emissions do not represent a meaningful threat to human health.

Status: Case pending; briefs to be filed in mid-2007.

CLASS ACTION -- ATTORNEYS' FEES. LiPuma v. American Express. On February 14, 2005, WLF filed a brief in federal court in Miami objecting to a proposed class action settlement against American Express Company, including \$11 million in attorneys' fees. A hearing was held on March 8, 2005. The suit claims that American Express improperly assessed and disclosed adjustments to foreign currency conversions for cardholders who used their American Express card overseas during the last five years. The adjustments, or surcharge, amounted to 1-2 percent of the currency conversion rate. WLF argued in its objections, filed on behalf of a class member from Atlanta, that the settlement was not fair, reasonable, or adequate, arguing that class members' accounts should be automatically credited without the necessity of their submitting claim forms since the account information is readily available to American Express. More importantly, WLF objected to the proposed attorneys' fees of \$11 million as being excessive, particularly because the suit appeared to be a copycat suit filed after a California trial court ruled against Visa and MasterCard for similar conduct. WLF also requested that the March 15 Final Hearing be postponed until 30 days after the attorneys file their formal fee request, and that WLF and all objectors be afforded an opportunity to further respond to that request as permitted by the rules. WLF also opposed so-called "incentive payments" of \$10,000 to lead plaintiffs. On December 22, 2005, the court approved the terms of the settlement, but reserved ruling on the application for attorneys' fees.

<u>Status</u>: Settlement approved; appeal pending.

CLASS ACTIONS -- EMPLOYMENT DISCRIMINATION. Dukes v. Wal-Mart Stores. On August 8, 2005, oral argument was held in this important class action case. On December 8, 2004, WLF had filed a brief in the U.S. Court of Appeals for the Ninth Circuit in San Francisco, urging the court to overturn a lower court decision that certified a massive class action against retailer Wal-Mart. The suit was filed by a small number of female Wal-Mart employees who claim that the company denied them equal pay and opportunities for promotion. But the trial court has certified them as representatives of a class of 1.6 million current and former female employees. WLF argued that the plaintiffs failed to demonstrate that the case could manageably be tried as a class action. WLF was particularly critical of the trial court's decision to rely on the testimony of the plaintiffs' "expert" witness; WLF argued that the plaintiffs failed to establish that the testimony met the standard of "scientific reliability" and thus the testimony never should have been admitted into evidence. WLF's brief was prepared with the *pro bono* assistance of James P. Muehlberger and William C. Martucci of the Kansas City law firm of Shook, Hardy & Bacon, L.L.P.

Status: Awaiting decision.

CLASS ACTIONS -- LACK OF COMMON ISSUES. Engle v. Liggett Group, Inc. On December 21, 2006, rehearing was denied in this important class action case. On July 6, 2006, the Florida Supreme Court rebuffed efforts by plaintiffs' lawyers to reinstate a \$145 billion punitive damages judgment against the tobacco industry, awarded by a trial court to a class consisting of all Florida smokers who have contracted diseases caused by cigarettes.

The decision was a victory for WLF, which filed a brief on behalf of itself and the National Association of Manufacturers urging that the judgment, which had been reversed by an intermediate appellate court, not be reinstated. The Florida Supreme Court agreed with WLF that the punitive damages award was improper because it had been entered without any determination that the approximately 700,000 plaintiffs had a valid basis for recovery. While a jury determined that tobacco companies had acted wrongfully in the manner in which they marketed their products, the court said that a determination of liability would have to await such factual determinations as whether the companies' conduct caused each plaintiff's injuries, whether that plaintiff relied on industry misstatements in deciding to smoke. the extent of each plaintiff's injuries, and the extent to which that plaintiff's own negligent conduct contributed to his or her injuries. Moreover, the court said that such factual determinations are necessarily individualized and thus cannot be made on a class-wide basis -- thereby precluding further use of class action proceedings in this case. The court held that any Floridian claiming to have suffered pre-1997 injuries due to smoking would be permitted to file a separate suit and rely on the jury's determination of tobacco industry wrongdoing; but each such plaintiff would be required to demonstrate causation, reliance, comparative fault, and damages on an individualized basis.

Status: Victory.

EXPERT TESTIMONY -- PROFESSIONAL PEER REVIEW. Fullerton v. Florida Medical Assoc. On July 11, 2006, the Florida District Court of Appeal reinstated a defamation lawsuit filed by a doctor against the Florida Medical Association (FMA) and several other doctors, based on the defendants having instigated professional peer review of the plaintiff's expert testimony in a medical malpractice suit. The defendants had begun their investigation because they did not believe that the opinions expressed by the plaintiff doctor in his expert testimony demonstrated professional competence. The decision was a setback for WLF, which filed a brief in the case, urging that the trial court's dismissal of the case be upheld. WLF argued that both Florida law and a federal statute (the Health Care Quality Improvement Act of 1986) provide immunity from money damages to doctors who criticize their peers in connection with peer review proceedings. In reinstating the defamation lawsuit, the appeals court ruled that immunity extends only to complaints regarding a doctor's competence in treating an actual patient, not to competence in expert testimony. The physician who brought the case, Dr. John Fullerton, had testified in an earlier, unsuccessful medical malpractice action. After the conclusion of that action, the doctors against whom Dr. Fullerton had testified wrote a letter of complaint to the FMA in 2003, alleging that his testimony was false and financially motivated. They further requested an investigation of Dr. Fullerton's testimony. That letter is the basis of the present lawsuit. Florida attorney Rebecca O'Dell Townsend provided pro bono assistance to WLF in connection with its filing.

Status: Loss.

LEGAL REFORM -- PUNITIVE DAMAGES. City of Hope Medical Center v. Genentech, Inc. On January 26, 2006, WLF filed a brief the California Supreme Court urging it to reverse a court of appeal ruling that upheld a compensatory damages award of \$300 million along with an unprecedented \$200 million punitive damages award against Genentech, a biotech company. The company was involved in a contract dispute over royalties with City of Hope Medical Center which developed synthesized DNA material. If not overturned on appeal, businesses involved in typical contract disputes risk debilitating lawsuits by plaintiffs' attorneys not only for normal contract damages, but also for multimillion dollar punitive damages awards. The \$200 million award was in addition to the \$300 million compensatory damages award, bringing the total to \$500 million. WLF argued in its brief that if the decision were left intact, all businesses involved in typical contract damages, but also for multimillion dollar punitive damages awards. WLF also argued that the excessive award was not justified and should not have been imposed simply because the company could afford to pay the amount without going bankrupt.

Status: Awaiting decision.

NATIONAL SECURITY -- SUITS AGAINST TERRORIST NATIONS. Jacobsen v. Oliver. On September 12, 2006, the U.S. District Court for the District of Columbia ruled that victims of Middle East terrorism are not permitted to seek punitive damages against MOIS (the Iranian foreign intelligence agency) based on MOIS's active involvement in Hezbollah's terrorist activities. The decision was a setback for WLF, which filed a brief urging the court to rule that MOIS could be forced to pay punitive damages. WLF argued that allowing punitive damage awards against government sponsors of terrorism will make it less likely that governments will be willing to provide such support in the future. WLF filed its brief in conjunction with the Jewish Institute for National Security Affairs (JINSA). The case involved David Jacobsen, an American who was kidnapped by the terrorist organization Hezbollah and held hostage for several years in the 1980s in Lebanon. The issue before the district court was whether MOIS, as an arm of the government of Iran, was entitled to sovereign immunity. WLF's brief argued that MOIS was not entitled to immunity from suit to the extent that it engaged in the kidnapping and torture of Americans. Although Iran has been designated as a state sponsor of terrorism, federal law imposes strict limits on the ability of an individual to seek damages in federal court against a foreign state. WLF argued that MOIS is not synonymous with the Islamic Republic of Iran but, rather, should be deemed an "agent or instrumentality" of Iran and thus liable for punitive damage awards; but the court disagreed. The court rejected WLF's argument that providing support for terrorists around the world is not a legitimate, core government function and thus does not warrant special protection from damage awards. Joel J. Sprayregan and Jared M. White, attorneys in Chicago, assisted in preparing WLF's brief.

Status: Loss.

LEGAL REFORM -- CLASS ACTIONS. Avery v. State Farm Mut. Automobile Ins. Co. On August 17, 2005, the Illinois Supreme Court overturned a massive \$1.2 billion judgment against auto insurer State Farm, which (when issued) was the largest judgment ever rendered in Illinois. The decision was a victory for WLF, which has filed three separate briefs over the course of the past seven years seeking to overturn the judgment. The case involved charges that State Farm defrauded its customers by requiring them to use generic parts (rather than parts manufactured by the original manufacturer) when having their cars repaired. Most consumer groups and many states favor use of generic parts as a way of holding down repair costs. In its briefs, WLF had argued that State Farm had done nothing wrong and that the suit was unlikely to benefit any consumers but could result in huge fees for the attorneys masterminding the litigation. The Illinois Supreme Court agreed with WLF that the case never should have been certified as a nationwide class action and that, in any event, the plaintiffs failed to establish breach of contract or consumer fraud.

Status: Victory. Petition for Supreme Court review denied March 6, 2006.

PATENTS -- INEQUITABLE CONDUCT. Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc. On February 1, 2006, the U.S. Court of Appeals for the Federal Circuit reversed its earlier decision to invalidate a multi-billion dollar pharmaceutical patent, and remanded the case to the district court to consider the invalidity issue anew. The decision was a major victory for WLF, which filed a brief in June 2005, urging the three-judge appeals court panel to reverse its prior decision. Particularly gratifying to WLF was that the panel reversed itself based on the precise arguments raised by WLF in its brief. The case now returns to the U.S. District Court for the Southern District of New York for reconsideration of the patent invalidity issue. Based on guidance provided by the appeals court regarding how the issue should be resolved, it was likely that the district court will ultimately uphold the patent. The patent at issue covers OxyContin, a powerful pain relief medication. A federal district court ruled in 2004 (and the appeals court panel affirmed in June 2005) that the patent should be invalidated as a penalty for alleged "inequitable conduct" committed by the drug's manufacturer when applying to the Patent and Trademark Office (PTO) for the patent. A patent can be invalidated on those grounds only upon a showing that the applicant omitted "material" information from its patent application and did so intending to deceive the PTO. WLF argued (and the latest appeals court decision largely agreed) that the district court improperly lowered the bar for demonstrating inequitable conduct by applying far too lax standards for intent. WLF argued that any information withheld in this case was trivial and that there was no evidence that the manufacturer intended to deceive the PTO.

Status: Victory.

PRODUCTS LIABILITY -- CLASS ACTIONS. U.S. ex rel. Gilligan v. Medtronic, Inc. On April 6, 2005, the U.S. Court of Appeals for the Sixth Circuit in Cincinnati dismissed a lawsuit that sought to second-guess decisions of the Food and Drug Administration (FDA) authorizing the sale of drugs or medical devices. The decision was a victory for WLF, which filed a brief in support of the manufacturer whose product was being challenged. WLF argued that permitting such suits to go forward would undermine the integrity of FDA's product-approval system and could result in patients being denied access to life-saving medical products. Although it dismissed the lawsuit, the Sixth Circuit did so on narrower grounds than WLF had argued. The plaintiffs were suing under the False Claims Act (FCA), a federal law that permits bounty-hunting private citizens to file a suit in the name of the federal government against anyone who makes a "false claim" to the government. They alleged that the defendant, a medical device manufacturer, induced health care providers to falsely claim that the manufacturer's products had been properly approved by FDA. The Sixth Circuit held that the information on which the plaintiffs based their lawsuit was publicly available before they filed suit. The appeals court held that under those circumstances, the FCA suit was barred by the "public disclosure" bar, which eliminates federal court jurisdiction over an FCA claim where the plaintiff is not the original source of the allegations.

Status: Victory. Petition for Supreme Court review denied January 9, 2006.

ILLEGAL IMMIGRANTS -- LOST WAGES. Balbuena v. IDR Realty LLC. On February 21, 2006, the New York Court of Appeals declined to bar illegal aliens who are plaintiffs in personal injury lawsuits from recovering wages lost as a result of their injuries. The decision was a setback for WLF, which filed a brief in the case, urging that such damages be barred. WLF argued that awarding illegal aliens the wages they would have earned if they had not been injured would be inequitable because it would have been illegal for them to actually earn those wages by taking a job in this country. WLF argued that such awards are preempted by federal law because they undermine federal immigration policy by encouraging more illegal aliens to enter the country and seek employment. The Court of Appeals rejected WLF's position, contending that to deny damages for lost wages would encourage employers to reap the economic benefits of hiring illegal aliens. This personal injury tort suit was filed by Gorgonio Balbuena, an illegal alien who was severely injured while working for Taman. Balbuena alleges that his injuries were caused by Taman's negligence. Because Taman no longer exists, Balbuena filed suit against (among others) IDR Realty LLC, which owns the property where the injury occurred. Balbuena's right to recover for his injuries and medical expenses was not challenged; but WLF challenged Balbuena's claim that he is entitled to recover the wages he could have earned in this country had he not been injured. WLF's brief was drafted with the pro bono assistance of Timothy R. Capowski, Steven J. Ahmuty. and Christopher Simone, lawyers with the firm of Shaub, Ahmuty, Citrin & Spratt, LLP in Lake Success, New York.

Status: Loss.

FEDERAL REGULATION -- EXCESSIVE PUNISHMENT. United States v. Rx Depot, Inc. On February 22, 2006, the U.S. Court of Appeals for the Tenth Circuit in Denver declined an opportunity to prevent FDA from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, affirming FDA's authority to seek a massive damage award against an internet pharmaceutical distributor, was a setback for WLF, which had filed a brief urging the court to deny FDA that authority. In its brief, WLF argued that FDA has no power to seek disgorgement or restitution from companies alleged to have violated federal drug laws. WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that disgorgement and restitution are not among them. WLF argued that FDA, throughout most of its history, never asserted a right to seek disgorgement; WLF charged that FDA only recently began asserting that power in order to have a big club with which to intimidate manufacturers who might otherwise seek to challenge FDA. The Tenth Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief.

#### Status: Loss.

STATE TAXATION -- RESTRICTIONS ON COMMERCE. Kiley v. Calif. Dep't of Alcoholic Beverage Control. On May 24, 2006, the California Supreme Court issued an order declining to review the dismissal of a suit designed to impose significant restrictions on flavored malt beverage (FMB) sales by increasing taxes and prohibiting their sale in convenience and grocery stores statewide. The decision was a victory for WLF, which had filed a brief urging that review be denied because the appeals court had acted properly in dismissing the suit. WLF argued that California's long-standing policy of classifying FMBs as "beer" for regulatory purposes fully complies with California law. WLF further argued that the appeals court properly deferred to the Department of Alcoholic Beverage Control's (ABC) interpretation of relevant statutes. WLF argued that further review of the case was particularly unwarranted in light of the California legislature's ongoing review of FMB sales regulations; WLF argued that it makes little sense for the Court to review the ABC's compliance with existing statutes given that those statutes may be amended in the near future. WLF also argued that there is no evidence that sales of FMBs are targeted to those under 21.

Status: Victory; review denied.

STATE TAX INCENTIVES -- DORMANT COMMERCE CLAUSE. DaimlerChrysler Corp. v. Cuno. On May 15, 2006, the U.S. Supreme Court overturned an appeals court ruling that had struck down a state program of tax incentives for economic development. The decision was a victory for WLF, which filed a brief asking that the appeals court decision be overturned. The appeals court held that an Ohio tax incentive program violated the Constitution's "dormant" Commerce Clause because it provided benefits to companies doing business in Ohio but not to those operating outside the state. The Supreme Court did not reach the merits of the Commerce Clause issue. Rather, it held that the appeals court should never have considered the issue because the plaintiffs (Ohio taxpayers) lacked "standing" to raise it. WLF's brief had challenged the plaintiffs' standing and had also argued that the Ohio program is constitutional because it does not in any way penalize companies that choose to do business outside the state. WLF's brief was drafted with the pro bono assistance of J. Pat Powers, partner in the Palo Alto office of Baker & McKenzie. Status: Victory.

ANTITRUST LIABILITY -- PATENT SETTLEMENTS. Schering-Plough Corp. and Upsher-Smith Laboratories v. FTC. On March 8, 2005, the U.S. Court of Appeals for the Eleventh Circuit overturned a ruling by the Federal Trade Commission that would have imposed antitrust liability on two drug companies based on the settlement of a patent dispute. WLF had filed a brief on June 9, 2004, encouraging the court to overturn the FTC's ruling. The settlement agreements (between Schering-Plough Corp., Upshur-Smith, and American Home Products) settled a dispute involving generic drug companies who wished to manufacture a drug for which Schering-Plough claimed patent rights. The FTC held that the settlement unreasonably restrained trade because the generic companies agreed to delay their entry into the market. In its brief, WLF argued that the FTC's view of patent settlements between drug companies is commercially unrealistic and counter to federal antitrust law. WLF further argued that the FTC's position would deter settlement of patent disputes. WLF also filed a brief when the matter was before the FTC.

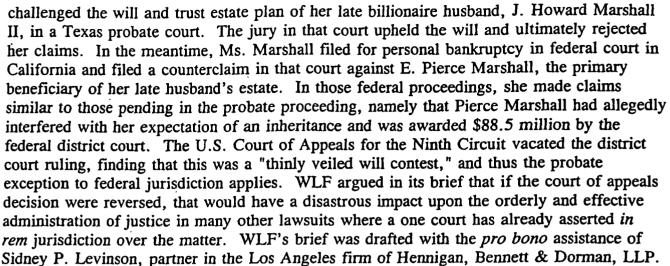
Status: Victory. Petition for Supreme Court denied on June 26, 2006.

SECURITIES CLASS ACTIONS -- APPEAL RIGHTS. Kircher v. Putnam Funds Trust. On June 15, 2006, the U.S. Supreme Court held that securities-law class action defendants do not have the right to appeal from rulings that keep securities class action cases in state courts rather than federal courts. The decision was a setback for WLF, which filed a brief urging the Court to recognize such a right of appeal. The case arises under the Securities Litigation Uniform Standards Act of 1998 (SLUSA), in which Congress acted to curb abusive class action claims for securities fraud. Congress enacted SLUSA to make federal courts the exclusive venue for most securities fraud class action litigation involving nationally-traded securities. The plaintiffs here filed security class actions in Illinois state court against mutual fund companies. The defendants sought to have the cases removed to federal court as provided by SLUSA, but the federal district court ruled that it had no jurisdiction and sent the claims back to state court. While acknowledging that the decision to send the case back to state court likely was incorrect, the Supreme Court held that the decision could not be appealed. A silver lining in the Court's decision was its statements that the defendants were entitled to raise their SLUSA defenses in state court, defenses that almost surely will result in dismissal of this case. WLF drafted its brief with the pro bono assistance of W. Reece Bader, James A. Myers, Diana L. Weiss, and Michael C. Tu, attorneys with Orrick, Herrington & Sutcliffe LLP.

Status: Loss.

FEDERAL JURISDICTION -- BANKRUPTCY COURT. Marshall v. Marshall. On May 1, 2006, the Supreme Court reversed a court of appeals decision that held that the federal bankruptcy court did not have jurisdiction to hear a challenge by the bankrupt to the rights to the estate of her late husband that were in probate proceedings in state court. In Vickie Lynn Marshall v. E. Pierce Marshall, the petitioner (also known as Anna Nicole Smith) originally

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Status: Loss.

NATIONAL SECURITY -- MILITARY TRIBUNALS. Hamdan v. Rumsfeld. On June 29, 2006, the U.S. Supreme Court struck down the Bush Administration's plan to convene military commissions to conduct trials of al Qaeda leaders accused of war crimes. The 5-3 decision was a setback for WLF, which filed a brief urging that the plan be upheld. The Court held that while the President has the authority to convene military commissions, the commissions that the Bush Administration established were improper because they did not provide defendants with all of the procedural rights required under the Uniform Code of Military Justice (UCMJ). The Court said that if the Administration wishes to employ its proposed procedures, it will have to go to Congress and ask it to amend the UCMJ. Alternatively, the Court ruled, the Administration could conduct trials before military commissions but using the same procedural rules commonly employed in military courts martial. The Court also rejected WLF's argument that any challenge to procedures to be employed by the military commission should be deferred until after a trial has been permitted to take place. The challenge was filed by an alleged al Qaeda member who faces charges that he conspired with Osama bin Laden to murder Americans. WLF filed its briefs in the Supreme Court and lower court on behalf of itself and the Allied Educational Foundation.

Status: Loss.

# **REGULATORY PROCEEDINGS**

# CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Proposed Regulations Requiring Preservation of Physical Evidence. On March 6, 2006, WLF submitted formal comments to the Chemical Safety and Hazard Investigation Board opposing proposed regulations that would require owners and operators of chemical and other companies to preserve certain physical evidence, including computer records and other information, following an accidental release of a toxic chemical or other hazardous substance into the ambient air. In addition, the proposed rule would trigger civil or criminal referral by the CSB if there is a "knowing failure to comply" with the proposed regulations. WLF argued that the CSB does not have the statutory authority to promulgate the proposed preservation of evidence rule, that the Board had failed to demonstrate that there was any need for the rule, and that the rule would allow the Board to make criminal referrals even if there was no criminal intent on the part of the company or its employees for not complying with the rule.

### DEPARTMENT OF HOMELAND SECURITY

In-State Tuition for Illegal Aliens. On August 9, 2005, WLF filed a formal complaint with the U.S. Department of Homeland Security (DHS) against the State of Texas, charging that Texas is violating the civil rights of U.S. citizens who live outside the State. WLF filed a similar complaint against New York State on September 7, 2005. WLF charged that Texas and New York are violating federal law by offering in-state college tuition rates to illegal aliens who live in those states, while denying those same rates to U.S. citizens who do not live in those states. WLF called on DHS to bring appropriate enforcement action against Texas and New York, including ordering them to make refunds to students who have been charged excessive tuition. The federal statute at issue, 8 U.S.C. § 1623, was adopted in 1996 and is designed to ensure that any state that offers discounted, in-state tuition rates to illegal aliens on the basis of their residence in the state must offer the same discounted rates to all U.S. citizens. In 2001-02, Texas and New York adopted laws that allow illegal aliens to attend public universities at in-state rates, but they have refused to extend that same opportunity to U.S. citizens living outside the states. Similar laws have since been adopted in seven other states: California, Utah, Illinois, Washington, Oklahoma, Kansas, and New Mexico.

### ENVIRONMENTAL PROTECTION AGENCY

Improper Assessment of Cancer Risks. On September 5, 2006, the Environmental Protection Agency (EPA) declined WLF's request that it reconsider its February 2006 decision to decline to hear a WLF petition to eliminate "junk science" from the process by which EPA determines whether a substance is likely to cause cancer in humans. In a petition filed pursuant to the Information Quality Act (IQA) in August 2005, WLF had argued that EPA guidelines for determining human carcinogenicity violate the IQA because they are not based on sound science but rather on an EPA policy judgment that extreme caution should be adopted in connection with substances that pose any possible cancer risk. EPA's response asserted that because its guidelines constitute a "policy" document, they are not subject to the IQA. WLF's March 21 reconsideration petition explained why EPA policy documents are not exempt from the IQA. WLF filed its initial petition and its reconsideration request on behalf of itself and the American Council on Science and Health ("ACSH"). ACSH recently published a study, *America's War on "Carcinogens,"* that is extremely critical of EPA's guidelines for determining cancer risks. Now that EPA's decision is final, WLF is considering its litigation options.

# NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Disciplinary Action Against "B Readers" Who Engage in Misconduct. On April 10, 2006, WLF filed a petition with NIOSH, urging it to take disciplinary action against "B Readers" who have acted inappropriately in connection with their analysis of x-rays of those being screened from asbestos-related disease. NIOSH is the licensing agency for all such B Readers. WLF charged that evidence being developed in pending asbestos litigation suggests that a small number of B Readers has been involved in a massive fraud in which thousands of healthy individuals have been diagnosed as suffering from asbestos and silica-related illnesses. WLF urged NIOSH to establish a program to look into these misconduct charges and to take appropriate disciplinary action. NIOSH responded in a lengthy letter dated May 30, 2006, assuring WLF that it intends to take an appropriate response and inviting WLF's continued participation in the issue.

### U.S. DEPARTMENT OF STATE

Foreign Cooperation with U.S. Deportations of Aliens. WLF filed comments on March 25, 2005, with Secretary of State Condoleezza Rice asking that the State Department take significant steps – including, where necessary, the imposition of economic sanctions – with regard to foreign governments that refuse to cooperate with U.S. deportations of their nationals. WLF urged the State Department to make explicit demands upon the governments involved. Where that does not bring cooperation, WLF urged the Department to impose sanctions, including sanctions under the power granted by the Immigration and Nationality Act, to discontinue granting visas to countries that refuse to cooperate in the issuance of travel documents for purposes of repatriation of excluded aliens, and under the Immigration Act of 1990, which authorizes the Secretary of State to exclude aliens for policy purposes.

### DEPARTMENT OF JUSTICE

Criminal Prosecution of Class Action Attorneys. On December 12, 2005, WLF called upon U.S. Attorney General Alberto Gonzales and the Justice Department to vigorously prosecute class action attorneys who may be involved in paying illegal secret kickbacks of attorneys' fees in some two dozen class action cases from 1984 to 2001, as alleged in a federal criminal

indictment. WLF requested that the Justice Department establish a task force similar to the Corporate Fraud Task Force established in 2002 to investigate other cases of possible plaintiff attorney misconduct. The Milberg Weiss firm and Bill Lerach have been identified as the attorneys in question but deny any wrongdoing; they claim the payments were not kickbacks but legitimate "referral fees" to their client's local attorney. In 2004, the Milberg Weiss firm split in two, with the New York law firm renamed Milberg Weiss Bershad & Schulman and the San Diego, California, firm of Lerach Coughlin Stoia Geller Rudman & Robbins, headed by William Lerach who was lead attorney in some of the cases. On May 18, 2006, the Milberg Weiss law firm, including two name partners, were indicted; however, neither Melvyn Weiss nor William Lerach were indicted. The case is pending.

Oversight of Criminal Investigations into Improper Drug Promotion. On March 24, 2005, WLF filed a petition with the U.S. Department of Justice (DOJ), urging DOJ to remove the Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetics Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF said that OCL has simply rubber-stamped whatever criminal investigation local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal investigation. WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal investigations of promotional activities have the potential to adversely affect the nation's health care delivery system.

Prosecutions Based on Communications about Off-Label Uses of Medicines. On October 5, 2004, the Assistant Attorney General in charge of the Justice Department's Civil Division responded to WLF's request for clarification of the Department's policies regarding off-label prescribing. Off-label uses of medicines – that is, prescribing of FDA-approved medicines for conditions that the FDA has not specifically approved – is standard medical practice and is heavily relied upon in areas such as cancer treatment, AIDS treatment, and pediatrics. WLF wrote to the Department on April 16 and June 15, 2004, to express concern about federal criminal and civil investigations of communications by pharmaceutical companies regarding off-label uses, which appear to violate speech rights and harm the interests of patients and doctors. The Department's response to WLF's response to the Justice Department was published in the March-April 2005 issue of FDLI Update, a leading industry trade journal. WLF is continuing to monitor DOJ enforcement policy in this area.

# DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

Regulation of Pain Medication Prescriptions. On November 6, 2006, WLF filed formal

comments with the Drug Enforcement Administration (DEA), urging DEA to make final its proposed rule regarding issuance of multiple prescriptions for Schedule II Controlled Substances. WLF stated that the proposed rule was an important first step in addressing a serious health care problem in this country: the underutilization of pain medication. WLF said that it understood the need for DEA to provide careful controls over potentially dangerous and addictive medications. At the same time, WLF argued, unless the need for controls is balanced with the need to provide ready access to those with a genuine medical need, health care will suffer. WLF argued that the proposed rule -- by permitting prescriptions of pain medications to be refilled under some circumstances without the need for the patient to make a separate visit to his or her doctor, thereby cutting down on medical costs -- takes a significant step toward bringing those competing interests into a proper balance.

Regulation of Pain Medication. On March 21, 2005, WLF filed formal comments with the Drug Enforcement Administration (DEA), urging that DEA regulation of pain medication not create a risk of denying needed pain medicines to terminally ill patients and chronic pain patients. In response to DEA's plan to issue new guidance regarding dispensing of controlled substances, WLF emphasized the importance of granting physicians leeway in treating *bona fide* pain patients, and stated that physicians should not be at risk of prosecution unless they distribute or prescribe controlled substances to a person outside the scope of legitimate practice. In separate comments filed the same day, WLF also expressed concern that DEA's new mandate to withhold approval for procurement of controlled substances used in the production of pain medicines should not be used by DEA to second-guess FDA approval decisions. WLF argued that DEA's role in this regard is advisory and that Congress has vested drug approval authority with FDA.

### DEPARTMENT OF TRANSPORATION NATIONAL HIGHWAY TRANSPORTATION SAFETY ADMINISTRATION

Federal Roof Strength Safety Standards Preempt State Law. On November 21, 2005, WLF filed comments with NHTSA that would extend roof safety rules to include vehicles with a gross weight of 10,000 pounds, increase the applied force for testing roof resistance to 2.5 times the weight of the unloaded vehicle from the current 1.5 factor, and replace the current headroom limit with a new requirement. WLF supported NHTSA's conclusion that its proposed safety rule would preempt state common law because such state tort rules would conflict with and frustrate's NHTSA's goals of reducing rollover crashes and the consequent injuries to the vehicles' occupants.

### FEDERAL TRADE COMMISSION

Word-of-Mouth Marketing. On February 2, 2006, WLF filed with the FTC a response to a petition seeking an investigation of word-of-mouth, or "buzz," marketing programs. The petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert claimed in its petition that programs inviting consumers (without

compensation) to tell their peers about new products are deceptive if the consumers do not also disclose that they are participating in a marketing program. WLF argued in its response that such communications are not deceptive and that there is no basis for requiring the disclosures sought by Commercial Alert. On December 7, 2006, the FTC rebuffed the petition by Commercial Alert and decided not to issue any guidance as requested.

Verifying Parental Consent for Online Activity. On June 27, 2005, WLF filed comments with the FTC, urging the agency to retain its "sliding scale" approach in mandating verifiable parental consent to their children's online activities. Under the Children's Online Privacy Protection Act (COPPA), the FTC is charged with ensuring that companies not collect, use, or disclose information about children under 13 who use their Internet sites, unless the children's parents consent to such activities. In 1999, the FTC adopted its "sliding scale" rule, pursuant to which the level of required verification depends on the uses the company plans to make of information it collects. If a website operator collects personal information for its internal use only, an email signed by the parent is sufficient to establish consent; but much more elaborate verification of consent is required if the operator intends to disclose information about a child to outsiders. In its comments, WLF argued that the "sliding scale" approach has been working well and thus there is no need to impose harsher verification requirements, as some groups have urged. On March 16, 2006, the FTC decided to retain its rule.

## HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Investigation of Grants for Political Activities. On April 28, 2006, WLF petitioned HHS's Office of Inspector General (OIG), urging the OIG to investigate the legality and propriety of certain grants made by the National Cancer Institute (NCI) in support of political activity. The grants in question were made to a variety of anti-tobacco activist groups to support those groups' efforts to bring about changes in government tobacco control policies. WLF charged that these grants appear to violate the congressional prohibition against lobbying with appropriated funds.

### HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE AND MEDICAID SERVICES

**Proof of Citizenship for Medicaid Applicants.** On July 11, 2006, WLF filed comments with CMS, urging the agency to tighten its requirements regarding the documentation that Medicaid applicants must provide to demonstrate that they are U.S. citizens (and thus eligible to receive Medicaid benefits). WLF argued that some of the guidelines adopted by CMS in this area are not as strict as Congress mandated in 2005 legislation. WLF argued that in the absence of stricter documentation requirements, Medicaid administrators could have little assurance that Medicaid program participants are actually eligible to receive benefits. WLF requested that CMS not permit administrators to waive documentation requirements for those claiming that it would be too burdensome to obtain proof-of-citizenship documents; it argued

that if documentation exists that would verify whether an applicant is a citizen, then the applicant should be required to provide the documentation.

**Restrictions on Speech About Part D Plans.** On April 4, 2006, WLF petitioned CMS to lift restrictions on commercial speech imposed by CMS's marketing guidelines for carriers offering Medicare prescription drug benefit plans. The guidelines prohibit carriers from making truthful and non-misleading statements comparing their plans to other plans. WLF's petition asserted that the speech restrictions are beyond the scope of CMS's authorizing regulations and violate the First Amendment rights of carriers and consumers.

CMS Guidance on "Part D" Drug Formularies. On August 19, 2005, WLF filed comments with the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, asking the agency to withdraw its plan to allow the exclusion of the lung cancer drug Iressa from drug plans under the new "Part D" prescription drug benefit. WLF's comments are in response to a CMS decision to exclude Iressa from a requirement that carriers offering coverage under the new benefit program must include in their formularies "all or substantially all" cancer drugs. WLF noted that Iressa is believed to represent the best available care for many lung cancer patients in the Medicare population for whom other therapies have failed. WLF filed the comments on behalf of itself, the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance.

CMS Proposal On Tying Coverage To Clinical Trial Participation. WLF filed comments on June 6, 2005, with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services (HHS) that operates the Medicare program, asking the agency to withdraw its proposal to tie reimbursement for selected new treatments to the patient's participation in a clinical trial or a similar evidence-gathering process. WLF argued that such requirements may restrict patients' access to needed care and that CMS has numerous alternative tools with which to spur research. WLF further argued that CMS has not justified such requirements under the Medicare statute's "reasonable and necessary" provision governing reimbursement. On July 12, 2006, CMS issued a Guidance document on this issue, and is continuing to seek public comment.

Obstacles to Medical Innovation. On August 20, 2004, WLF filed comments with HHS's newly created interdepartmental task force studying barriers to innovation in medical technology. WLF's comments – filed on behalf of itself, the Abigail Alliance for Better Access to Developmental Drugs, and the Lorenzen Cancer Foundation – argued that a number of government policies are having a profound effect on medical innovation. Among these are recent major expansions in criminal and civil liability on the part of pharmaceutical companies based on legal theories introduced on an *ad hoc* and retroactive basis by federal prosecutors. WLF argued that prosecutors do not have the expertise or responsibility to set health policy, and that such *ad hoc* expansions in liability will undermine the legal predictability that is needed by companies contemplating massive investments in new medical products. A public hearing was held and the matter remains under review.

Coverage of Cancer Drugs. On February 10, 2004, WLF filed a petition with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, asking the agency not to terminate coverage of "off-label" uses of certain cancer drugs. The petition is in response to national coverage reviews in which CMS is considering whether to end those reimbursements. In the petition, WLF noted that off-label prescribing – that is, a physician's use of a drug for conditions other than the specific ones for which the FDA has given marketing approval – is common and important to medical practice in obstetrics, pediatrics, and AIDS treatment, as well as cancer treatment. WLF is concerned that a denial of reimbursement for cancer drugs will not only deny the treatments of choice to thousands of dying cancer patients, but will set a precedent for denying proper treatment to other patients. WLF filed its comments on behalf of itself and two patient advocacy and support organizations, the Abigail Alliance for Better Access to Developmental Drugs and the Lorenzen Cancer Foundation.

### HEALTH AND HUMAN SERVICES NATIONAL CANCER INSTITUTE

Grants for Political Activity. On May 3, 2004, WLF filed comments with the Department of Health and Human Services, asking it to review the legality and propriety of grants made by the National Cancer Institute in support of political activity. The grants funded the staff and overhead costs of reviewing and analyzing masses of litigation documents, with the objective of generating research to determine how to enlist the support of various constituencies for new regulations of tobacco and tobacco marketing. WLF argued that the grants violate the congressional prohibition against agencies financing political activity with appropriated funds.

Oral Cancer Drug Demonstration Project. On June 25, 2004, WLF filed comments with CMS regarding the agency's proposed exclusions from a congressionally mandated Medicare demonstration project. As an interim measure prior to the implementation of the new prescription drug benefit in 2006, the demonstration project is to give 50,000 patients access to oral substitutes for drugs that would otherwise be administered in a doctor's office. WLF argued that the agency should abandon its proposal to exclude off-label uses of drugs from the project, because that exclusion would harm patients' health and violate congressional intent. WLF filed the comments on behalf of itself and two patient groups, the Abigail Alliance for Better Access to Developmental Drugs and the Lorenzen Cancer Foundation.

# HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Improper Regulation of Clinical Laboratories. On September 28, 2006, WLF filed a Citizen Petition with the Food and Drug Administration, calling on FDA to cease its efforts to enforce its "medical device" regulations against clinical laboratories that provide physicians with in-house developed and validated tests used to assist in making diagnoses and in developing treatment regimens. WLF's Citizen Petition asserted that FDA lacks statutory authority to regulate tests developed by laboratories for their own use and offered only to



health care professionals. WLF noted that clinical labs have long been subject to regulation by another federal agency – the Centers for Medicare and Medicaid Services (CMS) and its predecessors – pursuant to the Clinical Laboratory Improvement Amendments (CLIA). WLF argued that FDA enforcement efforts could undermine effective health care by crippling these labs' ability to quickly develop tests – e.g., for new or rapidly mutating infectious diseases.

"Lean" Labeling. On February 8, 2006, WLF filed comments with the FDA supporting the agency's proposal to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word "lean." WLF argued that the proposed change would assist consumers by giving providing them with accurate and relevant information and would also expand the market for lean foods.

User Fees. On December 14, 2005, WLF filed comments with the FDA on the reauthorization of the prescription drug user fee program. Under the Prescription Drug User Fee Act (PDUFA), sponsors of new drug applications pay user fees to allow FDA to hire more scientific review staff and improve its information technology for the purpose of expediting the new drug review process. In its comments, WLF argued that because PDUFA's purpose is to accelerate the availability of safe and effective new medicines, PDUFA fees should be expended only on direct application-related costs – not on unrelated costs as FDA officials have suggested. WLF argued that the prescription drug user fee program must not evolve into an industry-specific tax to finance FDA's normal regulatory and law enforcement activities.

Labeling of Soda Containers. On December 16, 2005, WLF filed comments with the FDA urging the agency to reject a petition filed by the Center for Science in the Public Interest (CSPI), a Washington, D.C.-based activist group founded by Ralph Nader, that would require warning labels on non-diet soda cans and bottles advising consumers, among other things, that "drinking too much soft drinks may contribute to weight gain." WLF argued that such warning labels are not mandated by law and, as a matter of public policy, are unnecessary since current labels on all beverages provide caloric content, sugar content, and other nutritional information to help consumers make informed choices.

Direct-to-Consumer Advertising of Prescription Drugs. On November 2, 2005, WLF Chief Counsel Richard Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer (DTC) advertising. Samp asserted that FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) needs to rein in its efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers. When FDA announced that it would be holding hearings on November 1 and 2, its announcement suggested that FDA is considering moving in the other direction and imposing additional restrictions on advertising. Many hearing witnesses called for severely limiting drug ads, calling them inherently biased and misleading. WLF's Samp countered that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options.

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Denial of Public Citizen's Petition on Silicone Breast Implants. On October 11, 2005. WLF filed formal comments with FDA, urging it to deny a Citizen Petition, filed by Public Citizen and others, seeking to block FDA approval of PMAs (premarket applications) for silicone gel-filled breast implants. WLF argued that the Citizen Petition is based on a misreading of the Administrative Procedure Act (APA) and the Federal Food, Drug, and Cosmetic Act (FDCA). WLF argued that Mentor Corp. and Inamed Corp., the manufacturers seeking PMAs, have provided adequate assurances that their products are safe and effective and that (contrary to Public Citizen's contention) a demonstration of absolute safety is neither possible nor required under federal law. An FDA Advisory Panel heard extensive public testimony in April regarding the PMAs, including testimony from WLF urging approval. FDA issued an "approvable" letter to Mentor in July and an "approvable" letter to Inamed in September. Public Citizen's petition was a last-ditch effort to block final marketing approval for silicone breast implants manufactured by the two companies. Although FDA has not acted on the Citizen Petition, it granted final marketing approval to both Mentor and Inamed in November 2006. Public Citizen has subsequently threatened efforts to block marketing, by taking the issue either to Congress or the courts.

Emergency Approval of Medical Products. On September 6, 2005, WLF filed comments in support of FDA's issuance of guidance on emergency approval of medical products. Congress has given FDA authority to allow the use of unapproved medical products, or to authorize unapproved uses of an approved product, in response to a heightened risk of attack from biological, chemical, radiological, or nuclear weapons. While expressing its support, WLF expressed concerns regarding the preemption aspects of the proposal. WLF argued that those provisions should be clarified to establish that the preemptive effect of an emergency authorization covers labeling matters and tort liability. WLF's comments noted that the emergency powers created by Congress to protect the public health would be frustrated by assertions of state or local authority in either of these areas - either to establish contrary or supplemental labeling requirements or to impose tort liability where a manufacturer is acting in compliance with an emergency use authorization.

Restriction on Lung Cancer Drug. On July 25, 2005, WLF filed comments with the Food and Drug Administration asking the agency to withdraw or modify its order for the restrictive labeling of the lung cancer drug Iressa. WLF's comments were joined by three patient groups, the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance. FDA's action effectively limits the use of Iressa in the United States to the approximately 4,000 patients already being treated with it. WLF's comments argued that this limitation on the availability of Iressa is unjustified and will harm lung cancer patients in the future who have no other approved treatment options and who may benefit from this medicine. WLF previously filed comments on April 20, 2005, with the FDA opposing a petition from the Nader group Public Citizen, Inc., in which Public Citizen sought the immediate withdrawal of Iressa.

Approval of Silicone Gel-Filled Breast Implants. On March 28, 2005, WLF filed comments with FDA's Medical Devices Advisory Committee, charging that FDA is violating clearly

established rules governing administrative procedure in its handling of premarket applications (PMAs) submitted by two companies seeking permission to market silicone gel-filled breast implants. WLF stated that the Administrative Procedure Act (APA) prohibits FDA from imposing far stricter approval requirements on silicone breast implants than it has imposed on similar medical devices. FDA has indicated that it wants Mentor and Inamed (the two manufacturers) to provide long-term data regarding the health consequences of breast implant failure (particularly rupture). Both PMAs include at least three years of post-implant data on the large number of women included in Mentor's and Inamed's studies. But because only a tiny fraction of breast implants rupture within seven years, gathering the breast implant failure information requested by FDA would require at least 10 years of post-implant clinical testing. Thus, if FDA stands by its request for long-term post-implant follow-up data, Mentor and Inamed would not be able to gain approval of their PMAs for many years to come. WLF charged that the APA prohibits FDA from imposing long-term pre-approval data requirements on the silicone breast implant PMAs, given that FDA has never previously imposed such requirements on similar medical devices. WLF Chief Counsel Richard Samp later elaborated on WLF's charges during testimony given to an FDA panel on April 11, 2005.

In re Tier 1 Initial Approval. In light of the continuing failure of the FDA to allow terminally ill patients to obtain promising new drugs in a timely manner, WLF filed a Citizen Petition with the FDA on June 11, 2003, to seek faster drug availability for these patients. WLF is representing the Abigail Alliance for Better Access to Developmental Drugs, an Arlington, Va.-based group of terminally ill patients and parents of terminally ill patients who have tried and failed to obtain access to drugs that are tied up in the FDA's approval process. WLF's petition urges the adoption of a preliminary approval program, "Tier 1 Initial Approval," that would make promising new drugs available to patients with lifethreatening illnesses while clinical trials and FDA reviews are underway. The petition shows in detail that such a program is within the FDA's statutory authority and does not require new legislation – contrary to past claims by FDA staff. WLF wrote to the new acting FDA commissioner on April 16, 2004, to urge prompt action on the issue. WLF's petition is still pending.

#### SECURITIES AND EXCHANGE COMMISSION

#### In re: Reports on Internal Control over Financial Reporting

Under Sarbanes-Oxley. On September 18, 2006, WLF filed comments with the SEC supporting the SEC's proposal to extend the compliance deadlines for smaller public companies to provide their management's reports on internal control over financial reporting (ICFR) under Section 404. WLF further urged the Commission to develop clearer and more flexible guidance for management regarding its evaluation and assessment of ICFR, and to adopt relevant recommendations of the Commission's Advisory Committee on Smaller Public Companies. WLF requested that the Commission reduce, as much as possible, the regulatory burden of Sarbanes-Oxley on all public companies, both large and small. WLF particularly supported those recommendations which include partial or complete exemptions

for specified types of smaller public companies until satisfactory guidance has been issued by the Commission and the PCAOB.

In re: Exempting Smaller Public Companies from Section 404 of Sarbanes-Oxley. On April 3, 2006, as part of its Investor Protection Program, WLF filed formal comments with the Advisory Committee on Smaller Public Companies to the U.S. Securities and Exchange Commission (SEC). The Committee released a final draft report recommending that the SEC exempt a category of smaller public companies from some of the burdensome and costly reporting requirements of Section 404 of the controversial Sarbanes-Oxley (SOX) legislation. SOX was originally intended to require more accurate financial reporting to the SEC, but is being administered unfairly, particularly for smaller companies. In particular, WLF supported the Committee's recommendation establishing a scaled or proportional securities regulation for smaller public companies, and the corresponding relief under SOX as recommended, including allowing smaller public companies to follow the financial statements rules now followed by small business issuers.

In re: SEC Fair Funds Distributions. On January 26, 2006, WLF filed formal comments with the Securities and Exchange Commission (SEC), urging it to amend its plan for distribution of funds collected from companies that engaged in unfair stock trading practices, to ensure that all such funds are distributed only to those who were injured by such practices. WLF argued that the proposed plan was deficient under the Sarbanes-Oxley Act (which established the Fair Funds for Investors program) because it did not provide for the distribution of \$50-70 million of collected funds. WLF said it feared that unless such a provision is adopted, the SEC may decide to deposit those funds into the U.S. Treasury. The SEC has amassed a \$250 million fund as a result of settlements with NYSE specialist firms accused of using improper trading practices. WLF argued that the SEC should retain left-over funds to allow interest to be paid on losses and to ensure that any late-filed claims for damages can be covered.

In re: Complaint on Dissemination of Damaging Information Against Bayer Company. On July 13, 2004, WLF filed a complaint with the Securities and Exchange Commission (SEC) requesting that it conduct a full and thorough investigation of the facts and circumstances regarding the lawfulness of certain communications by plaintiff's attorneys designed to depress the stock price of Bayer AG, a German company that is traded on the New York Stock Exchange, in order to pressure the company to settle the product liability lawsuits against Bayer over its cholesterol drug Baycol. A noted plaintiff's attorney was quoted as boasting that, in order to pressure Bayer to settle his questionable lawsuit seeking \$550 million, he was disseminating negative information about Bayer to the media to engender damaging stories, which in turn would drive down the price of Bayer stock.

**Proposed Rules on Director Nominations.** On May 7, 2004, WLF filed comments with the SEC opposing the SEC's proposed rule that would require the inclusion in proxy materials of shareholder nominees for election as a director of a publicly held corporation. WLF argued that the SEC lacks statutory authority to alter corporate governance procedures which are a

matter of state law rather than federal law.

In re: Petition for Rulemaking Regarding Disclosure of Contacts Between Plaintiffs' Attorneys and Analysts. On March 24, 2003, WLF filed a formal Petition for Rulemaking with the SEC that would require plaintiffs' attorneys to give pre-notification to the SEC and the public about any contact or communication between plaintiff's attorneys and financial analysts, short-sellers, and other persons whose recommendation or trading could affect the price of the stock of a publicly traded company. WLF's petition was based on reports of trial attorneys who file class action cases urging analysts to downgrade the value of a stock, hoping that the targeted company will settle the lawsuit.

# ALCOHOL AND TOBACCO TAX AND TRADE BUREAU, U.S. DEPARTMENT OF THE TREASURY

*Commercial Free Speech.* On September 26, 2005, WLF filed comments with the Alcohol and Tobacco Tax and Trade Bureau (TTB) requesting the TTB to revoke its ban on truthful alcohol labeling that discloses basic information to the consumer. WLF contended that such a ban violates sound public policy and the First Amendment commercial free speech rights of the alcohol industry. In its submission, WLF argued that proposed labels on alcoholic beverages that contain so-called "Serving Facts" listing the serving size of the beverage, the number of servings per container, and the amount of alcohol per serving, benefit consumers, are in the public interest, are truthful and not misleading, and are constitutionally protected by the First Amendment. WLF's comments were filed as part of a larger rulemaking proceeding where TTB is soliciting public comments on a wide range of alcohol labeling and advertising issues.

#### NEW YORK OFFICE OF COURT ADMINISTRATION

Disciplinary Rules Limiting Aggressive Solicitations of Clients by Lawyers. On September 13, 2006, WLF submitted comments to the New York Office of Court Administration supporting amendments to the Disciplinary Rules of the Code of Professional Responsibility governing advertising and solicitation of clients by attorneys similar to reforms proposed by WLF in 1992 as part of WLF's nationwide campaign to curtail abusive practices by aggressive plaintiffs' lawyers. The key provisions would 1) prohibit direct solicitation of accident victims within 30 days of an accident; 2) prohibit testimonials from current clients or actors to tout the lawyer's skills; 3) require that advertising, whether printed, broadcast, or on the Internet, be clearly labeled as advertising, and that copies of those materials be filed with bar authorities and retained; and 4) require that advertising that offers a contingency "no recovery, no fee" arrangement make clear that clients remain liable for costs and expenses. The amendments became effective on November 1, 2006.

#### STATE BAR DISCIPLINARY AUTHORITIES

Attorney-sponsored Asbestos Screenings. WLF filed petitions with state bar authorities

during 2004 asking those authorities to probe attorney-sponsored medical screenings of workers for asbestos-related illnesses. WLF's petitions contend that such screening programs commonly generate large numbers of spurious claims, and that these programs are a key component of the asbestos litigation crisis facing U.S. companies. Courts and scholars have observed that mass screenings, arranged by plaintiffs' attorneys and carried out by screening companies and doctors who are paid by the attorneys, lead to a high proportion of "positive" findings with respect to individuals who are actually suffering from no impairment. WLF's petitions detail the evidence that there has been substantial recruitment of plaintiffs with no impairment. The petitions ask bar authorities to initiate formal investigations and to treat such recruitment as a violation of legal ethics rules concerning false evidence and misrepresentation. WLF filed petitions with the bar authorities of Illinois, Mississippi, Missouri, Texas, Washington, and West Virginia.

#### MICHIGAN SUPREME COURT: ASBESTOS LITIGATION REFORM

Inactive Docket Proposal. On May 26, 2006, WLF joined with over a dozen leading industry and trade organizations in urging the Michigan Supreme Court to adopt either of the two proposed administrative procedures to help alleviate the asbestos litigation crisis. The crisis is fueled by thousands of lawsuits filed by plaintiffs' attorneys for individuals who may have been exposed at one time to asbestos but are not sick, forcing companies into bankruptcy while leaving little or no funds to compensate those with significant illnesses. This submission was a follow-up to a similar filing made in 2004 requesting that the Michigan Supreme Court grant a petition filed by over 60 Michigan asbestos lawsuit defendants that would allow the sickest asbestos claimants to have their cases litigated, and placing most of the other cases where claimants have no illness on an "inactive docket." Those placed on the inactive docket could later reactivate their lawsuits if they develop an asbestos-related disease. On November 26, 2006, WLF filed an additional comment supporting the court's rule change prohibiting the "bundling" or consolidation of abestosrelated cases.

#### UNITED STATES SENTENCING COMMISSION

Attorney-Client Privilege. On March 29, 2006, WLF filed comments with the Sentencing Commission along with a coalition of business groups, urging the Commission to remove certain language from amendments of the Sentencing Guidelines that, if left intact, would harm the attorney-client privilege. Lawyers for companies and other organizations play a key role in helping these entities and their officials comply with the law and act in the entity's best interests. To fulfill this role, lawyers must enjoy the trust and confidence of managers and boards and must be provided with all relevant information necessary to properly represent the entity. By requiring routine waiver of the attorney-client and work product privileges, the amendment will discourage companies and other organizations from consulting with their lawyers, thereby impeding the lawyers' ability to effectively counsel compliance with the law. Last year, WLF also urged the Commission to place this issue as a top priority on its agenda for the next round of amendments. On April 5, 2006, the Commission voted to delete the offending language from the proposed amendments.

#### SPECIAL PROJECTS

### DDMAC Watch

In June 2005, WLF inaugurated its "DDMAC Watch" program, designed to monitor federal regulation of prescription drug advertising. WLF has determined that the Food and Drug Administration (FDA), acting through its Division of Drug Marketing, Advertising, and Communications (DDMAC), has been using letters to the pharmaceutical industry to advance questionable legal theories and request remedial actions that the agency could not require under law. Under the DDMAC Watch program, when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF will immediately send back a response letter to DDMAC identifying the specific ways in which this is so. The goal of the program is to alert the press and public to abuses occurring at DDMAC. As of December 31, 2006, WLF has responded to 35 letters from DDMAC and related agencies, including three in the fourth quarter. Those letters were sent to Eli Lilly and Co., Endo Pharmaceuticals, MedImmune Vaccines, Dutch Ophthalmic USA, Hoffman LaRoche, Inc., Abbott Laboratories, Pfizer, Inc., Actelion Pharmaceuticals US, SuperGen. Inc., Allergan, Inc., Alcon Research, Ltd., Nephryx, LLC, ISTA Pharmaceuticals. Inc., Gen Trac, Inc., Medicis Pharmaceutical Corp., Sankyo Pharma Inc., Duramed Pharmaceuticals, Inc., Biogen Idec Inc., Mayne Pharma (USA), Inc., ZLB Behring LLC, Palatin Technologies, Inc., InterMune, Inc., VaxGen Inc., Bioniche Pharma Group Ltd., Boehringer Ingelheim Pharmaceuticals, Inc., Sandoz, Inc., Wyeth Pharmaceuticals, Inc., PrimaPharm, Inc., GlaxoSmithKline, Eli Lilly and Co., Astellas Pharma US, Inc., Reliant Pharmaceuticals, Inc., Mallinckrodt Inc., Alcon, Inc., and 3M Pharmaceuticals.

On August 7, 2006, WLF issued "The Year in Review," a comprehensive report on WLF's analysis of all DDMAC letters in the preceding 12 months. The report concluded that three DDMAC "policies" discernable from DDMAC's letters violate the First Amendment and various federal statutes. WLF submitted its report to FDA as a Citizen Petition, asking that FDA abandon those policies.

#### Investor Protection Program

On January 21, 2003, WLF launched its new INVESTOR PROTECTION PROGRAM (IPP) by filing a complaint with the Securities and Exchange Commission (SEC). WLF's complaint is the first in a series of legal actions, expert legal studies, and public educational/advertising campaigns that the Foundation will undertake.

The goals of WLF's IPP are comprehensive: to protect the stock markets from manipulation by trial attorneys; to protect employees, consumers, pensioners, and investors from stock losses caused by abusive class action litigation practices; to encourage Congressional and regulatory oversight of the conduct of the plaintiffs' bar with members of the securities industry; and to restore investor confidence in the financial markets through regulatory and judicial reform measures.

WLF engaged in a wide variety of litigation and regulatory activities under this program, which are described in greater detail throughout this report. Among other activities, WLF (1) filed three formal complaints with the SEC and the Department of Justice, urging an investigation into the questionable circumstances of short-selling in J.C. Penney Co. stock just before a major class action lawsuit was filed involving the company; requesting an investigation into the class action lawsuit against Terayon Communication Systems, Inc. by two short-sellers of the stock; and requesting an investigation into the class action lawsuit against Bayer Company; (2) filed Freedom of Information Act (FOIA) requests seeking SEC documents regarding enforcement actions involving possible violations of insider trading regulations or other SEC rules involving trial attorneys and related SEC policies, followed up by a FOIA lawsuit against the SEC; (3) filed a formal Petition for Rulemaking requiring disclosure of contacts made by trial attorneys with stock analysts and short-sellers; (4) testified before Congress on short-selling and class actions; (5) filed comments with the SEC on hedge fund regulation and Sarbanes-Oxley; (6) filed formal objections and briefs in several class action cases, and (7) filed a brief challenging the constitutionality of the Public Company Accounting Oversight Board (PCAOB) established by Sarbanes-Oxley. In addition, WLF published several op-eds and Legal Studies publications on the topic. Further details of these and related IPP activities can be found throughout this report under the Litigation, Regulatory, Civic Communications Program, and Legal Studies Division sections. Of particular note, WLF filed suit against the SEC in 2005 for failing to disclose documents requested by WLF relating to short-selling and class action lawsuits.

#### Working Group To Oppose Expanded EPA Authority

WLF's "Working Group To Oppose Expanded EPA Authority" filed a formal opposition to a petition for rulemaking by the International Center for Technology Assessment (ICTA) and other activist groups seeking to compel the Environmental Protection Agency (EPA) to regulate carbon dioxide and other emissions from new motor vehicles under Section 202 of the Clean Air Act. In its 45-page response to ICTA's petition filed in 2000, the Working Group argued that EPA had no authority under Section 202 of the Clean Air Act to regulate greenhouse gas emissions from new motor vehicles or from any other source, including utilities. The Working Group also argued that even if EPA did have the authority to regulate greenhouse gas emissions, there was no sound scientific basis for doing so, and any such regulation would pose excessive and unnecessary costs on our society and economy. The Working Group's response cites numerous scientific studies debunking the petitioners' claims that there is "global warming" and that carbon dioxide emissions are the cause; in fact, carbon dioxide has only 85% of the global warming potential scientists had

#### previously assumed.

ICTA's petition was joined by 19 other activist groups, including Ralph Nader's Public Citizen, Friends of the Earth, and Greenpeace USA. The Working Group's response to ICTA's petition was prepared with the *pro bono* assistance of Frederick D. Palmer, then-General Manager and Chief Executive Officer of Western Fuels Association, Inc.; Peter Glaser of Shook, Hardy & Bacon, LLP of Washington, D.C.; and the late William Lash III, then-professor at George Mason University School of Law. The Working Group submitted further comments to the EPA in May 2001. On July 14, 2005, WLF scored a victory when the court of appeals rejected the lawsuit against the EPA. The case was heard by the U.S. Supreme Court on November 29, 2006.

#### Civic Communications Program

WLF's highly acclaimed Civic Communications Program consists of a broad-based outreach program which disseminates our free enterprise message through print and electronic media, public education advertising campaigns, and on-site seminars and briefings. WLF attorneys and *pro bono* legal experts also engage in extensive "Litigation PR" efforts in high profile cases and legal matters.

WLF continued to be active during 2006 with its publication of hard-hitting public policy op-eds in the editorial pages of the *New York Times*. The op-eds, inaugurated in 1998 and published under the headline "*In All Fairness*," address a variety of topics of interest to the business community and appear regularly in the national edition of the *New York Times*, which reaches over five million readers in 70 major markets, as well as a diverse group of thought leaders, decision makers, and the public. WLF's op-eds have been well received and have generated substantial public discussion on the particular topics selected.

Titles and summaries of the op-eds published during 2006 include:

#### The State of Our Union

(Activists misuse the courts to promote their agenda by obstructing homeland security measures and using junk science in novel product liability lawsuits)

#### Cartoons Spark Outrage

(Anti-business groups threaten frivolous lawsuits against companies for marketing beverages)

#### Amnesty for Honest Businessmen

(While proposals for amnesty for illegal aliens are being considered, honest businessmen are being wrongfully prosecuted for trivial regulatory infractions)

#### Had Enough?

(Activist courts and lawyers have hijacked democratic policymaking by obstructing national energy and security programs)

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#### What Happened to Justice?

(Civil liberties of terror suspects are more protected than rights of honest businesses being targeted by aggressive prosecutors)

#### The Best of Intentions

(Donor intent is violated when charitable foundations provide funding grants to activist groups opposed to free enterprise philosophy of founding philanthropists)

#### Media Briefings & Educational Programs

Reaching out to journalists in the national media is critical to communicating WLF's free enterprise message. WLF uses its in-house facilities to host media briefings, which are often moderated by former U.S. Attorney General and WLF Legal Policy Advisory Board Chairman Dick Thornburgh. WLF's "Media Nosh" press conferences focus on a different, timely legal policy topic each week.

This component of the Civic Communications Program enables WLF to influence journalistic analyses of the issues and court cases and prevent activists from monopolizing the media by default. The briefings attract top reporters from high-profile electronic and print media such as USA Today, National Law Journal, Wall Street Journal, New York Times, Washington Post, Business Week, CNN, NBC News, ABC News, Voice of America, National Public Radio, C-SPAN, the major wire services, and syndicated legal reporters in the Washington, D.C., bureaus of national newspaper chains. These briefings are also webcast live and conveniently archived on WLF's website at www.wlf.org.

WLF media briefings during 2006 included the following:

#### Supreme Court Briefings

Previewing The 2006 U.S. Supreme Court Térm

- •The Honorable Dick Thornburgh, Kirkpatrick & Lockhart Nicholson Graham LLP
- •Jonathan S. Franklin, Fulbright & Jaworski L.L.P.
- •David B. Rivkin, Baker & Hostetler LLP

Reviewing the 2005 U.S. Supreme Court Term

- •Thomas C. Goldstein, Akin, Gump, Strauss, Hauer & Feld LLP
- •Andrew J. Pincus, Mayer, Brown, Rowe & Maw LLP
- •Miguel A. Estrada, Gibson, Dunn & Crutcher

Panel of Legal Experts to Assess High Court at Mid-Term

•Carter G. Philips, Sidley Austin LLP

•H. Christopher Batolomucci, Hogan & Hartson LLP

•Kevin J. Arquit, Simpson Thacher & Bartlett, LLP

#### Media Briefings

Self-Regulation of Advertising: Promoting Responsibility and Maintaining Commercial Speech

•Lynne J. Omlie, Distilled Spirits Council of the United States

•Joan Z. Bernstein, Bryan Cave LLP

•Lee E. Peeler, National Advertising Review Council

•Diane E. Bieri, Pharmaceutical Research and Manufacturers of America

KSR Int'l Co. v. Teleflex Inc.: The Supreme Court Examines the Patent "Obviousness" Standard

•The Hon. Gerald J. Mossinghoff, Oblon, Spivak, McClellan, Maier & Neustatdt, P.C.

•Thomas C. Goldstein, Akin, Gump, Hauer, Strauss & Feld LLP •James W. Dabney, Fried, Frank, Harris, Shiver & Jacobson LLP

Environmental Defense v. Duke Energy: Will U.S. Supreme Court Clear the Air on "New Source Review"?

•John C. Cruden, Deputy Assistant Attorney General, Envt. & Nat'l Resources Division, U.S. Department of Justice

•Robert M. Sussman, Partner, Latham & Watkins LLP

•Eric V. Schaeffer, Director, Environmental Integrity Project

A "Reasonable" Reaction?: Judicial Review of Criminal Sentences After Booker v. U.S. •Ronald J. Tenpas, Associate Deputy Attorney General, U.S. Department of Justice

•Carmen Hernandez, President-Elect, National Association of Criminal Defense Lawyers

WLF v. Leavitt: How CMS Speech Restriction Policy Harms Medicare Drug Beneficiaries

•V. Thomas DeVille, DeVille Pharmacies, Inc.

•Richard A. Samp, Washington Legal Foundation

Antitrust on the Docket: Renewed High Court Interest Reflect Flawed Federal Court Approach?

•John Thorne, Verizon Communications, Inc.

•A. Douglas Melamed, WilmerHale

•Roy T. Englert, Jr., Robbins, Russell, Englert, Oreseck & Untereiner, LLP

"Authorized" Generic Drugs: What Impact on Health Care Competition and Innovation?

•Michael S. Wroblewski, Federal Trade Commission

•David A. Balto, Robins, Kaplan, Miller & Ciresi L.L.P.

•Christopher J. Kelly, Mayer, Brown, Rowe & Maw LLP

FDA's Federal Preemption Policy: Implications for Drug Labeling and Product Liability Litigation

•Daniel E. Troy, Sidley Austin LLP •Mark S. Brown, King & Spalding LLP

Scrutiny of Medical Education Grants: A Chilling Wind for Doctors and Patients? •Jeffrey N. Gibbs, Hyman, Phelps & McNamara, P.C. •Steven E. Irizarry, ML Strategies

•Laura Frick Laemmle, Patton Boggs LLP

#### Web Seminars

WLF also continued its Web Seminar Series this year. Web Seminars present viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF's website. The speakers for the programs, who provide their insights on a pro bono basis, are leading experts in the field of law discussed.

The Foreign Corrupt Practices Act: Anticipating Government Enforcement and Managing Growing Legal Risks

•Simeon M. Kriesberg, Mayer, Brown, Rowe & Maw LLP •Claudius O. Sokenu, Mayer, Brown, Rowe & Maw LLP

Fighting "Serial" Product Liability Litigation: Parlodel® as a Defense Case Study •Joe G. Hollingsworth, Spriggs & Hollingsworth •Katharine R. Latimer, Spriggs & Hollingsworth

Twenty Years of Proposition 65: Its Present and Future Impact on California and Federal Regulatory Policy

•Gene Livingston, Greenberg Traurig LLP

•Eric G. Lasker, Spriggs & Hollingsworth

An Unattractive Legal Theory: Lessons from the Successful Defense of Anti-Alcohol Advertising Class Actions

•J. Russell Jackson, Skadden, Arps, Slate, Meagher & Flom LLP

The Rapanos and Carabell Rulings: Consequences for Clean Water Act Enforcement, Regulation, and Compliance

•Sue Ellen Wooldridge, U.S. Department of Justice

•Ann Klee, Environmental Protection Agency

•Barry M. Hartman, Kirkpatrick & Lockhart Nicholson Graham LLP

Incentivizing Whistleblower Litigation: Ramifications for Health Care Contractors as False Claims Laws Spread in the States

•John T. Boese, Fried Frank Harris Shriver & Jacobson LLP •Beth C. McClain, Fried Frank Harris Shriver & Jacobson LLP

Ten Years after BMW v. Gore: Punitive Damages at Trial and on Appeal •Andrew L. Frey, Mayer, Brown, Rowe & Maw LLP •Evan M. Tager, Mayer, Brown, Rowe & Maw LLP

Achieving Civil Justice Reform in Court: How Defendants Can Dismantle Arbitrary, Pro-Plaintiff Common Law Rules

•Victor E. Schwartz, Shook, Hardy & Bacon L.L.P.

The Class Action Fairness Act, One Year Later: Mission Accomplished? •John Beisner, O'Melveny & Myers LLP •Jessica Davidson Miller, O'Melveny & Myers LLP

SEC's New Civil Penalty Principles: Clearer Standards for Public Companies? •Gregory S. Bruch, Foley & Lardner LLP •Julie A. Smith, Foley & Lardner LLP

Merrill Lynch v. Dabit and Beyond: The Supreme Court Looks at Securities Fraud •Donald B. Verrilli, Jr., Jenner & Block LLP

#### SCALES

SCALES ("Stop the Collapse of America's Legal Ethics") is WLF's multi-state, multi-faceted project designed to reform the civil justice system, contain the "litigation explosion," and improve the professional and ethical standards of lawyers nationwide. SCALES represents a continuation of WLF's long-standing effort to increase accountability within the legal profession and bring the "litigation explosion" under control.

PHASE ONE: CONTINGENCY FEES. WLF's contingency fee proposal requires attorneys to provide their clients with a written Statement of Client's Rights and Lawyer's Responsibilities. The statement would inform clients that fees are negotiable and would provide a three-day cooling-off period during which clients could withdraw their authorization for representation without suffering any penalties. The WLF reform proposal would also require attorneys to set out the actual contingencies or risk of non-recovery, to disclose the use of retainer fees, to disclose the adverse risks of litigation including counterclaims and sanctions, and, at the conclusion of the litigation, to file a copy of the written fee agreement and "closing statement" with the court so that the court can exercise its supervisory powers to reduce any excessive fees. WLF filed petitions with all 50 states as well as the District of Columbia and Puerto Rico, thereby completing this phase of WLF's

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SCALES project. Several states have adopted various aspects of WLF's proposals and WLF continues to follow up in the remaining states to encourage them to do likewise.

PHASE TWO: CLIENT SOLICITATION. The filing of petitions with state supreme courts or state bar associations concerning client solicitation marked the second phase of WLF's SCALES project. WLF completed this phase with petitions filed in all 50 states plus the District of Columbia. While WLF recognizes lawyers' constitutional right to advertise, WLF has been concerned that states have not been doing enough to prevent misleading attorney advertising. WLF's petitions urged the state courts and state bars to require attorneys to disclose in their advertising and solicitation materials all costs that a prospective client might incur in litigation. WLF's petitions also urge the courts and state bars to require copies of all advertisements and client solicitation materials to be filed with the state bar authorities. A filing requirement will assist courts and state bars in monitoring attorney advertising and solicitation. In June 2006, New York proposed amendments to their rules on advertising and solicitation that are similar to those proposed by WLF in 1992. WLF filed comments with New York authorities on September 13, 2006, further supporting those amendments which went into effect on November 1, 2006.

PHASE THREE: JUDICIAL CAMPAIGN CONTRIBUTIONS. The third phase of WLF's SCALES project is designed to limit campaign contributions from attorneys to judges who are elected to office. WLF filed a proposal with the Board of Governors of the State Bar of California and the California Judicial Council to reform judicial campaign contribution rules in that state. In addition to California, WLF filed similar petitions in Alabama and Texas. Lawyers in Alabama, Texas, and California gave a total of almost \$20 million to state candidates in their respective states from 1990-1994; by contrast, the Democratic National Committee gave \$12.4 million to candidates *in all 50 states*, while the Republican National Committee gave \$10.8 million. WLF was successful in persuading the Supreme Court of Texas to alter its judicial ethics rules involving the receipt of contributions. WLF will study other states to determine whether similar petitions are warranted.

PHASE FOUR: DISCLOSURE OF ATTORNEY DISCIPLINARY PROCEEDINGS. As part of its SCALES Project, WLF investigated attorney disciplinary procedures in the various states to determine whether disciplinary proceedings are sufficiently open to the public. WLF's research revealed that attorney misconduct is handled in a secretive manner to the detriment of the complaining client and the public at large. WLF filed petitions in all 50 states and the District of Columbia urging them to open the disciplinary process to the public. WLF will continue to monitor these states for any proposed revisions to their attorney disciplinary program.

PHASE FIVE: EXCESSIVE ATTORNEYS' FEES. WLF has petitioned several state Bars to require attorneys to file copies of any court decision reducing a fee award or application for being excessive or improper, so that appropriate disciplinary proceedings

against those attorneys may be instituted where warranted. WLF filed petitions with the State Bars of Florida, Alabama and Texas.

#### Criminalization of Free Enterprise - Business Civil Liberties Program

There continues to be a growing and dangerous trend by federal and state authorities to violate business civil liberties and criminalize honest business activities when more appropriate administrative and civil remedies are available. WLF aggressively fights for economic rights and commercial free speech, and vigorously opposes wrongful criminal prosecution of free enterprise.

WLF activities during 2006 targeted government enforcement practices by the U.S. Department of Justice, U.S. Attorneys, U.S. Sentencing Commission, State Attorneys General, and state and federal regulatory agencies. In particular, WLF vigorously opposed the Department of Justice prosecutorial guidelines that would unfairly intrude on the attorney-client privilege between counsel and corporations. WLF has been working closely with the American Bar Association, the Coalition on Attorney-Client Privilege Waiver, and other groups on criminal law reform as it affects business interests. WLF also has been critical of the U.S. Sentencing Commission's guidelines, which unfairly punishes companies for failing to comply with the myriad of complex laws and regulations. WLF was the only pro-free enterprise public interest organization to file briefs in the U.S. Sentencing Guidelines cases before the U.S. Supreme Court and lower courts opposing the misuse of the Sentencing Guidelines by federal prosecutors.

#### Court Watch Project

WLF's Court Watch Project involves the investigation of judges who may have acted unethically or improperly in either civil or criminal cases. When appropriate, WLF not only brings these cases to public attention, but also files complaints with judicial misconduct commissions so as to make the civil and criminal justice system more responsive to the needs of everyday citizens. To date, WLF has investigated and/or filed complaints against more than 135 state and federal judges.

#### SAVE Program

WLF continues to spread its pro-free enterprise message to the nation's youth through its Salvatori American Values Education (SAVE) Program. WLF's SAVE Program is designed to help educate the thousands of high school and college students who travel to Washington, D.C., every year -- in organized educational programs, as interns, and on class trips -- by stressing the values of liberty, freedom, free enterprise, and limited government espoused by the Founding Fathers. The SAVE Program's approach is twofold. First, WLF attorneys make personal appearances at SAVE seminars to speak directly to students regarding the Founding Fathers' values and engage in question and answer sessions with the students. Second, WLF's Legal Studies Division publishes SAVE Program literature. SAVE Program appearances to date include presentations to students at events sponsored by the following groups:

- \* Institute for Jewish Leadership and Values
- \* Marquette University
- \* Washington Workshops Foundation
- \* The Washington Center for Politics and Journalism
- \* Smithsonian Institution's Campus on the Mall
- \* The American University Washington Semester Program
- \* The Luther Institute
- \* The Close-Up Foundation
- \* The University of Kansas
- \* The D.C. School of Law Federalist Society
- \* The American University, Washington College of Law
- \* . Georgetown University Law Center Federalist Society
- \* Catholic University Law School
- \* National Youth Leadership Forum
- \* United States Naval Academy
- \* Gallaudet University
- \* University of Baltimore Law School Federalist Society
- \* Hofstra University Law School
- Tulane University School of Law
- \* Oklahoma City University Law School Federalist Society
- Texas Tech Law School Federalist Society
- \* Duke University Law School Federalist Society
- \* Quinnipiac Law School Federalist Society
- \* George Washington University Law School Federalist Society
- \* George Mason University School of Law
- \* Panim el Panim
- \* Cazenovia College

#### **Outreach** Project

WLF continues to expand its nationwide network of attorneys to encourage them to engage in *pro bono* litigation activity on behalf of free enterprise and to give them an opportunity to write legal policy papers for national distribution through WLF's Legal Studies Division. During 2006, WLF received *pro bono* assistance from a number of law professors, lawyers, and law firms listed throughout this report.

#### Legal Studies Division Publications

WLF's Legal Studies Division published the following COUNSEL'S ADVISORIES, LEGAL OPINION LETTERS, LEGAL BACKGROUNDERS, WORKING PAPERS, CONTEMPORARY LEGAL NOTES, MONOGRAPHS, and CONVERSATIONS WITH in 2006.

COUNSEL'S ADVISORIES

Comments Sought On State Court Plan To Address Asbestos Suits By Thomas J. Foley and Richard S. Baron, founders of the Detroit-area law firm of Foley, Baron & Metzger.

"Honest Services" Criminal Claim Dealt Setback In Appeals Court By James B. Tucker and Amanda B. Barbour, members of the General Litigation group at Butler, Snow, O'Mara, Stevens, & Cannada PLLC in Jackson, Mississippi.

**DEA Seeks Comments On Pain Medication Proposal** By Richard A. Samp, Chief Counsel to Washington Legal Foundation.

Fresh Bagels And A Schmear: A Sign Of The Times Ruling On Commercial Free Speech

By Arnold I. Friede, Senior Corporate Counsel with Pfizer, Inc.

Federal Court Rejects Class Action Waivers In Arbitration Clauses By Donald M. Falk and Archis A. Parasharami, a partner and an associate, respectively, at the firm Mayer, Brown, Rowe & Maw LLP.

SEC Seeks Comments On Application Of "SOX" Section 404 By Damon D. Colbert is an associate in the Washington, D.C., office of the law firm Pillsbury Winthrop Shaw Pittman LLP.

Appeals Court Ruling Embraces "PMA" Device Preemption By Michael K. Brown and Lisa M. Baird partners in the international law firm of Reed Smith LLP who specialize in litigation involving the pharmaceutical and medical device industries.

English Court Permits "Forum Shopping" In Private Antitrust Suits By David Marks, a partner at the law firm CMS Cameron McKenna LLP.

Bilked Asbestos Plaintiffs Sue Florida Bar Association By John Stadler, Counsel in the Boston office of the Law Firm Nixon Peabody LLP.

#### D.C. Court Dismisses "Attractive Advertising" Class Action Lawsuit By J. Russell Jackson, a partner in the Complex Mass Torts Group of New York's Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School.

Federal Court Finds Medical Monitoring Tort Unavailable In Texas By Shawn D. Bryant, an attorney with the law firm Spriggs & Hollingsworth in Washington, D.C.

European Commission Paper On "Healthy Diets" Has Implications For Food Industry By Sarah A. Key, an associate in the Washington, D.C. office of Foley & Lardner LLP. She is a member of the Regulatory Department, its General Regulatory Practice Group, and the Food Industry and International Business Teams.

Supreme Court To Review Right To Automatic Injunction In Patent Cases By Blair M. Jacobs, a partner with the law firm Sutherland Asbill & Brennan LLP and member of the firm's IP Litigation Group.

Federal Court Applies Brakes To Alien Tort Statute Litigation By Konrad L. Cailteux, a partner with Weil, Gotshal & Manges LLP in the firm's New York office and B. Keith Gibson, an associate with the firm, also in its New York office.

FDA Preempts "Failure-To-Warn" Pharmaceutical Liability Claims By James Dabney Miller, a partner in the Washington, D.C. office of the law firm King & Spalding LLP.

Comments Due On Chemical Accident Evidence Preservation Proposal By Jane C. Luxton, a partner in the Washington, D.C. office of the law firm King & Spalding LLP.

LEGAL OPINION LETTERS

The First Amendment And Lawyer Blogs By Larry E. Ribstein, who authors the blog *Ideoblog* and is the Mildred Van Voorhis Jones Chair in Law at the University of Illinois College of Law.

ACLU v. National Security Agency: Unwarranted Intrusion Into Wartime Decision-Making

By Andrew C. McCarthy, the head of the Center for Law and Counterterrorism at the Foundation For The Defense Of Democracies.

#### U.S. v. Kandirakis: A Bellwether Ruling On Sentencing Guidelines?

By Brian M. Heberlig and Amy Lester, a partner in the New York office and an associate in the Washington, D.C. office, respectively, at the firm Steptoe & Johnson LLP.

#### State Court Finds SUV's Design Not Inherently Defective

By Joel D. Bertocchi, a partner with the Chicago law firm Hinshaw & Culbertson LLP.

#### Supreme Court Revisits Constitutional Limits on Punitive Damages

By Theodore B. Olson, the former Solicitor General of the United States, is a partner with the law firm Gibson Dunn & Crutcher LLP where he serves as co-chair of the Appellate and Constitutional Law Practice Group and Thomas H. Dupree, Jr., a partner in the firm's appellate group.

Court Rules Against Cross-Border Enforcement Of "European" Patent Rights By Beth Z. Shaw, an attorney at the law firm Finnegan Henderson Farrabow Garrett & Dunner LLP.

#### Federal Circuit Courts Send Mixed Messages On Sentencing

By James Flanagan, a second year law student at the Catholic University of America Columbus School of Law and a law clerk to Washington Legal Foundation's Legal Studies Division.

#### Legal Storms Intensify For Lead Paint Makers

By Charles E. Redmond II, an International Business and Finance Bachelor of Arts candidate at the University of South Carolina, was a Fellow with Washington Legal Foundation during the summer of 2006.

Court Upholds Government's Illegal Alien Detention Authority By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw.

Washington Spyware Law Addresses Serious Online Commerce Threat By The Honorable Rob McKenna, Attorney General to the State of Washington.

State Based Reforms: Making A Difference In Asbestos And Silica Cases By Mark A. Behrens and Frank Cruz-Alvarez, a partner and an associate, respectively, from the law firm Shook, Hardy & Bacon LLP.

State Court Rules Plaintiff's Illegal Acts Bar Tort Suit By Margaret Oertling Cupples, a partner at the Jackson, Mississippi office of Bradley, Arant Rose & White.

Applying *eBay* Court Rejects Injunction In Patent Case By Blair M. Jacobs, a partner at Sutherland Asbill & Brennan's IP Litigation Group. Judicial Chorus Against "Attractive Advertising" Suits Grows Louder With Ruling By J. Russell Jackson, a partner in the Complex Mass Torts Group of New York's Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School.

"Inequitable Conduct" Standard For Patent Suits Is Heightened By Peter A. Jackman, a director with the law firm Sterne, Kessler, Goldstein & Fox P.L.L.C.

Medical Monitoring Claim Pursued In New York State By Sean Wajert, a partner at Dechert LLP.

Financial Interest Disclosures Can Protect Markets From "Short And Distort" Manipulators By Alex J. Pollock, a Resident Fellow at the American Enterprise Institute.

Multiple Sclerosis Patients v. FDA Overcaution By Lauren Roberts, a multiple sclerosis patient living in California.

Supreme Court Should Rule Pleading Standards For Antitrust Mega-Litigation By Roy T. Englert Jr., a founding partner of Robbins, Russell, Englert, Orseck & Untereiner LLP in Washington, D.C.

Independent Contractors: Preserving The Model Is An Economic Imperative By Karen Kerrigan, President & CEO of the Small Business & Entrepreneurship Council.

U.S. Senate Considers Reforms To OSHA Law

By Christopher J. Armstrong, an attorney with the U.S. Office of Special Counsel.

Patents For Software Remain Viable And Vital In European Union By Robert D. Becker, a partner, and Greg T. Warder, an associate, in the Palo Alto office of the law firm Mannatt, Phelps & Phillips, LLP.

Avoiding Disparities Between Sentences Of Co-Defendants Is A Legitimate Sentencing Goal

By Brian M. Heberlig, a partner in the Washington, D.C., office of Steptoe & Johnson LLP, and a member of the defense team in *United States v. Ebbers*.

Advertising And Preemption Under FDA's New Drug Labeling Rule By Tish E. Paul, a principal with Olsson, Frank and Weeda, P.C.

**Don't Dilute Drug Approval Process With Non-Scientific Criteria** By Gilbert L. Ross, M.D., the Executive Director and Medical Director of the American Council on Science and Health (ACSH), a consumer education-public health organization; and Elizabeth M. Whelan, MPH, ScD, President and founder of the American Council on Science and Health.

Quietly Expanding Qui Tam: Federal Law Encourages New State False Claims Acts By John T. Boese, a partner in the Washington, D.C. office of the law firm Fried, Frank, Harris, Shriver & Jacobson LLP.

Judge Offers Frank Assessment of Lawyer-Driven Securities Suits By Joseph De Simone, a litigation partner and Andrew J. Calica, a litigation associate in the New York office of Mayer, Brown, Rowe & Maw LLP.

Federal Court Fires A Torpedo At "Submarine" Patent Practice By William T. Cook, an associate with Sutherland, Asbill & Brennan LLP in the firm's Atlanta office.

Congress Enacts Substantial Liability Protections For Public Health Emergencies By John M. Clerici, a partner with the law firm McKenna Long & Aldridge LLP in its government contracts practice and government affairs group; Frank M. Rapoport, also a partner and focuses on government contracts, information technology, federal litigation and public health law; and Douglas B. Farry, a Managing Director in the firm's Government Affairs practice.

Merrill Lynch v. Dabit: The Supreme Court Examines Securities Fraud Preemption By James Edward Maloney, a partner, and Ryan D. McConnell, an associate at the law firm Baker Botts L.L.P. in the firm's Houston office.

LEGAL BACKGROUNDERS

WTO Ruling On Biotech Foods Addresses "Precautionary Principle" By Lawrence A. Kogan, an international business, trade, and regulatory attorney. He is CEO of the Institute for Trade, Standards and Sustainable Development, Inc.

Nanotechnology: Don't Delay Liability Risk Assessments And Solutions By George J. Mannina, Jr., a Senior Partner at the law firm of O'Connor & Hannan, LLP, and a member of the Environmental Practice Group at the Firm.

Bell Atlantic v. Twombly: High Court Should Reverse In Antitrust Class Action By Christine C. Wilson and Adam J. Coates, a partner and an associate, respectively, at the law firm O'Melveny & Myers LLP in its Washington, D.C. office.

Rulings Slowly Reveal Impact Of California's Proposition 64 By Ross H. Hyslop, a partner with the law firm McKenna Long & Aldridge LLP in its San Diego office.

#### Climate Change & Insurance: Sweeping Regulations Are Not The Answer By Debra T. Ballen, the Executive Vice President, Public Policy Management and Corporate Secretary to the American Insurance Association.

Progressive Liability Reform Law Faces Repeal Effort In Michigan By Thomas J. Foley and Kim J. Sveska, a founder and a principal, respectively, at the firm Foley, Baron & Metzger.

A Priority For The FDA: Fix The "Warning Letter" Process By Larry R. Pilot, a partner with the law firm McKenna Long & Aldridge LLP in its Washington, D.C. office.

Alcohol Advertising: Federal And State Regulators Should Tread Lightly By David Versfelt, a partner with the law firm Kirkpatrick & Lockhart Nicholson Graham LLP and Adonis Hoffman, Senior Vice President and Counsel with the American Association of Advertising Agencies.

Legal Reform Inches Along In Illinois By Edward D. Murnane, President of the Illinois Civil Justice League.

# Separation Of Powers, ABA Style: "Signing Statements" Report At Odds With Constitution

By Timothy E. Flanigan, a Senior Vice President and Deputy General Counsel at Tyco International, and David B. Rivkin, Jr. and Lee A. Casey, partners in the Washington D.C. office of the law firm Baker & Hostetler LLP.

Court Refuses To Enforce Discovery Subpoena Against E-Mail Service Provider By Jeffrey D. Neuburger, a partner in the New York office of Brown Raysman Millstein Felder & Steiner LLP and is the Chair of the firm's Technology, Media and Communications Practice Group; and Maureen E. Garde, an associate at the firm and member of that practice group.

"Waters of the U.S.": Definition Remains In Doubt After Supreme Court Ruling By George J. Mannina, Jr., a Senior Partner at the law firm of O'Connor & Hannan, LLP and a member of the Environmental Practice Group at the Firm.

How Bad Is Bad? Courts Remain Split On Key Punitive Damages Issue By David T. Biderman, a partner with the law firm Perkins Coie LLP in the firm's Santa Monica office and Gabriel Liao, an associate in the firm's Los Angeles office.

#### **Drug Price Control Fails Constitutional Test**

By Grant P. Bagley and Rosemary Maxwell, members of the healthcare and pharmaceutical regulatory practice in the Washington D.C. office of the law firm Arnold & Porter LLP.

Victory In Tuna Trial Significant For All Proposition 65 Defendants By Ann G. Grimaldi, a partner at McKenna Long & Aldridge LLP in its San Francisco office.

CMS Information Policy Under Medicare "Part D" Creates 1<sup>st</sup> Amendment Problems By Ronald D. Rotunda, a professor of law at the George Mason University School of Law.

#### Ruling Criticizing Prop 65 Is Mixed Blessing For Defendants

By Lisa L. Halko, an associate with the law firm Greenberg Traurig, LLP in its Sacramento office.

#### Risks And Rewards Of Waiving The Attorney-Client Privilege

By Joel B. Harris, a partner, and Andrew I. Stemmer, a former associate, in the Litigation and Dispute Resolution Department of the law firm Thacher Proffitt & Wood LLP.

#### **Europe's REACH Initiative Will Impact Trade Secrets**

By Jeroen H. J. den Hartog and Mark G. Paulson, an attorney at the Brussell office and a partner at the Washington, D.C., office, respectively, of the law firm Mayer, Brown, Rowe, & Maw LLP.

Abusing Independent Contractors Imperils Vital Business Model By Richard A. Samp, Chief Counsel to the Washington Legal Foundation.

Activist Suits Challenging Terrorist Surveillance Should Be Dismissed By Andrew C. McCarthy, the head of the Center for Law and Counterterrorism at the Foundation for the Defense of Democracies.

Is Revision Of The PM<sub>2.5</sub> NAAQS Requisite To Protect Public Health? By F. William Brownell and Lucinda Minton Langworthy, a partner and Counsel, respectively, to the law firm Hunton & Williams in its Washington, D.C., office.

#### USG Settlement Reflects Sorry State Of Asbestos Bankruptcies

By Mark D. Taylor, a partner in the Financial Restructuring and Bankruptcy practice of Arent Fox PLLC where he represents debtors, Chapter 11 Trustees, and committees in asbestos related or other mass tort bankruptcies; and Brandi A. Richardson, an associate in the General Litigation and Government Relations practices of Arent Fox PLLC.

#### Organizing A Successful Corporate Internal Investigation

By The Honorable Dick Thornburgh, Of Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP.

#### Health And Speech Rights At Risk From Attacks On Medical Education By Jeffrey N. Gibbs, a principal with the law firm Hyman, Phelps & McNamara, P.C. in its Washington, D.C., office.

#### Holding Battlefield Contractors Accountable: Federal "Removal" Protects Federal Interests

By David C. Hammond, a partner in the law firm of Crowell & Moring LLP specializing in government contract law.

# Federal Court Draws Roadmap For Scrutiny of Attorneys' Fees in "Coupon" Settlements

By Thomas M. Smith, Counsel at McCarter & English, LLP, in the firm's New York office, and Natalie S. Watson, an associate at McCarter & English, LLP, in the firm's Newark, New Jersey office.

Medicines And The Environment: Legal And Regulatory Storms Ahead? By George J. Mannina, Jr., a Senior Partner at the law firm of O'Connor & Hannan, LLP and a member of the Environmental Practice Group at the firm.

State High Court Condemns Arbitration Provisions That Don't Allow Class Actions By Donald M. Falk, a partner in the Supreme Court and Appellate Practice Group of the law firm Mayer Brown Rowe & Maw LLP, resident in the Palo Alto office, and Archis A. Parasharami, an associate in the firm's Washington, D.C. office.

#### Federal And State Courts Reject "Attractive Advertising" Claims By J. Russell Jackson, a partner in the Complex Mass Torts Group of New York's Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School.

Impending Legal Attacks On Food Ads Should Not Be Welcome In Court By Scott A. Elder, a partner, and Anna Aven Sumner, an associate, with Alston & Bird LLP in the firm's Atlanta office.

Plaintiffs, Lawyers, And Short-Sellers: The Legal Status of "Dump & Sue" By Professor Moin A. Yahya, an assistant Professor of Law at the University of Alberta.

#### Federal Privilege Waiver Demands Impact Corporate Compliance

By Richard Ben-Veniste, a senior partner in the Washington, D.C. office of the law firm Mayer, Brown, Rowe & Maw LLP, specializing in white collar defense and civil litigation. Mr. Ben-Veniste formerly served as Chief of the Special Prosecutions Section of the U.S. Attorney's Office for the Southern District of New York, and was a member of the National Commission on Terrorist Attacks Upon the United States ("9/11 Commission"); and Raj De, an associate with the firm, and former counsel to the 9/11 Commission. Regulated Industries Benefit From Illinois Consumer Protection Ruling By Victor E. Schwartz, a partner in the law firm of Shook, Hardy & Bacon L.L.P. in Washington D.C. and Cary Silverman, an associate with the firm.

Court's Ruling Applying Credit Act To Insurers Legally Unsupportable By Robert Detlefsen, Director of Public Policy at the National Association of Mutual Insurance Companies.

Misaddressed Reform: The U.S. Postal Service's New Procurement Guidelines By David P. Hendel, a Shareholder with the law firm Wickwire Gavin PC in Vienna, Virginia. He concentrates his government contracts practice on Postal Service Procurements.

Courts Deny Plaintiff's Lawyers A Role In Enforcing Sarbanes-Oxley Section 304 By Peter L. Welsh, an associate in the Boston office of the law firm Ropes & Gray LLP. Mr. Welsh practices in the areas of securities litigation, director and officer litigation and representation, and corporate governance.

#### High Court Hears Key Case On Antitrust And Joint Ventures

By William Kolasky, a partner, and Steven Lehotsky, an associate at Wilmer Cutler Pickering Hale and Dorr LLP, in the firm's Washington and Boston offices, respectively. Mr. Kolasky was previously Deputy Assistant Attorney General for International Enforcement in the Antitrust Division of the U.S. Department of Justice.

WORKING PAPERS

Results-Oriented Class Certification: Schwab v. Philip Morris By Brian C. Anderson, a partner in the Washington, D.C. office of O'Melveny & Myers LLP and Andrew J. Trask, a Counsel to the firm.

Beyond The "Yuck Factor": Product Liability Implications Of Medical Device Reprocessing By Peter J. Goss, a partner in the Minneapolis office of the law firm Faegre & Benson

LLP.

Sovereign Debt Default: Cry For The United States, Not Argentina By Professor Hal S. Scott, Nomura Professor of Law at Harvard Law School and Director of its Program on International Financial Systems.

New False Claims Law Incentives Pose Risks To Contractors And States By John T. Boese and Beth C. McClain, a partner and a special counsel, respectively, to the law firm Fried, Frank, Harris, Shriver & Jacobson LLP in its Washington, D.C. office.

An Exaggerated And Ill-Conceived Sense Of Risk: The Ephemeral Nature Of California's Proposition 65 By Thomas H. Clarke, Jr., a senior partner with Ropers, Majeski, Kohn, & Bentley in their San Francisco office.

New False Claims Law Incentives Pose Risks To Contractors And States By John T. Boese and Beth C. McClain, a partner and a special counsel, respectively, to the law firm Fried, Frank, Harris, Shriver & Jacobson LLP in its Washington, D.C., office.

Foreign Governments' Misuse of Federal RICO: The Case For Reform By Ignacio Sanchez and Kevin O'Scannlain, a partner and a Counsel, respectively to the law firm DLA Piper Rudnick Gray Cary US LLP in its Washington, D.C., office.

Medical Monitoring: Innovative New Remedy Or Money For Nothing? By Steven J. Boranian, a partner in Reed Smith LLP's San Francisco office, and Kevin M. Hara, a litigation associate in the firm's Oakland office.

CONTEMPORARY LEGAL NOTES

Removing Lawsuits From State Court: The "Federal Officer" Option By Katharine R. Latimer and Michael L. Junk, a partner and an associate, respectively, with the Washington, D.C. law firm Spriggs & Hollingsworth.

New E-Discovery Rules & The Attorney-Client Privilege: A Middle Ground For Waiver? By Julie Anne Halter, a partner in the law firm Preston Gates & Ellis LLP in Seattle, Washington.

The SAFETY Act: A Vital Tool In The Fight Against Terrorism

By Joe Whitley and George Koenig, members of Alston & Bird LLP's Global Security & Enforcement Practice Team, and Parney Albright, Managing Director with the Civitas Group LLC.

Attorney-Client Privilege & Employee Interviews In Internal Investigations

By Paul B. Murphy, a partner with King & Spalding LLP's Special Matters and Government Investigations Group who previously served as the United States Attorney for the Southern District of Georgia, and Lucian E. Dervan, an associate with King & Spalding's Special Matters and Government Investigations Group.

Asserting Counterclaims And Third Party Claims In False Claims Act Litigation By Ronald H. Clark, a partner in the Washington, D.C. office of Arent Fox PLLC. Mr. Clark specializes in False Claims Act litigation, consulting, and expert testimony.

Securities Act Section 11: A Primer And Update Of Recent Trends

By Richard A. Spehr and Joseph De Simone, litigation partners, and Andrew J. Calica, a litigation associate, in the New York office of the law firm Mayer, Brown, Rowe & Maw LLP.

#### CONVERSATIONS WITH

CONVERSATIONS WITH: U.S. And International Anti-Corruption Efforts Features The Honorable Dick Thornburgh, Of Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP moderating a discussion with Paul A. Volcker, former Chairman of the Federal Reserve, and Miller & Chevalier Member Homer E. Moyer, Jr.

#### **MONOGRAPHS**

#### Foreign Corrupt Practices Act Enforcement After U.S. v. Kay

By Hector Gonzalez, a litigation partner in the New York office of the law firm Mayer, Brown, Rowe & Maw LLP, and Claudius O. Sokenu, a senior associate with the firm. Foreword by The Honorable Dick Thornburgh, counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP and former Attorney General of the United States. Introduction by Kenneth R. Cunningham, Senior Counsel to Grant Thornton LLP's Risk, Regulatory, and Legal Affairs group.

Ideology Masked As Scientific Truth: The Debate About Children And Advertising By Dr. John C. Luik, a public and science policy researcher who is a Senior Fellow with the Democracy Institute. Foreword by Professor Todd J. Zywicki of the George Mason University School of Law.

#### Waiver Of The Attorney-Client Privilege: A Balanced Approach

By The Honorable Dick Thornburgh, Of Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP. Foreword by The Honorable John Engler, President and CEO of the National Association of Manufacturers. Introduction by Laura Stein, Senior Vice President - General Counsel and Secretary, The Clorox Company.

#### PUBLIC APPEARANCES

WLF attorneys are regularly quoted or featured by the print media in numerous news and trade publications. Highlights of public, television, and radio appearances made by WLF attorneys during 2006 include:

- \* February 28, 2006, WLF Senior Executive Counsel Paul Kamenar appeared on Court TV to discuss the legal issues involved in the Supreme Court case, *Marshall v. Marshall*, regarding federal jurisdiction over probate and other state law claims.
- \* March 27, WLF Chief Counsel Richard Samp participated in a debate, sponsored by the Cato Institute, against Charles Swift, the military attorney for Salim

Hamdan, who faces a war crimes trial for his work as an aide to Osama bin Laden. Hamdan's challenge to the military tribunal process is currently before the Supreme Court. The debate, which was broadcast on C-SPAN, addressed whether the President has the authority to establish military tribunals to try war crimes suspects.

- \* March 29, Kamenar discussed the role of the Supreme Court and key Court cases before a group of 300 high school students visiting Washington, D.C., sponsored by the Close-Up Foundation.
- \* March 30, Samp was a featured panelist at the Medical Device Regulatory and Compliance Congress held at Harvard University. Samp discussed manufacturers' First Amendment rights to speak truthfully about FDA-approved medical products.
- \* May 11, Kamenar was a featured speaker before 200 high school students from across the country sponsored by the Close-Up Foundation. Kamenar discussed the judiciary and Supreme Court cases.
- \* May 16, Samp was a featured speaker at the annual conference of the ALS Association, a patient advocacy group that promotes improved treatment and medical research for those suffering from ALS. Samp discussed WLF's recent victory in *Abigail Alliance v. von Eschenbach*, a federal appeals court decision that established that terminally ill patients have a constitutional right to access to experimental, potentially life-saving medications.
- \* June 6, Samp was a featured speaker on a teleconference sponsored by Mealey's, regarding FDA's recently announced policy regarding federal preemption of statelaw failure-to-warn tort suits against pharmaceutical manufacturers and health practitioners.
- \* June 8, Kamenar was a featured speaker at the inaugural summer speakers program of Rutgers College in Washington for both alumni and undergraduate summer interns. Kamenar discussed WLF's litigation practice and was joined by Tony Mauro, Supreme Court reporter for Legal Times. Both Kamenar and Mauro are Rutgers alumni.
- \* June 21, Samp was interviewed on National Public Radio's nationally syndicated "Fresh Air" program, regarding the propriety of continued detention of "enemy combatants" at Guantanamo Bay, Cuba.
- \* June 29, Samp was interviewed regarding the Supreme Court's decision in *Hamdan v. Rumsfeld* (which struck down the Bush Administration's plan to try

alleged al Qaeda war criminals before military tribunals) by Fox News, ABC-Radio, CBS-Radio, NPR's "To the Point," and Court TV.

- \* July 5, Samp was interviewed on Voice of America regarding the Supreme Court's decision in *Hamdan v. Rumsfeld* (which struck down the Bush Administration's plan to try alleged al Qaeda war criminals before military tribunals).
- \* September 30, WLF Legal Studies Division Chief Counsel Glenn Lammi was interviewed for CNBC's preview of the U.S. Supreme Court term, which focused on free enterprise cases.
- \* November 27, Samp was interviewed by the Lou Dobbs Show on CNN regarding enactment by cities across the country (including Hazelton, Pennsylvania) of laws designed to crack down on illegal immigrants.
- \* October 5, Samp was interviewed by the Regional News Network (a network of numerous radio stations) regarding the U.S. Supreme Court's 2006-2007 term.
- \* October 3, Samp participated in an on-air debate on National Public Radio's "On Point" program, on Bush Administration policy regarding detention of enemy combatants at Guantanamo Bay, Cuba.



### **ACTIVITIES REPORT**

to the

## WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

SUPPORTING PATIENTS' RIGHTS AND IMPROVED HEALTH CARE

July 7, 2006

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#### JULY 7, 2006

### ACTIVITIES REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

### SUPPORTING PATIENTS' RIGHTS AND IMPROVED HEALTH CARE

The ideals upon which America was founded -- individual freedom, limited government, a free-market economy, and national security -- are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. Adherence to those principles is essential to maintaining America's position as the possessor of the finest health care system in the world.

Throughout its 29 years, the Washington Legal Foundation (WLF) has devoted a significant portion of its resources to improving the health care available to all Americans. WLF believes that goal can best be achieved through free market solutions: providing consumers with the widest range of choices in health care, assisting them in making those choices by giving them access to all relevant information, providing private industry with the incentives to engage in vigorous research and development, and ensuring that health care is not stifled by excessive litigation.

WLF has worked to achieve those objectives through its precedent-setting litigation, its involvement in government regulatory proceedings, its publication of timely articles on health-related issues, and its tireless advocacy for free-market solutions in the news media and other public forums. This report highlights some of the of more significant WLF health-related activities over the past decade.

### I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF's public interest programs. The Foundation litigates across the country before state and federal courts and administrative agencies. WLF represents only those who are otherwise unable to retain counsel on their own. Its clients have included numerous patients and patient-advocacy groups who have turned to WLF for assistance when government bureaucrats denied them adequate health care and access to health-care information.





Some bureaucrats argue that health care decisions should be dictated by providers and government officials because most consumers cannot begin to understand treatment issues. WLF takes the opposite approach. It believes that providing consumers with unlimited access to accurate medical information vastly improves health care delivery. Accordingly, WLF has worked tirelessly over the past decade to eliminate government restrictions on dissemination of truthful medical information. WLF has worked to lift advertising restrictions, regulations that prevent dissemination of information on off-label uses of FDA-approved products, overly strict rules governing product labeling, and rules that limit discussions at Continuing Medical Education (CME) events.

Washington Legal Foundation v. Henney. On February 11, 2000, the U.S. Court of Appeals for the District of Columbia Circuit dismissed FDA's appeal from a district court decision that struck down FDA regulations that severely restricted the flow of truthful information regarding off-label uses of FDA-approved drugs and medical devices. The decision was a major victory for WLF in its long-running battle against FDA speech restrictions; WLF had filed suit against FDA in 1994, after FDA rejected a 1993 WLF Citizen Petition that asked that the regulations be lifted. In 1998 and 1999, the district court ruled that the regulations violated the First Amendment rights of consumers who wished to learn truthful information about off-label product uses that are widely accepted within the medical community as safe and effective. As a result of WLF's victory, FDA has not initiated enforcement actions against any of the manufacturers who have exercised their First Amendment rights by distributing peer-reviewed journal articles that discuss off-label uses of their products.

"DDMAC Watch." In June 2005, WLF inaugurated its "DDMAC Watch" program, designed to monitor federal regulation of prescription drug advertising. WLF has determined that the Food and Drug Administration (FDA), acting through its Division of Drug Marketing, Advertising, and Communications (DDMAC), has been using letters to industry to advance questionable legal theories and request remedial actions that the agency could not require under law. Under the DDMAC Watch program, when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF will immediately send back a response letter to DDMAC identifying the specific ways in which this is so. The goal of the program is to alert the press and public to abuses occurring at DDMAC. As of June 2006, WLF has responded to 26 letters from DDMAC and related agencies. Those letters were sent to Eli Lilly and Co., Endo Pharmaceuticals, MedImmune Vaccines, Dutch Ophthalmic USA, Hoffman LaRoche, Abbott Laboratories, Pfizer, Pharmaceuticals US, SuperGen, Allergan, Alcon Research, Nephrx, ISTA Pharmaceuticals, GenTrac, Medicis Pharmaceuticals, Sankyo Pharma, Duramed Pharmaceuticals, Biogen Idec, Mayne Pharma (USA), ZLB Behring, Palatin Technologies, InterMune, VaxGen, Bioniche Pharma Group, Sandoz, BIPI, and Wyeth Pharmaceuticals.

*Physician Comm. for Responsible Medicine v. General Mills.* On September 2, 2005, WLF filed a brief in the U.S. District Court for the Eastern District of Virginia, urging the court to dismiss a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. WLF argued that the suit threatens to undermine manufacturers' commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by



activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled as manufacturers become increasingly unwilling to comment on such issues. The suit targets a recent milk industry advertising campaign that advocates increased consumption of dairy products as a method of losing weight. The Physicians Committee for Responsible Medicine (PCRM) challenges the validity of the scientific studies that form the basis for the industry's advertising. PCRM argues that the weight-loss claim is false and violates Virginia's consumer protection and false advertising laws. Their principal request is that the court issue an injunction against any further promotion of the weight-loss claims. WLF argued that Virginia law does not permit individuals to obtain injunctions against speech. WLF also argued that such suits raise serious First Amendment issues because of their potential to chill truthful speech on issues of public importance, such as whether increases in consumption of dairy products are good for one's health.

**Preserving Direct-to-Consumer Advertising of Prescription Drugs.** On November 2, 2005, WLF Chief Counsel Richard Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer (DTC) advertising. Samp asserted that FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) needs to rein in its efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers. When FDA announced that it would be holding hearings on November 1 and 2, 2005, its announcement suggested that FDA is considering moving in the other direction and imposing additional restrictions on advertising. Many hearing witnesses called for severely limiting drug ads, calling them inherently biased and misleading. WLF's Samp countered that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options.

*Fullerton v. Florida Medical Association.* On June 20, 2005, WLF filed a brief in Florida state court, asking the court to rule that a federal statute (the Health Care Quality Improvement Act of 1986) protects participants in peer review of medical testimony from liability for money damages. The lawsuit, a defamation action, was brought by a physician who had given expert testimony in a medical malpractice case. The physician brought the lawsuit in response to a complaint filed against him with the Florida Medical Association alleging that his testimony in the malpractice case was false and financially-motivated. WLF entered the case in the trial court because the lawsuit presents an important legal issue regarding peer review of expert testimony. Improper expert testimony is a concern of the business community, particularly in asbestos litigation, where studies have indicated that most claims of asbestos-related diseases are backed by unfounded "expert" interpretations of screening X-rays. WLF also filed a brief in the case in September 2004. The court heard oral arguments in the case on May 31, 2006.

**Oversight of Criminal Investigations into Improper Drug Promotion.** On March 24, 2005, WLF filed a petition with the U.S. Department of Justice (DOJ), urging DOJ to remove the Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetics Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF said that OCL has simply rubber-stamped whatever criminal investigation local U.S. Attorney Offices have

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sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal investigation. WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal investigations of promotional activities have the potential to adversely affect the nation's health care delivery system.

In re: ACCME Restrictions on Continuing Medical Education. On January 29, 2003, WLF filed comments with the Accreditation Council for Continuing Medical Education (ACCME), severely criticizing the ACCME for its proposal to impose draconian restrictions on who may speak at CME activities. WLF argued that the proposed restrictions are an unwarranted infringement on free speech rights. Current ACCME standards are designed to ensure unbiased CME presentations by, among other things, requiring speakers to disclose whether they have received any funding from the manufacturer of any of the drugs being discussed. The proposed standards go considerably further; they would altogether prohibit doctors who have been compensated by a pharmaceutical company from speaking at a CME activity. WLF noted in its comments that most of the top medical authorities in the country are employed in some capacity by one or more of the country's drug companies and thus would no longer be permitted to participate in CME events. Without the participation of top doctors, CME would no longer be the important source of new medical information that it is today, WLF argued. WLF attorneys repeated their criticisms of the proposed restrictions at several well-attended ACCME-related forums in 2003. The revised ACCME rules became final and took effect in late 2004. While not as objectionable as earlier drafts, the final rules continue to be a significant obstacle to the open dissemination of truthful speech. WLF continues to speak out against the rules and is considering all options for additional response.

*"Lean" Labeling.* On February 8, 2006, WLF filed comments with FDA supporting the agency's proposal to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word "lean." WLF argued that the proposed change would assist consumers by providing them with accurate and relevant information and would also expand the market for lean foods.

In re: FDA Request for Comments on First Amendment Issues. FDA has lost several major First Amendment lawsuits in recent years, including WLF v. Henney. FDA responded in 2002 by requesting public input on whether any current FDA policies violate the First Amendment. On September 13, 2002, WLF filed extensive comments, citing a broad array of FDA regulatory activities that violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. On October 28, 2002, WLF filed a second round of comments, responding to arguments (made by several U.S. Senators in connection with the initial round of comments) that public health concerns justify exempting FDA from First Amendment constraints applicable to other government entities. WLF criticized the contention of those Senators that consumers are likely to misuse truthful information. FDA has pledged to address these First Amendment concerns but to date has established no timetable for doing so.

Citizen Petition Regarding Restrictions on Truthful Speech. Following WLF's victory in WLF v. Henney (see above), FDA began to suggest that it was not bound by the court's decision in WLF's favor. FDA issued statements to manufacturers, suggesting that they might be



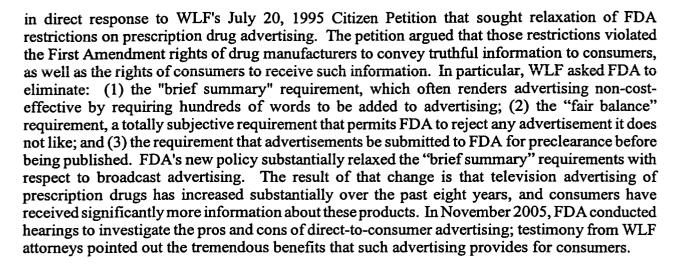
sanctioned for engaging in the types of off-label speech that WLF v. Henney had held to be constitutionally protected. Accordingly, on May 23, 2001, WLF filed a Citizen Petition with FDA, urging the agency to repudiate those statements and to announce that it had lifted restrictions on manufacturers' rights to disseminate non-misleading information concerning off-label uses of FDA-approved products. WLF argued that by raising the threat of enforcement action against manufacturers that exercise their free-speech rights, FDA was violating the First Amendment rights of manufacturers who wish to speak in a non-misleading manner about off-label uses of their products, and of those who wish to hear such speech. WLF noted that WLF v. Henney had resulted in a ruling that the First Amendment prohibits FDA from restricting manufacturer dissemination of "enduring materials" (medical texts and reprints of peer-reviewed medical journal articles) that discuss off-label uses of FDA-approved products. WLF charged that FDA was flouting that ruling by threatening enforcement action against manufacturers who disseminate enduring materials. FDA's response to the petition amounted to another WLF victory. Although continuing to argue that the ruling in WLF v. Henney was not as broad as WLF asserted, FDA pledged that in the future (in light of its limited resources) it would not bring enforcement actions based on the types of manufacturer speech described by WLF.

*Nike, Inc. v. Kasky.* On June 26, 2003, the U.S. Supreme Court decided not to review a California decision that threatens to impose severe restrictions on the right of corporations to speak freely on matter of public importance – including drug companies seeking to speak truthfully about off-label uses of their products. The Court in January 2003 agreed to review the case but five months later changed its mind and dismissed as "improvidently granted" its original order granting review. In two separate briefs filed in the case, WLF argued that the California court effectively held that *all* corporate speech – even speech on matters of great public importance – is entitled to reduced levels of First Amendment protection. WLF argued that the decision is contrary to a long line of Supreme Court decisions and threatens to chill significant amounts of speech by corporations.

Investigating Efforts to Evade WLF Courtroom Victory. Although WLF established in WLF v. Henney (see above) that the First Amendment protects the right of drug manufacturers, in certain instances, to disseminate truthful information about off-label uses of their products, WLF has become increasingly concerned that various federal officials are seeking to evade that decision. In particular, the United States Attorney's office in Boston has threatened criminal prosecution of companies that disseminate truthful off-label information, while other federal officials have indicated that such conduct may violate the federal False Claims Act or the anti-kickback statute. WLF in December 2003 began an investigation into whether such federal officials are violating the terms of the injunction entered in WLF v. Henney. That investigation includes a series of document requests (pursuant to the Freedom of Information Act) directed to (among others) FDA and the Office of Inspector General of the U.S. Department of Health and Human Services. WLF has also asked a number of pharmaceutical companies to share with WLF their experiences in such investigations. WLF hopes that it can gather enough information to determine whether actions by federal officials are sufficient to constitute a policy of suppressing constitutionally protected speech.

WLF Petition Regarding Direct-to-Consumer Advertising of Prescription Drugs. In 1997, FDA adopted substantial revisions to its direct-to-consumer advertising policy. FDA's action was





Labeling of Soda Containers. On December 16, 2005, WLF filed comments with FDA, urging the agency to reject a petition filed by the Center for Science in the Public Interest (CSPI), a Washington, D.C. based activist group founded by Ralph Nader, that would require warning labels on non-diet soda cans and bottles advising consumers, among other things, that "drinking too much soft drinks may contribute to weight gain." WLF argued that such warning labels are not mandated by law and, as a matter of public policy, are unnecessary since current labels on all beverages provide caloric content, sugar content, and other nutritional information to help consumers make informed choices.

**Opposing Regulation of Internet**. On November 10, 2001, FDA responded to an April 12, 2001 WLF Citizen Petition that urged the agency to adopt a rule or policy that would make it clear that health claims and other consumer information that appear on a company's website do not constitute "labeling" of that company's product, and thus, are not subject to FDA's stringent and detailed food and drug labeling requirements. Rather, any such promotional information should be regarded, at best, as advertising, and thus subject in certain circumstances to review by the Federal Trade Commission (FTC) under its "false and misleading" advertising standard. The FTC standard is more consistent with First Amendment protections of commercial speech than FDA labeling requirements. WLF's filing was prompted by an alarming FDA Warning Letter sent to Ocean Spray Cranberries, Inc. on January 19, 2001, the last day of the Clinton Administration. FDA claimed that Ocean Spray's cranberry and grapefruit juices were "misbranded" and subject to seizure simply because of certain health claims and other information that appeared on the company's website and related links. In its response to WLF's petition, FDA indicated that it would not be issuing an across-the-board regulation at this time, but that it would not generally regard a company's website content as labeling if the company does not sell products online.

**Petition Regarding Disclosure of Clinical Trial Results.** On December 28, 1995, WLF filed a joint petition for rulemaking with FDA and the Securities and Exchange Commission (SEC), urging FDA to exempt from FDA regulation the public disclosure of clinical test results of Investigational New Drugs (INDs). Such information is required by SEC rules to be disclosed to the investment community. Current FDA rules and policies prohibit drug companies from "promoting" or "commercializing" an IND until the drug obtains final approval. Yet the SEC



requires that drug companies file reports with that agency and inform the investment community of major product developments. FDA has interpreted its rule against "promoting" an IND to include press releases and other communications made by companies regarding the results of clinical tests of INDs. FDA has not taken any decisive action on this issue, and WLF continues to press for relaxation of speech restrictions in this area. WLF argues that investors need to receive truthful information about drugs in "the pipeline" if they are to measure accurately the value of a pharmaceutical company's stock.

**Proposal Regarding Trans Fatty Acid Nutrition Labeling.** On March 27, 2003, WLF filed comments with FDA, objecting to FDA's proposal to require all food containing trans fatty acids (trans fat) to include on its label the following statement: "Intake of trans fat should be as low as possible." WLF argued that requiring that statement would violate the First Amendment protection against compelled speech. WLF argued that although the First Amendment permits the government to compel commercial speech when necessary to prevent consumers from being confused or deceived, there is no serious argument that the proposed statement is necessary to prevent food labels from being confusing or deceptive. WLF stated that FDA may do no more than mandate disclosure of the quantity of trans fat contained in each serving of the food being sold. While the proposed statement may contain sound health information, it may unnecessarily alarm consumers; and WLF argued that it is not the role of the government to commandeer the property of others for the purpose of spreading information that may promote public health. In a victory for WLF, FDA announced on July 11, 2003 that it would not require food labels to include the controversial statement.

**Defending Corporate Speech on Food Irradiation.** On August 7, 2003, WLF filed comments with the Federal Trade Commission, objecting to efforts by activists to censure speech about food irradiation. Two activist groups, Public Citizen and the Center for Food Safety, petitioned the FTC to take enforcement action against Giant Food based on statements Giant made regarding the irradiation of its food products. Giant issued a pamphlet that, in an effort to add to consumers' understanding of irradiation, compared the irradiation process to milk pasteurization. The activist groups asserted that the law prohibits food sellers from representing irradiated food as "pasteurized." WLF's response argued that the comparison of irradiation and pasteurization is not misleading and assists American consumers in understanding that irradiation is a process designed to enhance food safety and cleanliness. WLF argued that the First Amendment protects Giant's right to make truthful statements regarding the irradiation process.

**FDA Proposals to Regulate Food Labeling.** WLF has long been at the forefront of efforts to ease FDA regulation of food labeling. For example, in a series of submissions to FDA in the early 1990s, WLF urged FDA to lift the ban on health-related information and certain types of pictures on food labels. The ban on health-related information eventually was lifted by Congress, and WLF has worked to ensure that the new legislation is being fairly administered.

*Novartis Corp. v. Federal Trade Commission*. On August 18, 2000, the U.S. Court of Appeals for the D.C. Circuit upheld an Federal Trade Commission (FTC) order requiring Novartis Corp., a pharmaceutical company, to include a governmentally-dictated message in its advertising. The court ruled that the First Amendment posed no bar to the FTC's so-called corrective advertising order. The decision was a setback for WLF, which on October 29, 1999, filed a brief

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urging the court to set aside the FTC's order. The case involved an order from the FTC -- which had determined that Novartis's advertisements for Doan's Pills had been misleading in suggesting that Doan's offers more effective relief for back pain than other pain relievers -- directing Novartis to include the following statement in all Doan's advertising: "Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain." In its brief filed with the court, WLF argued that the FTC's corrective advertising order ought to be set aside because it violated Novartis's right not to speak. WLF said that the FTC order was particularly troublesome because the result was that Novartis had refrained from advertising at all rather than conveying the FTC's "corrective" message.

**Draft Compliance Policy Guide on Labeling.** On July 23, 1999, WLF filed comments with FDA, opposing its efforts to expand the definition of "labeling" under federal food and drug law. Under FDA's proposed definition, "labeling" of a drug would have included books and other publications that merely discuss a particular drug, even though that material does not "accompany" the drug as that term is commonly understood and as Congress intended. FDA ultimately abandoned its effort to expand the definition of what constitutes "labeling" of a drug or medical device.

Labeling of Genetically Engineered Products. On March 19, 2001, WLF filed comments with FDA, generally supporting the agency's proposed guidelines for the labeling of food with respect to whether it has been developed using biotechnology. WLF strongly supported FDA's tentative decision to continue its policy against mandatory labeling on the subject; WLF noted that such labeling does not provide any nutritionally meaningful information. WLF asserted, however, that industry should be afforded broad leeway when it comes to voluntary labeling with regard to bioengineering, because any effort to restrict industry choice significantly would raise major First Amendment issues. WLF asserted that the one area in which FDA restrictions are warranted is the area of health claims; WLF argued that labeling should not be permitted if it suggests that the labeled food is safer based on the presence/absence of genetically engineered ingredients -because there is no sound scientific basis for such claims. FDA ultimately adopted guidelines that closely tracked WLF's suggestions.

*Citizen Petition on Pharmacy Compounding.* On March 6, 1992, WLF filed a Citizen Petition with FDA, alleging that the agency's efforts to control advertising by pharmacies regarding their drug compounding capabilities violated the First Amendment, and urging the agency to utilize notice-and-comment rulemaking before adopting new regulations on that subject. FDA failed to heed WLF's warnings; the result was the U.S. Supreme Court's 2002 decision in *Thompson v. Western States*, which struck down on First Amendment grounds FDA's efforts to regulate advertising regarding pharmacy compounding of drugs.

**FDA Draft Guidance on Medical Product Promotion.** On April 6, 1998, WLF filed comments expressing its deep reservations regarding FDA's Draft Guidance regarding "medical product promotion by health care organizations or pharmacy benefits management companies." WLF argued that FDA failed to demonstrate any need for the guidance and that it would have an adverse impact on health care. WLF also argued that FDA lacked statutory authority to issue the guidance and that it infringed the First Amendment rights of drug companies, doctors, and consumers. WLF requested that FDA withdraw the Draft Guidance and not issue it in final form.



In light of intense opposition, FDA placed the proposal on hold in July 1998 and has taken no further action.

### **B.** Excessive FDA Caution

FDA often has exhibited excessive caution when it comes to the review and approval of new life-saving therapies. The source of that excess caution is easy to understand: government bureaucrats are fearful that they will be held responsible if they approve a product that later turns out to have adverse health effects. But as WLF has repeatedly pointed out, excessive caution by government regulators often leads to thousands of needless deaths; patients who could have been saved by a new therapy end up dying while they wait years for the new therapy to win FDA approval. WLF has worked tirelessly to ensure that FDA officials do not unnecessary delay their review of products for safety and effectiveness. WLF recently won a major lawsuit against FDA for failing to permit the marketing of promising (but as-yet not-fully-approved) drugs to terminally ill patients who lack effective alternative treatments.

Abigail Alliance for Better Access to Investigational Drugs v. von Eschenbach. In a major victory for WLF, the U.S. Court of Appeals for the District of Columbia Circuit ruled on May 2, 2006 that terminally ill patients have a "fundamental right" - protected by the U.S. Constitution - to access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA). The decision is the culmination of a three-year WLF effort to overturn FDA policies that deny such access. WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group. The district court dismissed the suit, ruling that the Constitution imposes no barriers to FDA efforts to regulate the treatment decisions of terminally ill patients and their doctors. WLF appealed from that decision. The appeals court reversed, ruling 2-1 that once FDA has determined, after Phase I trials, that a potentially life-saving investigational new drug is sufficiently safe for expanded human trials, terminally ill patients have a constitutional right to seek treatment with the drug if there are no other FDA-approved drugs available to the patient. The court held that the Fifth Amendment's Due Process Clause encompasses a right, recognized throughout American history, of all individuals facing terminal illnesses to make fundamental decisions regarding whether to seek or not to seek medical treatment. The court said that if FDA wishes to prevent such patients from gaining access to investigational drugs that have completed Phase I trials, it bears the burden of demonstrating that its restrictions are "narrowly tailored" to serve a compelling governmental interest. On June 16, 2006, FDA petitioned the appeals court to rehear the case.

In re Tier 1 Initial Approval. In light of the continuing failure of the FDA to allow terminally ill patients to obtain promising new drugs in a timely manner, WLF filed a Citizen Petition with FDA on June 11, 2003, seeking faster drug availability for these patients. As in its lawsuit, WLF is representing the Abigail Alliance for Better Access to Developmental Drugs, an Arlington, Va.-based group of terminally ill patients and parents of terminally ill patients who have tried and failed to obtain access to drugs that are tied up in the FDA's approval process (see above). WLF's petition urges the adoption of a preliminary approval program, "Tier 1 Initial Approval," that would make promising new drugs available to patients with life-threatening illnesses while clinical trials and FDA reviews are underway. The petition shows in detail that such a program is within the



FDA's statutory authority and does not require new legislation – contrary to past contentions by FDA staff. WLF wrote to the new acting FDA commissioner on April 16, 2004, to urge prompt action on the issue.

Washington Legal Foundation v. Shalala. In the early 1990s, FDA adopted a policy that imposed virtually insurmountable roadblocks in the path of heart patients who sought humantissue heart valve transplant surgery. Although human-tissue heart valve surgery had been widely performed since the early 1960s, FDA suddenly decided for the first time that such valves were subject to FDA regulation, and a multi-year review process was imposed before FDA would consider approving use of what FDA now deemed a "medical device." The effect of that decision was to render such surgery unavailable to all but the wealthiest Americans. Infant children were most directly affected by the policy, because they did not have available to them any equally effective, alternative procedures. On May 20, 1992, WLF filed a Citizen Petition with FDA, asking that its new policy be rescinded. WLF filed the petition on behalf of itself, two patients in need of heart valve implant surgery, and three of the nation's leading heart surgeons -- Dr. Robert B. Karp of the University of Chicago, Dr. Richard A. Hopkins of Georgetown University, and Dr. A.D. Pacifico of the University of Alabama at Birmingham. After FDA denied WLF's petition in 1993, WLF filed suit on behalf of its clients in federal court in the District of Columbia, challenging FDA's new policy as a violation of federal law. WLF won a huge victory in the case in 1994 when FDA abandoned its controversial policy. FDA's sudden policy shift was prompted by WLF's suit and a related suit in Chicago; FDA acted only after it realized, based on preliminary rulings, that it faced near-certain defeat in court.

Approval of Silicone Gel-Filled Breast Implants. On March 28, 2005, WLF filed comments with FDA's Medical Devices Advisory Committee, charging that FDA denial of premarket applications (PMAs) submitted by two companies seeking permission to market silicone gel-filled breast implants would violate clearly established rules governing administrative procedure. WLF stated that the Administrative Procedure Act (APA) prohibits FDA from imposing (as it has contemplated doing) far stricter approval requirements on silicone breast implants than it has imposed on similar medical devices. FDA indicated that it wanted Mentor and Inamed (the two manufacturers) to provide ten years of data regarding the health consequences of breast implant failure (particularly rupture). Both PMAs include at least three years of postimplant data on the large number of women included in Mentor's and Inamed's studies. Were FDA to require long-term post-implant follow-up data, Mentor and Inamed would not be able to gain approval of their PMAs for many years to come. WLF charged that the APA prohibits FDA from imposing long-term pre-approval data requirements on the silicone breast implant PMAs, given that FDA has never previously imposed such requirements on similar medical devices. WLF Chief Counsel Richard Samp later elaborated on WLF's charges during testimony given to an FDA panel on April 11. On October 11, 2005, WLF reiterated those same arguments in a brief to FDA that responded to a petition from Public Citizen and others that urged rejection of the PMAs. Recent signs from FDA have been encouraging: in the summer of 2005, it tentatively approved both PMAs.

*Emergency Approval of Medical Products.* On September 6, 2005, WLF filed comments in support of FDA's issuance of guidance on emergency approval of medical products. Congress has given FDA authority to allow the use of unapproved medical products, or to authorize



unapproved uses of an approved product, in response to a heightened risk of attack from biological, chemical, radiological, or nuclear weapons. While expressing its support, WLF expressed concerns regarding the preemption aspects of the proposal. WLF argued that those provisions should be clarified to establish that the preemptive effect of an emergency authorization covers labeling matters and tort liability. WLF's comments noted that the emergency powers created by Congress to protect the public health would be frustrated by assertions of state or local authority in either of these areas - either to establish contrary or supplemental labeling requirements or to impose tort liability where a manufacturer is acting in compliance with an emergency use authorization.

**Restriction on Lung Cancer Drug.** On July 25, 2005, WLF filed comments with the Food and Drug Administration asking the agency to withdraw or modify its order for the restrictive labeling of the lung cancer drug Iressa. FDA's action effectively limits the use of Iressa in the United States to the approximately 4,000 patients already being treated with it. WLF's comments argued that this limitation on the availability of Iressa is unjustified and will harm lung cancer patients in the future who have no other approved treatment options and who may benefit from this medicine. WLF previously filed comments on April 20, 2005, with the FDA opposing a petition from the Nader group Public Citizen, Inc. in which Public Citizen sought the immediate withdrawal of Iressa.

**Regulation of Pain Medication.** On March 21, 2005, WLF filed formal comments with the Drug Enforcement Administration (DEA), urging that DEA regulation of pain medication not create a risk of denying needed pain medicines to terminally ill patients and chronic pain patients. In response to DEA's plan to issue new guidance regarding dispensing of controlled substances, WLF emphasized the importance of granting physicians leeway in treating *bona fide* pain patients, and stated that physicians should not be at risk of prosecution unless they distribute or prescribe controlled substances to a person outside the scope of legitimate practice. In separate comments filed the same day, WLF also expressed concern that DEA's new mandate to withhold approval for procurement of controlled substances used in the production of pain medicines should not be used by DEA to second-guess FDA approval decisions. WLF argued that DEA's role in this regard is advisory and that Congress has vested drug approval authority with FDA.

WLF Advertising Campaigns. In combating excessive FDA caution, WLF has not confined its efforts to litigation and publishing. WLF has also undertaken numerous advertising campaigns designed to focus public attention on FDA's shortcomings. When 1994 studies showed that FDA's delays had led to a record backlog of products awaiting approval, WLF sought to publicize those delays by launching a major public relations campaign that featured six different advertisements in the national editions of the *Wall Street Journal*, USA Today, Washington Post, The New York Times, and National Journal. The advertisements were widely praised for their effectiveness, each winning a prestigious Addy Award in 1995. WLF's work was widely credited with forcing FDA to streamline its product approval process and also brought the issue to the attention of major decision makers in government. Congress subsequently adopted major reform legislation in 1997.

Financial Disclosures by Investigators Conducting Clinical Studies. On December 21, 1994, WLF filed with FDA its opposition to FDA's proposal to require detailed disclosure of



financial interests that could potentially bias the outcome of clinical trials. WLF argued that this proposal would needlessly complicate and slow the product-approval process, because there was *no* evidence of such bias in any clinical trials, yet the burdensome nature of these disclosure and reporting requirements would lead some leading doctors simply to forgo participation in clinical trials. Despite WLF's strong opposition, FDA adopted this proposal on February 2, 1998. WLF continues to agitate for repeal of this unnecessary and counter-productive regulatory requirement.

*CFC-Containing Inhalers*. On May 5, 1997, WLF filed comments with the FDA opposing any effort to ban the use of Chlorofluorocarbon (CFC) propellants in self-pressuring containers that are used by asthmatics. FDA had proposed such a ban because it feared that the propellants might be damaging the earth's ozone layer and believed that such propellants were no longer essential. WLF supported the position taken by the Allergy and Asthma Network and Mothers of Asthmatics organization that such inhalers should not be banned in the absence of an effective alternative, especially in light of EPA's current proposal to limit ozone levels in the name of asthmatics. FDA delayed making its proposal final; when it eventually issued a new proposed rule on July 24, 2002, the proposal was far less objectionable to asthmatics.

Waiver of FDA Regulations for Operation Desert Storm. On January 22, 1991, WLF petitioned FDA to permit the waiver – in connection with military operations in the Persian Gulf – of regulations prohibiting the administration of certain drugs without the informed consent of the recipient. WLF argued that military necessity required granting the waiver; WLF argued that the effectiveness of military units could not be assured unless all soldiers in those units were inoculated against possible biological attack. WLF noted that the drugs in question had been determined to be safe. FDA ultimately granted the waiver.

# **C.** Opposing Interference with the Free Market

WLF believes that the best way to ensure an adequate supply of medical products and services is to allow the free market to decide how to price such products and services. The experience in Canada (where widespread government intervention in the market has led to product shortages, long waiting lists for surgery, and patients crossing into the United States in search of high-quality health care) well demonstrates the folly of price controls. Nonetheless, a number of States in recent years have reacted to increases in health care costs by seeking to impose price controls, particularly with respect to prescription drugs. WLF has gone to court repeatedly to challenge such efforts. WLF has filed its court papers on behalf of a broad coalition of patients-rights groups that have seen first-hand the damage caused by price-control efforts: the Kidney Cancer Association, the Allied Educational Foundation, the Seniors Coalition, the International Patient Advocacy Association, and the 60 Plus Association. WLF has also opposed proposed federal initiatives – designed to cut costs – whereby the federal government would deny Medicare patients coverage for expensive but life-saving drugs which their doctors have prescribed for them, and would divert funds raised through "user fees" (ostensibly imposed to cover costs associated with product approval reviews) to cover routine FDA expenditures.

Pharmaceutical Research and Manufacturers of America ["PhRMA"] v. Walsh. On May 19, 2003, the U.S. Supreme Court declined to strike down a Maine law that imposes strict controls



on the price of all prescription drugs sold in the State. The decision was a setback for WLF, which filed a brief arguing that the price control scheme is void because it conflicts with federal laws regulating the sale of drugs. The Court held that the challenge to the Maine law was premature, because the program has not been operating long enough to allow a determination whether (as alleged by WLF) the price controls are reducing Medicaid recipients' access to life-saving drugs. The Court also stated that it was reluctant to strike down the Maine law in the absence of a ruling by federal officials that the Maine law conflicts with federal law. Such a ruling is a distinct possibility, because the federal government filed a brief with the Supreme Court asking that the Maine law be struck down. The Court remanded the case to the trial court and indicated that, on remand, the law should be struck down unless Maine can demonstrate that its program in some way serves the Medicaid law's purposes.

**PhRMA v. Thompson.** On December 23, 2002, the U.S. Court of Appeals for the District of Columbia Circuit struck down a separate Maine law (not the one at issue in *Walsh*) that also imposed strict controls on the price of many prescription drugs sold in the State. The decision was a victory for WLF, which filed a brief urging that the law be struck down. The court agreed with WLF that the Maine price control scheme was invalid because it conflicted with federal laws regulating the sale of prescription drugs. The court further agreed that the U.S. Department of Health and Human Services (HHS) acted improperly in approving the Maine program. WLF had noted that although Maine purported to adopt the program pursuant to its authority under the Medicaid law, those covered under the Maine program are moderate income individuals who are too wealthy to qualify for Medicaid.

**PhRMA v. Thompson II.** On April 2, 2004, the U.S. Court of Appeals for the District of Columbia Circuit upheld a Michigan statute that imposes price controls on pharmaceuticals sold to Medicaid recipients in the State. The decision was a setback for WLF, which filed a brief challenging the statute. The appeals court rejected WLF's argument that the Michigan program is invalid because it conflicts with the federal Medicaid law. While agreeing with WLF that the Medicaid statutes in question could reasonably be interpreted as prohibiting the type of price control scheme imposed by Michigan, the court held that Medicaid officials' contrary interpretation was also plausible and that it was required to defer to those officials' interpretation of the law. WLF also argued that the program will result in substandard care for Michigan's poorest citizens, because it will result in their being denied access to essential drugs that the State has deemed too expensive.

**Opposing Unwarranted User Fees.** On December 14, 2005, WLF filed comments with the FDA on the reauthorization of the prescription drug user fee program. WLF warned against abuse of the program. Under the Prescription Drug User Fee Act (PDUFA), sponsors of new drug applications pay user fees to allow FDA to hire more scientific review staff and improve its information technology for the purpose of expediting the new drug review process. In its comments, WLF argued that because PDUFA's purpose is to accelerate the availability of safe and effective new medicines, PDUFA fees should be expended only on direct application-related costs – not on unrelated costs as FDA officials have suggested. WLF argued that the prescription drug user fee program must not evolve into an industry-specific tax to finance FDA's normal regulatory and law enforcement activities.





**CMS Proposal On Tying Coverage To Clinical Trial Participation**. WLF filed comments on June 6, 2005, with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, asking the agency to withdraw its proposal to tie reimbursement for selected new treatments to the patient's participation in a clinical trial or a similar evidence-gathering process. WLF argued that such requirements may restrict patients' access to needed care and that CMS has numerous alternative tools with which to spur research. WLF further argued that CMS has not justified such requirements under the Medicare statute's "reasonable and necessary" provision governing reimbursement.

Oral Cancer Drug Demonstration Project. On June 25, 2004, WLF filed comments with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, regarding the agency's proposed exclusions from a congressionally-mandated Medicare demonstration project known as the "Section 641" demonstration. CMS subsequently announced that it was reversing its decision to exclude all off-label prescriptions from the demonstration, and that it would cover a narrow class of off-label uses – those for which the indication "is being reviewed by the FDA" and for which the FDA has stated that "no filing issues remain." As an interim measure prior to the implementation of the newly enacted prescription drug benefit in 2006, the demonstration project was to give 50,000 patients access to oral substitutes for drugs that would otherwise have been administered in a doctor's office. WLF argued that the agency should abandon its proposal to exclude off-label uses of drugs from the project because that exclusion would harm patients' health and violate congressional intent.

**CMS Guidance on "Part D" Drug Formularies.** On August 19, 2005, WLF filed comments with the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, asking the agency to withdraw its plan to allow the exclusion of the lung cancer drug Iressa from drug plans under the new "Part D" prescription drug benefit. WLF's comments are in response to a CMS decision to exclude Iressa from a requirement that carriers offering coverage under the new benefit program must include in their formularies "all or substantially all" cancer drugs. WLF noted that Iressa is believed to represent the best available care for many lung cancer patients in the Medicare population for whom other therapies have failed.

**Coverage of Cancer Drugs.** On February 10, 2004, WLF filed a petition with CMS, asking the agency not to terminate coverage of "off-label" uses of certain cancer drugs. The petition was in response to national coverage reviews in which CMS is considering whether to end those reimbursements. In the petition, WLF noted that off-label prescribing – that is, a physician's use of a drug for conditions other than the specific ones for which the FDA has given marketing approval – is common and important to medical practice in obstetrics, pediatrics, and AIDS treatment, as well as cancer treatment. WLF was concerned that a denial of reimbursement for cancer drugs would not only deny the treatments of choice to thousands of dying cancer patients, but would set a precedent for denying proper treatment to other patients.

**PhRMA v. Medows.** On May 27, 2003, the U.S. Supreme Court declined to review a decision that upheld a Florida statute that imposes strict price controls on prescription drugs sold to Medicaid recipients in the State. WLF had urged the Court to review the case, arguing that the Florida price control scheme is invalid because it conflicts with federal Medicaid law. WLF also



argued that the Florida statute will result in substandard medical care for the State's poorest citizens, because it will result in their being denied access to essential drugs that the States has deemed too expensive. WLF also filed a brief in the case when it was before the U.S. Court of Appeals for the Eleventh Circuit in Atlanta, which upheld the statute in a September 6, 2003 decision.

**PhRMA v. Michigan Dept of Community Health.** This was a state-court challenge to Michigan's price control scheme for prescription drugs. On June 27, 2003, the Michigan Supreme Court declined to review a decision that upheld a program that imposes strict price controls on pharmaceuticals sold to Medicaid recipients in the State. The decision was a setback for WLF, which filed a brief on February 5, 2003, urging that review be granted. WLF argued that the program was invalid because it conflicted with Michigan law and violated separation-of-powers principles of the Michigan Constitution. WLF also argued that the program would result in substandard care for the State's poorest citizens, because it would result in their being denied access to essential drugs that the State has deemed too expensive. WLF argued that the price control statute was inconsistent with the Michigan Constitution because the Michigan legislature purported to retain a "legislative veto" over any price controls adopted by the Executive Branch – a retention of power that WLF contended violates separation-of-powers principles. WLF also filed a brief in the case when it was before the Michigan Court of Appeals, which issued a decision on December 13, 2002 upholding the program.

**Proposal That Prescription Allergy Medications Be Switched to OTC Status.** On May 11, 2001, WLF filed comments with FDA, objecting to a proposal that three popular prescription allergy drugs – Allegra, Claritin, and Zyrtec – be switched to over-the-counter (OTC) status over the objections of their manufacturers. WLF renewed its objections in petitions submitted to FDA Commissioner Mark McClellan (on May 13, 2003) and HHS Secretary Tommy Thompson (on October 8, 2003). WLF argued that the proposed switch would undermine the intellectual property rights of the manufacturers of the drugs in question and would have significant adverse effects on health care in this country. WLF noted that FDA to date has never approved a switch to OTC status over the manufacturer's objection. WLF argued that if the switch is approved here, the lesson to be learned by manufacturers is that the financial rewards they heretofore have hoped to gain from the successful development of pioneer drugs can no longer be counted on. The inevitable results will be a reduction in research and development expenditures by major pharmaceutical companies. Such a reduction will have long-term adverse effects on health care, WLF argued.

United Seniors Association, Inc. v. Shalala. In July 1999, the U.S. Court of Appeals for the District of Columbia Circuit ruled that Medicare laws that restrict the right of senior citizens to contract with their physicians do not violate the Constitution. The decision was a setback for WLF, which filed a brief in support of the senior citizens who were challenging the law. WLF argued that Section 4507 of the Medicare laws effectively prohibits seniors from entering into private contracts with their physicians, by requiring physicians entering into such contracts to forgo participation in the Medicare program for two years. WLF argued that the Constitution recognizes an individual's right to autonomy in pursuit of health, and that that right encompasses selection of a physician and a course of treatment.

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# **D.** Exposing FDA Misconduct

The great majority of FDA employees are hard-working and dedicated individuals who act in good faith to improve health care. However, a handful of FDA employees has from time-totime undermined FDA's goals by surreptitiously working with plaintiffs' attorneys whose focus is to earn millions in fee awards by bringing tort suits (usually unwarranted) against the pharmaceutical industry. WLF has worked throughout the past decade to expose such misconduct.

Improper Contacts with Plaintiffs' Bar. Through a series of requests filed under the Freedom of Information Act in the mid 1990s, WLF slowly uncovered a pattern of improper contacts between senior FDA officials and members of the plaintiffs' bar. The attorneys were seeking to delay FDA-approval of certain medical devices, in hopes of gaining an advantage in pending litigation against several device manufacturers. Documents WLF uncovered led to a formal investigation (by FDA's Office of Internal Affairs) of Mitch Zeller, a Special Assistant to then-FDA Commissioner David Kessler. Documents uncovered by WLF in July 1997 revealed that Zeller had met with John J. Cummings, the lead plaintiffs' attorney in pending multi-district product liability litigation against pedicle screw manufacturers. WLF also discovered that Zeller took handwritten notes of that meeting. FDA officials at first denied the existence of those notes, then refused to release all but one page of the notes. In July 1997, WLF appealed FDA's decision not to release the notes. On April 23, 1998, FDA finally released those notes to WLF.

Violations of FDA Regulations by Senior FDA Personnel. After uncovering a meeting between FDA's Mitch Zeller and senior members of the plaintiffs' bar (see above), WLF discovered that Zeller never filed an official report of the meeting – as is required by FDA regulations. WLF thereafter filed a complaint against Zeller with FDA's Office of Internal Affairs (OIA), complaining of Zeller's misconduct. After conducting a complete investigation, OIA sustained WLF's charges.

WLF Investigation of Abusive Federal Inspections and Enforcement Actions. In September 2003, WLF launched an investigation of abusive federal agency inspection and enforcement actions against businesses and individuals. In a series of Freedom of Information Act requests filed with FDA and five other regulatory agencies, WLF demanded that the agencies disclose copies of complaints filed against any enforcement agent, as well as the result of any investigation by the agencies' Inspector General or similar official. WLF also asked that the agencies disclose any training manuals that disclose enforcement policies. WLF's probe into agency misconduct was spurred by a number of instances in which enforcement agents harassed and threatened company managers, their employees, and others in the course of investigating suspected violations of agency regulations.

**Petition Regarding Leaks of Confidential Information.** On February 6, 1995, WLF filed a Citizen Petition with FDA, asking the agency to begin cracking down on widespread leaks of confidential information in its possession. WLF asked FDA to establish procedures whereby it would be required to investigate significant unauthorized document disclosures and to punish those found responsible. WLF also asked FDA to establish an office whose purpose it would be to receive complaints regarding unauthorized releases and to track the frequency and patterns of such releases. WLF cited "adverse reaction reports" – reports voluntarily submitted by a manufacturer



to FDA in which the manufacturer discloses health problems experienced by a user of its product – as a particular problem area. Much of the information in such reports is supposed to be kept confidential, but such information was regularly finding its way into the hands of plaintiffs' attorneys. FDA responded to WLF in August 1995, stating that it was taking unspecified steps to address the issue. The problem appeared to abate somewhat in following years, particularly after HHS's Office of the Inspector General (at WLF's request) began an investigation of the issue.

Sofamor Danek Group, Inc. v. Gaus. On August 4, 1995, the U.S. Court of Appeals for the District of Columbia Circuit ruled that expert panels convened by the Department of Health and Human Services (HHS) to develop clinical practice guidelines for medical providers did not violate the Federal Advisory Committee Act (FACA) by meeting in secret. The decision was a setback for WLF, which filed a brief arguing that the secret meetings violated FACA. WLF argued that the courts were creating a "giant loophole" in FACA by ruling that a panel of private citizens convened by HHS is not an "advisory committee" (as defined by FACA) when its advice is directed primarily to the private sector rather than to government officials. WLF argued that FACA was intended by Congress to require openness among all advisory groups that are utilized by government officials, regardless whether a group's advice is also directed to the private sector.

# **E.** Opposing Unwarranted Tort Suits

It has become a mantra of plaintiffs' lawyers: *anyone* who suffers any injury deserves to be compensated by one or more deep-pocketed corporations. WLF strongly disagrees and works to ensure that our tort system permits recovery only against the blameworthy. Unfortunately, our health care system is being undermined because the huge liability verdicts being rendered against health care providers and drug manufacturers are discouraging the level of investment – both of money and human resources – necessary to maintain public health. Throughout the past decade, WLF has participated in numerous proceedings in an effort to counteract that trend.

Abdullahi v. Pfizer, Inc. On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging the court to dismiss claims that a pharmaceutical company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits in federal court asserting that doctors violated international law by allegedly treating patients without first obtaining the patients' informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a 1789 law that lay dormant for nearly 200 years before activists began seeking to invoke it in the past several decades. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF charged that the ATS has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations.

Zito v. Zabarsky. On May 16, 2006, the Appellate Division of the New York Supreme Court issued an order declining to reconsider a decision that permits questionable expert testimony to be introduced in a medical malpractice case. The decision was a setback for WLF, which filed





a brief urging reconsideration. WLF's brief argued that expert medical testimony must be excluded from court proceedings when it is based on "junk science." WLF argued that the testimony in this case should have been excluded because the medical conclusions reached by the "experts" lacked support in the medical literature. The American Medical Association also urged the appeals court to reconsider its decision. WLF argued that allowing the "expert" testimony in this case was particularly inappropriate because it consisted of a claim that an FDA-drug had caused the plaintiff's disease, yet the drug in question has been marketed for decades without any indication in the medical literature that the drug can trigger that disease.

*City of Hope Medical Center v. Genentech, Inc.* On January 26, 2006, WLF filed a brief the California Supreme Court urging it to reverse a court of appeal ruling that upheld a compensatory damages award of \$300 million along with an unprecedented \$200 million punitive damages award against Genentech, a biotech company. The company was involved in a contract dispute over royalties with City of Hope Medical Center which developed synthesized DNA material. WLF argued that if the massive award is not overturned on appeal, businesses involved in typical contract disputes risk debilitating lawsuits by plaintiffs' attorneys not only for normal contract damages, but also for multimillion dollar punitive damages awards. WLF also argued that the excessive award was not justified and should not have been imposed simply because the company could afford to pay the amount without going bankrupt. WLF also filed a brief in this case in 2004, urging the California Supreme Court to agree to hear Genentech's appeal; the court's January 2005 decision to grant review was a significant victory for WLF.

United States v. Rx Depot, Inc. On February 22, 2006, the U.S. Court of Appeals for the Tenth Circuit in Denver declined an opportunity to prevent FDA from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, affirming FDA's authority to seek a massive damage award against an internet pharmaceutical distributor, was a setback for WLF, which had filed a brief urging the court to deny FDA that authority. In its brief, WLF argued that FDA has no power to seek disgorgement or restitution from companies alleged to have violated federal drug laws. WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that disgorgement and restitution are not among them. WLF argued that FDA only recently began asserting that power, to have a big club with which to intimidate manufacturers who might otherwise seek to challenge FDA. The Tenth Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief. On May 23, 2006, the defendant petitioned the U.S. Supreme Court to review the case.

United States v. Lane Labs-USA, Inc. On October 21, 2005, the U.S. Court of Appeals for the Third Circuit in Philadelphia declined an opportunity to prevent the Food and Drug Administration (FDA) from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, upholding a massive \$109 million restitution award against a dietary supplement manufacturer, was a setback for WLF, which had filed a brief urging the court to overturn the award. WLF had argued that FDA has no power to seek restitution from manufacturers alleged to have violated the Federal Food, Drug, and Cosmetics Act (FDCA). WLF argued that Congress has spelled out precisely what enforcement powers it has given to



FDA, and that restitution is not among them. The Third Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief. The case involves a dietary supplement manufacturer accused by FDA of improperly promoting its products as a treatment for cancer; it was ordered to refund to consumers all money used to buy its products.

Howland v. Purdue Pharma, L.P. On December 15, 2004, the Ohio Supreme Court overturned a lower court's decision to certify as a state-wide class action a product liability suit brought by three individuals who claim they were injured due to their use of the defendant's painrelief medication. The decision was a victory for WLF, which filed a brief urging that the class be decertified. WLF argued that personal injury product liability suits are virtually never appropriate for class action treatment because the claims of each class member are unique – for example, each plaintiff must separately establish such elements of his/her tort claim as inadequacy of warning, reliance, causation, and damages. The court agreed with WLF that when, as here, individual issues of fact and law predominate over common issues, class action treatment is rarely appropriate, and that the trial court had given inadequate consideration to the "predominance" issue when it certified the class.

American Home Products, Inc. v. Collins. On April 18, 2005, the U.S. Supreme Court issued an order declining to review an appeals court decision that makes it much more difficult for out-of-state defendants to move their lawsuits from state court to federal court. The decision was a setback for WLF, which had filed a brief urging the Court to review (and ultimately overturn) the lower court decision. The suit at issue is one filed against all the major childhood vaccine manufacturers, and threatens to drive even more manufacturers out of the market. WLF argued that the lower court defined "fraudulent joinder" in an unnecessarily narrow manner. WLF argued that plaintiffs' lawyers regularly join fraudulent defendants to their lawsuits in an effort to prevent out-of-state corporations from moving lawsuits to federal court, which are generally considered less hostile to out-of-state corporations than are state courts. WLF argued that the appeals court decision frustrates the will of Congress that cases of this sort be removable to federal court as a means of ensuring that out-of-state defendants can have their cases heard in an impartial forum.

Legal Advice Regarding National Uniformity for Food Act. On November 29, 2005, at the request of U.S. Representative Edolphus Towns, WLF attorneys provided him with legal counsel regarding the propriety of the proposed National Uniformity for Food Act of 2005 ("NUFA"), which would require national uniformity in food safety and warning requirements. WLF's legal memorandum concluded that Congress would be acting appropriately were it to adopt the legislation. WLF concluded that NUFA is consistent with the federal government's traditional role in the regulation of interstate commerce and an appropriate response to the disruptions in interstate commerce caused by tort suits filed pursuant to California's Proposition 65. WLF praised NUFA as "a carefully designed effort to balance the respective roles of the federal and State governments in food safety issues." WLF said that NUFA would have a significant impact only in those few States – such as California – in which excessive imposition of food warning requirements (requirements often imposed by means of lawsuits filed by private citizens) is having a negative effect on interstate commerce.

Dura Pharmaceuticals v. Broudo. On April 18, 2005, the Supreme Court unanimously



reversed an appeals court ruling that had established a highly relaxed pleading standard for attorneys filing securities class action cases against publicly-held companies. Instead, the Supreme Court agreed with WLF that a plaintiff in such suits must establish "loss causation" – that is, that the stock price was inflated due to the company's misstatements and that a later drop in the stock price was causally related to the disclosure of the truth about the misstatements. The Court noted that there may be many reasons, unrelated to alleged wrongdoing, why the price of the stock dropped. The Court agreed with WLF that Congress had enacted the Private Securities Litigation Reform Act (PSLRA) in 1995 to prevent class action attorneys from filing securities fraud cases based on nothing more than a drop in stock price. The decision could go a long way in reducing the number of abusive lawsuits filed against pharmaceutical companies.

Baxter International Inc. v. Asher. On March 21, 2005, the U.S. Supreme Court declined to review this case, thereby passing on an opportunity to give real meaning to a 1996 federal law that was intended to limit the liability of corporations that make projections ("forward-looking statements") regarding future sales and earnings. The decision was a setback for WLF, which had filed a brief urging that review be granted. The Private Securities Litigation Reform Act ("PSLRA") creates a "safe harbor" for forward-looking statements; provided that such statements are accompanied by "meaningful" cautionary statements, the safe harbor provides that the statements cannot be used to hold a publicly held corporation liable to its shareholders for making false statements, regardless how inaccurate the statements turn out to be. In this case, the appeals court held that the PSLRA safe harbor cannot be invoked to win dismissal of a securities law class action at the pleadings stage because the issue of whether the accompanying cautionary statements are sufficiently "meaningful" can never be determined until after all pre-trial discovery is complete and the facts of the case have been fully fleshed out. In urging that the Court review (and ultimately overturn) the appeals court decision, WLF argued that the PSLRA was intended to permit defendants to invoke the "safe harbor" provision to win dismissal of suits at the pleadings stage. WLF argued that by precluding all possibility of early dismissal, the appeals court essentially wrote the safe harbor out of the law, because the principal purpose of the provision was to allow corporations to win dismissal of "forward-looking statement" lawsuits without having to incur the huge drain on resources that the litigation discovery process generally entails.

Stetser v. TAP Pharmaceutical Products, Inc. On July 6, 2004, the North Carolina Court of Appeals issued an opinion that imposes strict limits on nationwide class action suits against drug manufacturers. The decision was a victory for WLF, which had filed a brief urging that the lower court's class certification order be overturned. WLF's brief argued that plaintiffs' lawyers often bring such nationwide class actions as a means of coercing a settlement, without regard to the merits of the suit. Such suits tend to be totally unmanageable, because class members often have widely varying damage claims, and different sets of laws often apply to class members from different states. In this case, the trial judge certified a nationwide class of consumers allegedly injured by the pricing policies of several drug companies. He attempted to avoid unmanageability problems by decreeing that all claims would be judged under North Carolina law, the state in which the suit was filed. The court of appeals agreed with WLF that applying North Carolina law violated the due process rights of the vast majority of litigants who had no connection with North Carolina, and that even the defendants (which are headquartered in other states) had no more than minimal contacts with North Carolina. The court of appeals remanded the case to the trial court for reconsideration; its opinion indicates that if the trial court chooses to certify any plaintiff class



at all, the class must be limited to North Carolina residents.

**PacifiCare Health Systems, Inc. v. Book.** On April 7, 2003, the U.S. Supreme Court mandated the enforcement of agreements to arbitrate commercial disputes, regardless whether the remedies available in an arbitration proceeding are less broad than those available in a lawsuit. The decision was a victory for WLF, which filed a brief urging that the enforceability of arbitration agreements be upheld. The decision (involving a dispute between HMOs and a group of doctors) likely will lead to reduced health care costs. The court of appeals refused to enforce an arbitration agreement between the HMO and the doctors because the arbitrator likely would not have been permitted to award punitive damages, a remedy that the plaintiffs could seek in a federal court action. WLF argued that a party that decides in advance that it will arbitrate all disputes – a very rational decision given arbitration's speed and efficiency advantages over litigation – should not be permitted to wriggle out from that agreement simply because it later concludes that litigation offers it tactical advantages.

In re Vitamin Cases/Philion v. Lonza. The California Supreme Court on June 11, 2003 let stand a class action settlement in which the plaintiffs' lawyers are to receive millions in fees, while consumers – their purported clients – will receive nothing. WLF had filed a brief on May 9, 2003 in support of the objecting class members, arguing that the settlement violated California law and urging the High Court to grant review. The suit raised price-fixing charges against various vitamin manufacturers. As a result of the settlement to which WLF objected, the consumers will have no opportunity to seek compensation of any kind. Instead, the so-called *cy pres* settlement of \$38 million will be paid to governmental and nonprofit organizations; the plaintiffs' attorneys will receive an award of \$16 million in fees. WLF argued that the case was a classic example of abuse of the litigation process by plaintiffs' attorneys.

**Taylor v. SmithKline Beecham Corp.** On March 24, 2003, the Michigan Supreme Court upheld a Michigan statute that precludes design-defect tort actions against the manufacturer of any drug that has been approved for sale by FDA. The decision was a victory for WLF, which filed a brief in the case, urging that the statute be upheld. The court agreed with WLF that the Michigan legislature acted properly in adopting the statute and that it did not violate a state constitutional provision that prohibits the legislature from delegating its powers to a federal administrative agency. WLF has argued repeatedly that such measures are necessary to hold down health care costs and to ensure that low-income Americans continue to have access to quality health care.

**Pegram v. Herdrich.** On June 12, 2000, the U.S. Supreme Court issued a decision that is likely to rein in the continuing expansion of civil lawsuits brought under ERISA, the federal pension law. The decision was a victory for WLF, which had argued in a November 12, 1999 brief that the lower court's decision threatened to undermine health care in this nation by allowing a patient to sue his health care provider under ERISA anytime the provider takes into account cost considerations when deciding how to treat the patient. The Court noted that patients are already permitted to sue their doctors for malpractice under state tort law. The Court agreed with WLF's argument that a patient should not *also* be permitted to file an ERISA suit against his HMOs and doctors (based on a claim that they allegedly violated a fiduciary duty under ERISA to act in the patient's best interests). WLF had argued that allowing such suits would lead to dramatically increased health-care costs by preventing doctors and HMOs from trying to control costs. WLF

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filed an earlier brief in the case on July 28, 1999, successfully urging the Court to grant review.

**Dow Chemical Company v. Mahlum.** On December 31, 1998, the Nevada Supreme Court upheld the imposition of compensatory damages against Dow Chemical Co. for breast implants manufactured by Dow Corning, but struck down the imposition of punitive damages against the company. The decision was a partial victory for WLF, which in August 1996 had filed a brief urging the court to reverse a trial court ruling that imposed a \$14 million judgment upon Dow Chemical for the manufacture and sale of silicone breast implants by another company, Dow Corning. The plaintiffs sued Dow Chemical for injuries allegedly suffered in 1985 by silicone breast implants that were tested, manufactured, and sold by Dow Corning, a legally distinct company from Dow Chemical. The plaintiffs' attorneys argued that Dow Chemical should be held liable for not disclosing studies done in 1948, 1956, and 1970 regarding the industrial uses of certain silicones. But those studies had nothing to do with the different type of gel silicone developed and tested many years later by Dow Corning.

Artiglio v. Corning, Inc. On July 20, 1998, WLF scored a major victory when the California Supreme Court affirmed a lower court ruling that Dow Chemical Co. was not liable for any damages allegedly caused by breast implants manufactured by another company, Dow Corning Corp. WLF filed a brief in the case in June 1997, urging the court to affirm the lower court ruling. The plaintiffs sued Dow Chemical, Corning, and Dow Corning for injuries allegedly caused by silicone breast implants tested, manufactured, and sold only by Dow Corning. Because Dow Corning later declared bankruptcy, the plaintiffs' attorneys pursued Dow Chemical on the novel theory that it should be held liable for not disclosing studies done in 1948, 1956, and 1970 regarding the industrial uses of certain silicones.

Daubert v. Merrell Dow Pharmaceuticals. In June 1993, the U.S. Supreme Court struck a blow against use of "junk science" in the courtroom, ruling that judges must exclude expert scientific testimony from reaching a jury unless that evidence is generally accepted within the scientific community. The result of the decision was to throw out the thousands of suits that alleged that the drug Bendectin causes birth defects; lower courts have agreed that the evidence used to establish such a link was nothing more than "junk science." The decision was a victory for WLF, which filed a brief in the case arguing that allowing juries to consider scientific evidence that is rejected by the majority of scientists undermines the role of the courts as truth-finding institutions.

**Petition Urging Balanced Study of Silicone Implants.** On January 20, 1992, WLF filed a petition with Secretary of Health and Human Services Louis Sullivan, urging him to convene an unbiased panel of health experts to review the data on silicone breast implants. WLF argued that FDA had mishandled the issue, noting that FDA's unwarranted restrictions on silicone implants had provided the impetus for an unprecedented wave of product liability suits against implant manufacturers. WLF argued that FDA Commissioner David Kessler acted without statutory authority and used biased, "junk" science in making decisions on the issue. WLF was ultimately vindicated when later studies showed that FDA's concerns were totally unfounded.

In re Dow Corning Corp. On November 22, 2000, WLF scored a victory when the U.S. District Court for the Eastern District of Michigan overturned a ruling by a bankruptcy court



invalidating a third-party release of liability in a bankruptcy settlement. Under the settlement, which reorganized Dow Corning Corporation in the face of numerous product-liability claims for silicone breast implants, Dow Corning's parent companies, Dow Chemical Company and Corning, Inc., were released from future tort claims. Instead, claimants receive compensation out of the settlement fund. WLF maintained in its brief filed in March 2000 that such a release is permissible under the bankruptcy code and would put an end to the quagmire of litigation surrounding this case. Moreover, WLF noted, the vast majority of tort claimants, along with Dow Corning, Dow Chemical, and Corning, supported the plan, which the bankruptcy court's decision threatened to unravel.

### F. Preemption of Medical Device Suits

Federal law provides certain special protections to medical device manufacturers. In particular, once FDA has determined that a medical device is safe and effective for its intended use, a state court may not reach a contrary conclusion in connection with a tort suit alleging that the device is defectively designed. WLF has gone to court repeatedly to support a broad interpretation of the federal law that requires "preemption" of contrary state laws and court judgments. The Supreme Court significantly cut back on the extent of preemption in *Medtronic, Inc. v. Lohr,* but its later decision in *Buckman Co. v. Plaintiffs' Legal Committee* restored a fair degree of the protection previously afforded to device manufacturers. WLF continues to litigate against plaintiffs' efforts to circumvent the *Buckman* decision.

*Medtronic, Inc. v. Lohr.* On June 26, 1995, the U.S. Supreme Court ruled 5-4 against WLF in this important product liability case when it found that state tort claims against medical device manufacturers are not preempted by federal law. A federal statute provides that if a medical device is subject to regulation by FDA, it may not also be subjected to state law "requirements." The lower courts had been split on whether tort claims qualify as "requirements" imposed by state law; the Supreme Court held that they generally do not so qualify, albeit the Court left the door open to preempting tort claims in some limited contexts. WLF had argued in its brief that federal regulation of medical device design, manufacture, and marketing is sufficient to ensure that medical devices are safe, and that additional regulation at the state level discourages development of new and useful medical devices.

Buckman Co. v. Plaintiffs' Legal Committee. On February 21, 2001, the U.S. Supreme Court ruled that plaintiffs' lawyers may not second-guess FDA product approval decisions by filing state-law suits against the product manufacturer. The decision was a victory for WLF, which had filed a brief with the Court arguing that federal law does not permit such challenges because they would undermine FDA's authority to regulate the pharmaceutical industry. The suits here were product liability claims against the manufacturers of orthopedic screws used in spinal surgery; the plaintiffs asserted that the screws never should have been permitted on the market and that FDA approved marketing only because manufacturers defrauded the FDA in connection with their product-approval applications. The Court agreed with WLF that because FDA has stood by its decision to permit marketing of the screws, federal law prohibits plaintiffs from filing state-law tort actions that in essence second-guess FDA's approval.

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U.S. ex rel. Gilligan v. Medtronic, Inc. On April 6, 2005, the U.S. Court of Appeals for the Sixth Circuit in Cincinnati dismissed a lawsuit that sought to second-guess decisions of the Food and Drug Administration (FDA) authorizing the sale of drugs or medical devices. The decision was a victory for WLF, which filed a brief in support of the manufacturer whose product was being challenged. WLF argued that permitting such suits to go forward would undermine the integrity of FDA's product-approval system and could result in patients being denied access to lifesaving medical products. Although it dismissed the lawsuit, the Sixth Circuit did so on narrower grounds than WLF had argued. The plaintiffs were suing under the False Claims Act (FCA), a federal law that permits bounty-hunting private citizens to file a suit in the name of the federal government against anyone who makes a "false claim" to the government. They alleged that the defendant, a medical device manufacturer, induced health care providers to falsely claim that the manufacturer's products had been properly approved by FDA. The Sixth Circuit held that the information on which the plaintiffs based their lawsuit was publicly available before they filed suit. The appeals court held that under those circumstances, the FCA suit was barred by the "public disclosure" bar, which eliminates federal court jurisdiction over an FCA claim where the plaintiff is not the original source of the allegations. On January 9, 2006, the U.S. Supreme Court denied a petition to review the Sixth Circuit's decision, thereby sealing WLF's victory.

**Reeves v. Acromed.** On February 10, 1995, the U.S. Court of Appeals for the Fifth Circuit in New Orleans ruled that state-law suits claiming injuries caused by alleged defects in FDAapproved medical devices are impermissible because they are preempted by federal law, at least when the suits are premised on a failure-to-warn claim. The decision was a victory for WLF, which had filed a brief in the case in 1994 urging that the tort claims be dismissed on preemption grounds. WLF argued that federal regulation of medical device design and marketing is sufficient to ensure that medical devices are safe, and that additional regulation at the state level discourages development of new and useful medical devices.

Smith & Nephew Dyonics, Inc. v. Violette. On August 1, 1995, the U.S. Court of Appeals for the First Circuit affirmed a tort judgment for a plaintiff who claimed he was not warned about the dangers of a medical device despite the manufacturer's compliance with FDA's strict labeling requirements. WLF had urged the court to rule that state-law suits claiming injuries caused by alleged defects in FDA-approved medical devices are impermissible because they are preempted by federal law. The device at issue was the ECTRA System, used by physicians in performing wrist surgery. The court declined to rule on WLF's preemption argument; it held that the manufacturer had waived that argument by failing to raise it in the trial court.

Feldt v. Mentor. On August 21, 1995, the U.S. Court of Appeals for the Fifth Circuit ruled that most state-law product liability claims brought against a medical device manufacturer are preempted by federal law. The court held that because FDA already closely regulates medical devices, additional state regulation in the form of tort liability is unwarranted -- except for claims that the device is defectively designed. The decision was a victory for WLF, which had filed a brief urging dismissal of the claims. WLF successfully argued that preemption occurs even when, as here, the medical device in question is being marketed pursuant to an FDA § 510(k) "substantial equivalence" finding, rather than pursuant to the more rigorous pre-market approval process. WLF argued that in the absence of such preemption, development of new and useful medical devices would be stifled.



**English v. Mentor.** On September 29, 1995, the U.S. Court of Appeals for the Third Circuit ruled that most state-law claims against a medical device manufacturer are preempted by federal law. The decision was a victory for WLF, which had filed a brief supporting the district court's dismissal of the plaintiffs' product liability claims. The plaintiffs sought damages under theories of strict liability, negligent design, and breach of express and implied warranties of merchantability because the plaintiffs' prosthesis began malfunctioning. The only claim that the appeals court held was not preempted was that the manufacturer breached express warranties regarding the performance of its product.

**Rosci v. Acromed.** On December 19, 1995, a Pennsylvania court handed WLF a partial victory in a products liability action. The court ruled that some, but not all, state tort claims against medical device manufacturers are preempted by federal law. WLF had filed a brief in the case, urging the Superior Court of Pennsylvania to affirm a lower court's dismissal of the plaintiff's claim that a device manufacturer violated express and implied warranties when its bone plates and screws, which were inserted into the plaintiff's back, did not produce the results desired by the plaintiff. WLF argued that federal law preempted the plaintiff's state-law claims. The court ruled that federal law preempts breach of warranty claims where the warranty is one implied by state law, but does not preempt claims that the manufacturer breached a warranty it expressly made at the time of sale.

Guidance Document on Medical Devices Preemption. WLF achieved a major victory in July 1998, when FDA agreed to withdraw a proposed guidance document regarding when federal law preempts state tort lawsuits against medical device manufacturers. In February 1998, WLF had filed comments urging that the proposed guidance be withdrawn. In Medtronic, Inc. v. Lohr, the Supreme Court ruled that federal law operates to preempt at least some state tort suits against device manufacturers. Despite that decision, FDA's proposed guidance declared that state tort suits are virtually never preempted by the relevant federal statutes. WLF argued that the FDA guidance document was directly contrary to the plain language of the federal statutes and flouted the Medtronic decision.

# **G.** Protecting Patent Rights

If advances in health care are to continue, it is vital that research-based pharmaceutical companies that develop new drugs and medical devices be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. When it adopted the Hatch-Waxman Act in 1984, Congress carefully balanced the need, on the one hand, for a strong patent system that rewards companies that develop new therapies and, on the other hand, for the competition among manufacturers that provides lower prices for consumers. Numerous politicians have been pushing the courts to upset that balance by abridging patent rights created by Hatch-Waxman. WLF has vigorously opposed such efforts, going to court repeatedly to support those rights.

Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc. On February 1, 2006, the U.S. Court of Appeals for the Federal Circuit reversed its earlier decision to invalidate a multi-billion dollar pharmaceutical patent, and remanded the case to the district court to consider the invalidity issue



anew. The decision was a major victory for WLF, which filed a brief in June 2005, urging the three-judge appeals court panel to reverse its prior decision. Particularly gratifying to WLF was that the panel reversed itself based on the precise arguments raised by WLF in its brief. The case now returns to the U.S. District Court for the Southern District of New York for reconsideration of the patent invalidity issue. Based on guidance provided by the appeals court regarding how the issue should be resolved, it was likely that the district court will ultimately uphold the patent. The patent at issue covers OxyContin, a powerful pain relief medication. A federal district court ruled in 2004 (and the appeals court panel affirmed in June 2005) that the patent should be invalidated as a penalty for alleged "inequitable conduct" committed by the drug's manufacturer when applying to the Patent and Trademark Office (PTO) for the patent. A patent can be invalidated on those grounds only upon a showing that the applicant omitted "material" information from its patent application and did so intending to deceive the PTO. WLF argued (and the latest appeals court decision largely agreed) that the district court improperly lowered the bar for demonstrating inequitable conduct by applying far too lax standards for intent. WLF argued that any information withheld in this case was trivial and that there was no evidence that the manufacturer intended to deceive the PTO.

Mylan Pharmaceuticals, Inc. v. Thompson. On October 12, 2001, the U.S. Court of Appeals for the Federal Circuit ruled that those challenging patents held by pharmaceutical companies are not permitted to circumvent the procedural protections that Congress granted to patent holders when it adopted the Hatch-Waxman Act in 1984. The ruling was a victory for WLF, which on April 20, 2001, had filed a brief urging that the procedural rights of patent holders be upheld. The court agreed with WLF that those challenging patents should be required to raise their claims in connection with the normal procedures established for such challenges; they should not be permitted to circumvent those procedures with novel legal claims, such as suits challenging a drug company's decision to list a patent in the "Orange Book" maintained by FDA. WLF also argued that undermining the patent rights of drug manufacturers inevitably will slow development of new, life-saving therapies by reducing financial incentives for research spending.

SmithKline Beecham Corp. v. Apotex Corp. On June 19, 2006, the U.S. Supreme Court issued an order declining to review an appeals court decision that invalidated a significant pharmaceutical patent based on a finding that the drug was not "novel" when the patent application was filed in 1986 – even though it is undisputed that if the drug existed before then, it was in such minute quantities as to be undetectable. The order, issued without comment, was a setback for WLF, which filed a brief urging that review be granted. WLF argued that if allowed to stand, the decision of the U.S. Court of Appeals for the Federal Circuit would undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights. WLF argued that under the doctrine of "accidental prior use," an invention should not be deemed to have been "anticipated" by the prior art if the prior art's disclosure of the claimed invention is accidental or unwitting and no one – not even experts in the field – would have recognized the existence of the disclosure. WLF argued that the challenged patent should have been upheld under the "accidental prior use" doctrine. WLF also filed briefs in the case – supporting the validity of the underlying patent – in the Federal Circuit in 2004 and 2005.

Allergan, Inc. v. Alcon Laboratories. On December 1, 2003, the U.S. Supreme Court declined to review an appeals court decision that barred a pharmaceutical company from seeking



recourse in the courts as soon as one of its patents is threatened by a generic drug company's announced plan to market a generic version of the drug covered by the patent. The decision was a setback for WLF, which on October 24, 2003 had filed a brief urging the Court to grant review. WLF also filed two briefs in 2002/2003 when the case was in the appeals court. The Court's order provided no explanation for its decision to deny review. In its brief urging Supreme Court review, WLF argued that permitting early resolution of patent disputes between pioneer and generic drug companies was one of Congress's principal purposes in adopting the Hatch-Waxman Act in 1984. WLF argued that the lower courts' decision dismissing the pioneer company's claim on ripeness grounds undermines congressional intent and ought to be reversed.

*Pfizer, Inc. v. Dr. Reddy's Laboratories, Inc.* On February 27, 2004, the U.S. Court of Appeals for the Federal Circuit (in a victory for WLF) overturned a district court decision that threatened to cut short patent rights granted to pharmaceutical companies under the Hatch-Waxman Act. The appeals court rejected the district court's rationale, under which generic companies would have had little difficulty avoiding patent infringement actions by merely altering one of the inactive ingredients of the patented product. The appeals court agreed with WLF's argument that by assigning too restrictive a definition of what constitutes the chemical substance protected by a patent, the district court undermined patent rights and thereby significantly reduced the economic incentives for companies to invest the vast sums necessary to develop new life-saving products. The district court had held that a generic drug does not infringe a product whose patent term has been extended under the Hatch-Waxman Act, so long as it is combined with an "addition salt" different from the one used in the patented drug – even if the generic drug includes the same active ingredient as the patented product.

**Opposition to Activist Petition Threatening Patent Rights.** The National Institutes of Health (NIH) announced on September 17, 2004, that it would not grant a "march-in" petition from an activist group seeking to abrogate the exclusivity of patent rights held by a pharmaceutical company. The petition, filed by a group called Essential Inventions, argued that federal law gives federal agencies the authority to regulate the prices of products that are based on technology wholly or partly funded by federal grants and licensed to the private sector. NIH's decision was a victory for WLF, which had filed comments on August 9, 2004, urging NIH to deny the petition. The Essential Inventions petition claimed that Pfizer had set excessive prices for its glaucoma drug Xalatan by charging more for the drug in the U.S. than overseas. The petition argued that the march-in provision of the Bayh-Dole Act could be invoked based on a licensee's decision to set "unreasonable" prices for a product. WLF's response analyzed the Act and its legislative history to show that the Act was never intended to serve as a price-control law.

**Revision of Hatch-Waxman Act Regulations.** On December 23, 2002, WLF wrote to FDA, generally supporting the agency's proposed revision of rules implementing the Hatch-Waxman Act's procedures for resolving patent disputes between pioneer and generic drug manufacturers. WLF agreed with FDA that, in order to prevent pioneer manufacturers from abusing Hatch-Waxman procedures in an effort to delay entry of generic competition, they should be allowed to invoke the Act's 30-month stay provision only once in connection with a single Abbreviated New Drug Application (ANDA). However, WLF contended that FDA's proposed rule goes too far in this regard. FDA proposes that a pioneer manufacturer's sole opportunity to invoke the 30-month stay should arise only in the period immediately following the *first* occasion





on which a generic company has filed a "Paragraph IV Certification" in connection with its ANDA. WLF argued that FDA's proposal is based on a misreading of the relevant statute; pioneer manufacturers should not be deemed to have waived the stay if they do not deem it necessary to file an infringement suit in response to the generic company's first Paragraph IV Certification. Rather, WLF argued, the 30-month stay should not be triggered until the pioneer manufacturer has filed a patent infringement lawsuit. On June 18, 2003, FDA adopted final regulations in substantially the same form as it had proposed in December 2002.

**Proposed Rulemaking to Implement Pediatric Exclusivity Laws.** On January 28, 2002, WLF petitioned FDA to initiate a rulemaking proceeding to implement the pediatric exclusivity provisions of the newly enacted Best Pharmaceuticals for Children Act (BPCA). The BPCA authorizes FDA to approve a marketing application from a generic drug manufacturer even when the brand-name manufacturer still holds exclusive rights to market the drug to children. WLF argued that allowing generic drugs to be marketed without any sort of pediatric labeling raises serious health concerns. WLF argued that, in general, generic manufacturers should be required to purchase a license from the brand-name manufacturer that would allow them to include pediatric labeling on their products.

# H. Misuse of Antitrust Law

When the government grants a limited-time patent to the inventor of a product, it recognizes that the antitrust laws (which normally operate to prohibit all "restraints of trade") are generally inapplicable to the actions of the patent holder. Nonetheless, plaintiffs' lawyers with increasing frequency have been filing antitrust claims against patent holders and those who enter into marketing agreements with patent holders – thereby threatening the viability of the patent system. WLF has regularly litigated in the federal courts against those who would use the antitrust laws to limit the rights of patent holders – rights that are essential if research and development are to be encouraged.

Schering-Plough Corp. v. FTC. On March 8, 2005, the U.S. Court of Appeals for the Eleventh Circuit overturned an FTC decision that would have imposed antitrust liability on two drug companies based on the settlement of a patent dispute. WLF had filed a brief on June 9, 2004, encouraging the court to overturn the FTC's ruling. The settlement agreements (between Schering-Plough Corp., Upshur-Smith, and American Home Products) settled a dispute involving generic drug companies who wished to manufacture a drug for which Schering-Plough claimed patent rights. The FTC held that the settlement unreasonably restrained trade because the generic companies agreed to delay their entry into the market. In its brief, WLF argued that the FTC's view of patent settlements between drug companies is commercially unrealistic and counter to federal antitrust law. WLF further argued that the FTC's position would deter settlement of patent disputes. WLF also filed a brief when the matter was before the FTC. In August 2005, the FTC filed a petition for certiorari with the Supreme Court seeking review of the Eleventh Circuit decision. Interestingly, the U.S. Department of Justice has filed a brief urging that the Court *reject* the FTC's petition.

Valley Drug Co. v. Geneva Pharmaceuticals. On September 15, 2003, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta rejected claims that agreements to settle patent disputes



can amount to *per se* violations of the antitrust laws. The decision was a victory for WLF, which filed a brief in the case urging against blanket condemnation of such agreements. The appeals court explained that patents are intended to provide holders with the power to exclude competition; the court agreed with WLF that agreements that settle patent disputes by simply confirming patent holders' power to exclude do not violate the antitrust laws. The appeals court reversed a district court decision that had condemned a patent settlement as a *per se* antitrust violation. The case involves the settlement of a patent dispute between Abbott Laboratories (which held a patent to manufacture the drug Hytrin) and several companies that wished to manufacture generic equivalents of Hytrin. Under the settlement, the generic manufacturers agreed to delay their entry into the field. The court agreed with WLF that the antitrust analysis was unchanged by the fact that Abbott paid money to the generic companies in connection with the settlement. In October 2004, the U.S. Supreme Court declined a petition to review the Eleventh Circuit's decision.

Andrx Pharmaceuticals, Inc. v. Kroger Co. On October 12, 2004, the U.S. Supreme Court declined to review a lower-court ruling that agreements to settle patent disputes can amount to per se violations of the antitrust laws. The decision not to hear the case was a setback for WLF, which filed a brief in the case, urging that review be granted. WLF argued that parties ought to be encouraged to settle their patent disputes. By raising the possibility that settlements will be subjected to per se condemnation under the antitrust laws, the federal appeals court in Cincinnati is unnecessarily discouraging settlements, WLF argued. The case involves the settlement of a patent dispute between Hoescht Marion Roussel (which held a patent to manufacture the drug Cardizem CD) and a generic drug manufacturer, Andrx Pharmaceuticals, which had announced plans to market a generic version of Cardizem CD. Under the settlement, Andrx agreed to delay its entry into the field. The plaintiffs, purchasers of Cardizem CD, allege that the settlement constituted an unreasonable restraint of trade in violation of antitrust laws. WLF argued that litigation settlements often have significant procompetitive effects and thus that they ought to be judged under the "rule of reason" rather than being condemned as per se illegal in all cases.



# **II. CIVIC COMMUNICATION**

WLF recognizes that its litigation and regulatory activities cannot alone suffice if it is to have a significant impact in shaping the nation's healthcare policy. WLF has also sought to influence public debate and provide information through its Civic Communications Program. This targeted and broad-based program features WLF's sponsorship of frequent, well-attended media briefings featuring experts on a wide range of health-related topics, web seminars featuring analysis and commentary by noted legal experts on timely developments in law and public policy, the publication of advocacy advertisements in national journals and newspapers, and participation in countless healthcare symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media – from reporters for general-circulation newspapers to writers for specialized FDA journals.

# A. Media Briefings

The centerpiece of WLF's Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on health-related topics. Recent media briefings (dubbed media "noshes") on healthrelated issues have included the following:

# *"Authorized" Generic Drugs: What Impact on Health Care Competition and Innovation?*, May 17, 2006

•Michael S. Wroblewski, Federal Trade Commission
•David A. Balto, Robins, Kaplan, Miller & Ciresi L.L.P.
•Christopher J. Kelly, Mayer, Brown, Rowe & Maw LLP

FDA's Federal Preemption Policy: Implications for Drug Labeling and Product Liability Litigation, March 8, 2006

•Daniel E. Troy, Sidley Austin LLP •Mark S. Brown, King & Spalding LLP

Scrutiny of Medical Education Grants: A Chilling Wind for Doctors and Patients?, February 9, 2006

•Jeffrey N. Gibbs, Hyman, Phelps & McNamara, P.C. •Steven E. Irizarry, ML Strategies •Laura Frick Laemmle, Patton Boggs LLP

Regulating Drug Promotion: Assessing a Tumultuous 2005 and Prospects for the New Year, December 13, 2005

•David Bloch, Reed Smith •Adonis Hoffman, American Association of Advertising Agencies •Richard A. Samp, Washington Legal Foundation



Hospital-Physician "Gainsharing": Legal and Healthcare Implications for Patients, Providers, and Product Producers, May 25, 2005

•David Nexon, AdvaMed •D. McCarty Thornton, Sonnenschein Nath & Rosenthal LLP •William T. Mathias, Ober Kaler

**Cold Medicines and Meth: What is the Right Approach to Curbing Illegal Use of OTC Drugs?**, May 18, 2005

•The Honorable Dennis C. Vacco, Crane & Vacco •James R. Phelps, Hyman, Phelps & McNamara, P.C.

Drug "Reimportation:" A Prescription To Put U.S. Biotech and Pharma On Life Support?, June 15, 2004

•David M. McIntosh, Mayer, Brown, Rowe & Maw LLP •Thomas J. McGinnis, R.Ph., Food & Drug Administration •Jayson S. Slotnik, Biotechnology Industry Organization

"Off Label" Communications At Risk: Promoting Prescription Drugs in an Uncertain Legal Environment, February 3, 2004

John F. Kamp, Wiley, Rein & Fielding
Stephen Paul Mahinka, Morgan Lewis LLP
Richard A. Samp, Washington Legal Foundation

From Prescription to "OTC": The Legal and Policy Issues FDA Would Face on Forcing a Switch, June 17, 2003

•Andrew S. Krulwich, Wiley, Rein & Fielding •Linda F. Golodner, National Consumers League •Nathan A. Beaver, McDermott, Will & Emery

Defending Against Bio-Terrorism: Legal Policy Challenges For Government And Private Industry, April 22, 2003

•Dr. Ken Alibek, George Mason University
•Christine Grant, Aventis Pasteur
•Frank M. Rapoport, McKenna Long & Aldridge LLP

Free Speech & Public Health: FDA, Congress, and the Future of Food and Drug Promotion, May 30, 2002

•John E. Calfee, American Enterprise Institute •Richard L. Frank, Olsson, Frank & Weeda •Sandra J. P. Dennis, Morgan Lewis LLP

Drug Patent and Pricing Litigation: Will it Help or Hinder Health Care?, March 13, 2002
•James M. Spears, Ropes & Gray
•Daniel A. Small, Cohen, Millstein, Hausfeld & Toll
•Elizabeth A. Leff, Rothwell, Figg, Ernst & Manbeck
•Jeffrey D. Pariser, Common Good





•Alan Slobodin, House Energy and Commerce Committee •John W. Bode, Olsson, Frank & Weeda

•Larry R. Pilot, McKenna Long & Aldridge

Drug Pricing and Intellectual Property: Will Government Intervention Help or Hinder Health Care?, May 2, 2001

•Willard K. Tom, Morgan, Morgan & Lewis

•Robert Goldbergh, Ph.D., National Center for Policy Analysis

•Frank M. Rapoport, McKenna Long & Aldridge

•Michie I. Hunt, Ph.D., Michie I. Hunt & Associates

Biotech Foods after the StarLink Corn Recall: Is More Federal Regulation Needed?, November 14, 2000

•Dr. Lester M. Crawford, Georgetown University Center for Food and Nutrition Policy •Gregory Conko, Competitive Enterprise Institute •Edward L. Korwek, Hogan & Hartson L.L.P.

Washington Legal Foundation v. Henney: The Appeals Court's Ruling and FDA's Curious Response on Off-label Promotion, March 22, 2000
Bert W. Rein, Wiley, Rein & Fielding
Robert A. Dormer, Hyman, Phelps & McNamara
Richard A. Samp, Washington Legal Foundation

WLF v. Henney: What's Next And What Impact on FDA and Off-label Promotion?, August 18, 1999

•Daniel E. Troy, Food & Drug Administration •George S. Burditt, Bell, Boyd & Lloyd •Howard Cohen, Greenberg Traurig

Regulating Off-label Drug Promotion: Impact of WLF v. Friedman and FDAMA, March 3, 1999

•Richard A. Samp, Washington Legal Foundation •James W. Hawkins, III, Bergner Bockorny, Inc. •Alan R. Bennett, Ropes & Gray

# **B.** Web Seminars

WLF inaugurated its *Web Seminar Series* in 2005. Web Seminars present viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF's website. The speakers for the programs, who provide their insights on a *pro bono* basis, are leading experts in the field of law to be discussed. Recent web seminars on health-related issues have included the following:



Incentivizing Whistleblower Litigation: Ramifications for Health Care Contractors as False Claims Laws Spread in the States, April 27, 2006

•John T. Boese, Fried Frank Harris Shriver & Jacobson LLP •Beth C. McClain, Fried Frank Harris Shriver & Jacobson LLP

Abigail Alliance v. Crawford: Litigating Access Rights to Lifesaving Medicine, October 24, 2005

•J. Scott Ballenger, Latham & Watkins LLP •David Price, Washington Legal Foundation

Reuse of Medical Devices: Issues in Federal Policy, October 18, 2005 •James D. Miller, King & Spalding LLP •Pamela J. Furman, Olsson, Frank and Weeda, P.C.

# C. Advocacy Ads

In 1998, WLF began running a series of opinion editorials on the op-ed page of the national edition of *The New York Times* called "In All Fairness." The op-ed has appeared over 100 times, reaching over five million readers in 70 major markets and 90 percent of major newspaper editors. Healthcare policy and FDA regulation has been the focus of a number of "In All Fairness" columns:

•Bureaucrats Practicing Medicine, April 24, 2004 (Government efforts to limit and regulate health care causes substandard medical care for patients and can even be life-threatening.)

•*Why We're Suing HHS*, October 14, 2003 (Two agencies within HHS are keeping gravelly ill Americans from getting lifesaving medicines, and unfortunately litigation is required to fight for their rights.)

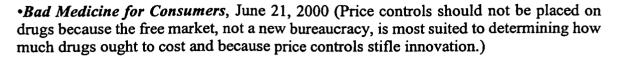
•*Who's Tampering with Your Medicines?*, June 30, 2003 (Development of new medicines is harmed by trial lawyers who file novel lawsuits against drug companies and by government preferences of generic and over-the-counter drugs.)

•A New FDA?, December 16, 2002 (FDA should expedite its drug approval procedures to improve public health and stop micromanaging drug advertising.)

•Bring Accountability to FDA, August 6, 2001 (Excessive FDA enforcement and misguided regulatory policies harm the health of Americans.)

•*Phony Food Safety Scares*, November 20, 2000 (Professional activists whip up public hysteria with phony allegations aimed at genetically modified food, pesticides, and food irradiation, when in fact these technological tools hold the potential for cheaper, safer, more abundant food.)





•The World According to FDA, September 27, 1999 (FDA's policy to regulate the dissemination of publications describing off-label use of FDA-approved drugs harms the health of Americans and violates the First Amendment.)

•*Pound-Foolish Public Policy*, June 21, 1999 (Price controls on products such as prescription drugs are counterproductive and undermine the free market system.)

These and other "In All Fairness" columns can be accessed from WLF's comprehensive website, <u>www.wlf.org</u>.

In addition to its high-profile "In All Fairness" series, WLF also creates and places advocacy ads in national newspapers and periodicals to focus the public's attention on important legal issues.

When 1994 studies showed that FDA's delays had led to a record backlog of products awaiting approval, WLF sought to publicize those delays by launching a major public relations campaign that featured six different advertisements in the national editions of the *Wall Street Journal, USA Today, Washington Post, The New York Times*, and *National Journal*. The advertisements were widely praised for their effectiveness, each winning a prestigious Addy Award in 1995. WLF's work was widely credited with forcing FDA to streamline its product approval process and also brought the issue to the attention of major decision makers in government. Congress subsequently adopted major reform legislation in 1997.

# **D.** Public Appearances

WLF attorneys have appeared as featured panelists and speakers on health care issues before such groups as the Food and Drug Administration, the Federal Trade Commission, the Food and Drug Law Institute, the American Medical Association, the North American Spine Society, the Regulatory Affairs Professional Society, the Federalist Society, the Heritage Foundation, the American Bar Association, the Pharmaceutical Research and Manufacturers of America, and Medical Alley. What follows are highlights of the numerous public appearances that WLF attorneys have made in the past 12 years, to address health-related issues:

June 6, 2006, WLF Chief Counsel Richard Samp was a featured speaker on a teleconference sponsored by Mealey's, regarding FDA's recently announced policy regarding federal preemption of state-law failure-to-warn tort suits against pharmaceutical manufacturers and health practitioners.

March 30, 2006, Samp was a featured panelist at the Medical Device Regulatory and Compliance Congress, held at Harvard University; Samp discussed manufacturers' First Amendment rights to speak truthfully about FDA-approved medical products.



December 14, 2005, Samp was the keynote speaker at a breakfast symposium in Minneapolis sponsored by Medical Alley and MNBIO. Samp's speech focused on recent federal government enforcement actions under the False Claims Act and the anti-kickback statute.

December 6, 2005, Samp was a featured panelist at the Food and Drug Law Institute's Fourth Annual Enforcement and Litigation Conference in Washington, D.C. Samp spoke on the federal government's efforts to obtain restitution/disgorgement as a remedy for violations of the Federal Food, Drug, and Cosmetic Act.

November 2, 2005, Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer advertising.

May 11, 2005, Samp was a featured speaker at a seminar in New York City sponsored by Harvard Business School Publishing. Samp spoke on the corporate community's First Amendment rights to speak out on issues of public importance, particularly on health care issues.

January 27, 2005, Samp was a featured speaker at a conference organized by the Food & Drug Law Institute in Washington, D.C. entitled, "Product Liability for FDA Regulated Products: In What Kind of World Are We Living?" Samp addressed potential pitfalls to manufacturers created by the federal False Claims Act.

June 10, 2004, WLF Senior Vice President David Price was a panelist at a forum sponsored by the Cato Institute, together with volunteers from WLF's client, the Abigail Alliance for Better Access to Developmental Drugs. Price discussed WLF's lawsuit on behalf of itself and the Abigail Alliance against the FDA seeking earlier availability of investigational drugs for the terminally ill.

January 23, 2004, Samp was a featured speaker at the annual meeting in Atlanta of NAAMECC (a trade group for companies that produce continuing medical education symposia), warning against government restrictions on the First Amendment right to speak truthfully regarding medical issues.

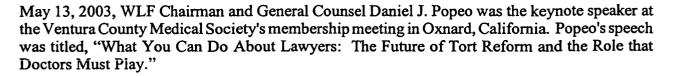
November 20, 2003, Samp addressed the American Bar Association's annual pharmaceutical conference in Philadelphia, arguing that expanded use of the False Claims Act as a vehicle for suing drug companies is jeopardizing free speech rights and the ability of drug company's to continue to develop new, life-saving therapies.

November 8, 2003, Samp addressed the annual meeting of the Society for Academic Continuing Medical Education in Washington, arguing that proposed restrictions on who may speak at Continuing Medical Education events are far too restrictive.

September 25, 2003, Samp spoke in Washington, DC at a symposium organized by Pharmaceutical Education Associates, on the right to enforce drug patents that cover off-label uses of FDA-approved drugs.

September 9, 2003, Samp addressed the American Medical Association's National Task Force on Continuing Medical Education (CME) in Chicago; Samp argued that proposed restrictions on who can speak at CME gatherings violate First Amendment norms.





April 23 and again June 26, 2003, Samp appeared on CNBC to discuss *Nike v. Kasky*, the Supreme Court case that addressed the First Amendment right of corporations to freely discuss matters of public interest.

October 25, 2002, Samp was a featured panelist at a symposium organized by the Federalist Society, entitled, "FDA and the First Amendment."

October 7, 2002, Samp was a panelist at the annual conference of the Regulatory Affairs Professional Society in Washington, D.C., speaking on "The First Amendment and FDA Regulation."

September 11, 2002, Samp spoke at the Food and Drug Law Institute's ("FDLI") annual conference in Washington, regarding First Amendment constraints on FDA regulation of speech by pharmaceutical companies.

September 10, 2002, Samp testified before the Federal Trade Commission in connection with the FTC's hearings on "Health Care and Competition."

September 10, 2002, Samp spoke at the annual conference of the National Task Force on CME Provider/Industry Collaboration in Baltimore, on the topic of whether CME (Continuing Medical Education) should be subject to FDA regulation.

August 1, 2002, Samp was a featured panelist in an audio conference sponsored by FDLI on "First Amendment Issues Facing the Food and Drug Administration."

May 22, 2002, Popeo was the featured speaker at the Annual Meeting of the Medical Device Manufacturers Association (MDMA). At the MDMA Chairman's Luncheon, Popeo discussed the crucial work of WLF in promoting open markets, free enterprise, and competition, and WLF's legal activities challenging excessive regulation by FDA.

October 10, 2001, Samp appeared on a program sponsored by Maine Public Radio regarding the propriety of States' efforts to impose price controls on prescription drugs.

May 18, 2001, Samp spoke at a luncheon of the Philadelphia chapter of the Federalist Society, regarding FDA regulation of manufacturer speech.

April 20, 2000, Samp was a featured panelist at a New York City symposium sponsored by the Federalist Society, entitled, "The Future of Commercial Speech."

April 6, 2000, Samp addressed a symposium in Washington, D.C. sponsored by the Drug Information Association, regarding "Promoting, Prescribing, and Paying for Off-Label Indications."



September 28, 1999, Samp was interviewed on ABC Radio regarding *Pegram v. Herdich*, a Supreme Court case in which a patient sought to sue her HMO under ERISA (the federal pension law) because the HMO took steps to reduce medical treatment costs.

September 13, 1999, Samp was a panelist at the FDLI's annual conference, discussing First Amendment restrictions on FDA regulation.

August 25, 1999, Samp was the keynote speaker at the annual meeting of the Indiana Medical Device Manufacturers Association in Indianapolis, where he discussed WLF's successful challenge to FDA speech restrictions.

June 29, 1999, Samp addressed an FDLI conference regarding manufacturer dissemination of peer-reviewed journal articles that discuss off-label uses of FDA-approved products.

May 20, 1999, Samp addressed an FDLI conference regarding WLF's First Amendment victory over the FDA in *WLF v. Henney*.

January 28, 1999, Samp addressed the Food, Drug, and Cosmetics law section of the New York Bar Association on WLF's victory in *WLF v. Henney*.

January 13, 1999, WLF Legal Studies Division Chief Glenn Lammi provided educational commentary on the *WLF v. Henney* case to a group of pharmaceutical marketers at a Center for Business Intelligence seminar.

September 10, 1998, Samp addressed a FDLI symposium, to discuss WLF's court victories over FDA on First Amendment issues.

August 19, 1997, WLF Executive Legal Director Paul Kamenar was featured on FOX 24 Hour News discussing the tort reform implications of a large silicone breast implant verdict by a Louisiana jury against Dow Chemical Company.

June 13, 1997, Kamenar was a featured speaker at the 6th Annual Conference on Biologics and Pharmaceuticals sponsored by International Business Communications, discussing WLF's First Amendment lawsuit against FDA.

April 9, 1997, Samp addressed a conference sponsored by the Drug Information Association in New Orleans, regarding efforts by FDA to suppress speech regarding off-label uses of approved drugs and medical devices.

November 25, 1996, Samp appeared on National Public Radio to discuss the resignation of FDA Commissioner David Kessler.

August 6, 1996, Samp spoke at the American Bar Association's annual convention in Orlando, Florida on the topic, "Is the FDA Really Reforming Itself?"



March 20, 1996, Popeo was a keynote speaker at a conference of the Healthcare Marketing & Communications Council in New York City discussing reform of FDA, WLF's litigation against FDA, and other related programs promoting commercial free speech.

December 7, 1995, Samp spoke to a group of pharmaceutical executives at a Rockville, Maryland forum sponsored by International Business Conferences, regarding WLF's continuing efforts to prevent FDA abuse of First Amendment rights.

December 7, 1995, Samp was a featured speaker (along with Rep. Joe Barton) at a forum sponsored by the Heritage Foundation entitled, "Is the FDA Killing America?"

November 16, 1995, Samp spoke in Philadelphia at a legal forum sponsored by Mealey's Publications regarding federal preemption of state tort claims against medical device manufacturers.

October 20, 1995, Samp addressed (along with U.S. Senator Bill Frist of Tennessee) a gathering of orthopedic surgeons at a symposium of the North American Spine Society on the need to streamline FDA.

October 18, 1995, Samp testified before an FDA panel, urging FDA to lift restrictions on direct-toconsumer advertising of prescription drugs.

September 20, 1995, Lammi spoke at a meeting of the Ad Hoc In-House Counsels Working Group, a group of attorneys for pharmaceutical companies, on FDA's restrictions on advertising and promotion.

September 19, 1995, Popeo served on the faculty at the American Medical Association's Sixth National Conference on Continuing Medical Education. Popeo discussed WLF's lawsuit against FDA regarding the suppression of medical literature discussing off-label uses of FDA-approved drugs and devices.

June 27, 1995, Kamenar was a featured speaker at an FDLI conference in Washington, D.C. He discussed WLF's FDA-reform project and its lawsuit against FDA for prohibiting the dissemination of information about off-label uses of approved drugs and devices.

June 16, 1995, Lammi appeared on National Empowerment Television to discuss FDA reform.

May 22, 1995, Kamenar debated U.S. Representative Don Wyden (D-Ore.) and Bruce Silverglade of the Center for Science in the Public Interest on "America's Talking" cable television network, regarding FDA reform.

March 13, 1995, Samp addressed the annual meeting of the Pharmaceutical Research and Manufacturers of America (PhRMA) on the need for reform of FDA.

January 31, 1995, Samp was a featured guest on the Diane Rehm Show (syndicated by WAMU-Radio in Washington, D.C.), debating the need for reform of FDA with Dr. Sidney Wolfe of the Public Citizen Health Research Group.



# **III. PUBLICATIONS**

WLF's Legal Studies Division is the preeminent publisher of persuasive, expertly researched, and highly respected legal papers. They do more than inform the legal community and the public about issues vital to the fundamental rights of every American - they are the very substance that tips the scales in favor of those rights. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDERS covering current developments affecting the American legal system, to comprehensive MONOGRAPHS providing law-review-length inquiries into significant legal issues.

A large percentage of WLF publications have focused on health-related topics. WLF's recent health-related publications include the following:

#### New False Claims Law Incentives Pose Risks To Contractors And States

By John T. Boese and Beth C. McClain, a partner and a special counsel, respectively, to the law firm Fried, Frank, Harris, Shriver & Jacobson LLP in its Washington, D.C. office. WORKING PAPER, June 2006, 16 pages

#### **Multiple Sclerosis Patients v. FDA Overcaution**

By Lauren Roberts, a multiple sclerosis patient living in California. LEGAL OPINION LETTER, May 19, 2006, 2 pages

#### Health And Speech Rights At Risk from Attacks On Medical Education

By Jeffrey N. Gibbs, a principal with the law firm Hyman, Phelps & McNamara, P.C. in its Washington, D.C. office. LEGAL BACKGROUNDER, April 7, 2006, 4 pages

Advertising And Preemption Under FDA's New Drug Labeling Rule By Tish E. Pahl, a principal with Olsson, Frank and Weeda, P.C. LEGAL OPINION LETTER, March 24, 2006, 2 pages

Quietly Expanding Qui Tam: Federal Law Encourages New State False Claims Acts By John T. Boese, a partner in the Washington, D.C. office of the law firm Fried, Frank, Harris, Shriver & Jacobson LLP. LEGAL OPINION LETTER, March 10, 2006, 2 pages

#### European Commission Paper On "Healthy Diets" Has Implications For Food Industry

By Sarah A. Key, an associate in the Washington D.C. office of Foley & Lardner LLP. She is a member of the Regulatory Department, its General Regulatory Practice Group, and the Food Industry and International Business Teams. COUNSEL'S ADVISORY, March 10, 2006, 1 page

#### Don't Dilute Drug Approval Process With Non-Scientific Criteria

By Gilbert L. Ross, M.D., the Executive Director and Medical Director of the American Council on Science and Health (ACSH), a consumer education-public health organization; and Elizabeth M. Whelan, MPH, ScD, President and founder of the American Council on Science and Health. LEGAL OPINION LETTER, March 10, 2006, 2 pages





By Ralph F. Hall, Visiting Associate Professor of Law at the University of Minnesota Law School and Counsel to the law firm Baker & Daniels, Indianapolis, Indiana, and Washington D.C. LEGAL BACKGROUNDER, December 2, 2005, 4 pages

#### **Streamlining Appeals At FDA: A Modest Proposal**

By Donald E. Segal, a partner in the Food, Drug and Device Group of the law firm Alston & Bird LLP, and Sharon D. Brooks, an associate in the firm's Washington, D.C. office. LEGAL BACKGROUNDER, November 4, 2005, 4 pages

#### **Courts Scrutinize FDA "Disgorgement" Demands**

By Christine P. Bump, an associate with the law firm Hyman, Phelps & McNamara, P.C. LEGAL BACKGROUNDER, November 4, 2005, 4 pages

#### **DOJ Prosecution Guidance Impacts Health Care Businesses**

By Karen Owen Dunlop, a partner in the Chicago office of the law firm Sidley Austin Brown & Wood LLP. LEGAL OPINION LETTER, August 26, 2005, 2 pages

#### FDA's Unauthorized User Fee Money Grab

By Robert A. Dormer, a director, and Kurt R. Karst, an associate, at the Washington, D.C. law firm Hyman, Phelps & McNamara, P.C. LEGAL BACKGROUNDER, August 12, 2005, 4 pages

Impact On Patient Care Must Be Factor When Assessing "Gainsharing" Arrangements By Bradley Merrill Thompson, a partner in the law firm of Baker & Daniels in its Indianapolis office.

LEGAL BACKGROUNDER, July 15, 2005, 4 pages

Conditioning FDA Approval On Agreement Not To Advertise Violates Law And Constitution By Christopher A. Brown, an associate in the Food and Drug practice group of the law firm Sonnenschein Nath & Rosenthal LLP in its Washington, D.C. office, and Teisha C. Johnson, who was a summer associate with the law firm of Sonnenschein Nath & Rosenthal LLP in its Washington, D.C. office during the summer of 2005. LEGAL BACKGROUNDER, July 15, 2005, 4 pages

"Gainsharing" Arrangements Present Challenging Issues For Policymakers & Participants By Sanford V. Teplitzky, a Principal and Chairman of the Health Law Department of the law firm Ober, Kaler, Grimes & Shriver in its Baltimore office; and William T. Mathias, a Principal in the Health Law Department of Ober, Kaler, Grimes & Shriver. LEGAL BACKGROUNDER, July 1, 2005, 4 pages

**Proposal Limiting Distribution Of Health Care Information Infringes Free Speech Rights** By Glenn G. Lammi, Chief Counsel to Washington Legal Foundation's Legal Studies Division. LEGAL OPINION LETTER, June 17, 2005, 2 pages



Measured, Uniform Approach Needed To Battle "Meth" Makers' Abuse Of OTC Medicines By John A. Gilbert, Jr., a partner with the law firm Hyman, Phelps & McNamara, P.C. He was previously an attorney in the Drug Enforcement Administration's Office of Chief Counsel, Diversion/Regulatory Section.

LEGAL BACKGROUNDER, June 3, 2005, 4 pages

#### Linking Medicare Coverage to Research Participation: Reasonable and Necessary?

By Grant P. Bagley, M.D., J.D., a partner in Arnold & Porter LLP's Washington, D.C., office, where his practice focuses on the representation of drug and device manufacturers for regulatory and reimbursement matters before public and private agencies; and Rosemary Maxwell, Counsel to the law firm Arnold & Porter LLP in its Washington, D.C. office. Ms. Maxwell focuses on healthcare compliance and public policy issues. WORKING PAPER, May 2005, 23 pages

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# Petition Seeks Transfer Of Oversight For Drug Promotion Investigations

By **Richard Samp**, Chief Counsel of the Washington Legal Foundation. COUNSEL'S ADVISORY, May 6, 2005, 1 page

#### State Drug Ad "Rebate" Proposal Treads On Commercial Speech Rights

By Rosemary C. Harold, a partner, and Mark A. McAndrew, an associate in the Washington, D.C. law firm Wiley, Rein & Fielding LLP. LEGAL OPINION LETTER, March 25, 2005, 2 pages

#### DEA's Review Of Drug Approvals Could Limit Access To Vital Medicines

By James R. Phelps, a founding partner of the law firm Hyman, Phelps & McNamara, P.C. and John A. Gilbert, Jr., also a partner with the firm. LEGAL BACKGROUNDER, March 11, 2005, 4 pages

#### **Making FDA Work For Patients**

By Steven Walker, Regulatory Advisor to the Abigail Alliance for Better Access to Developmental Drugs, an Arlington, Virginia-based patient group dedicated to helping cancer patients and others with life-threatening and serious diseases. LEGAL BACKGROUNDER, February 25, 2005, 4 pages

#### Conversations With: Prescription Drug Abuse

Features The Honorable Dick Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP leading a discussion with The Honorable Rudolph W. Giuliani, Chairman and Chief Executive Officer, Giuliani Partners LLC. CONVERSATIONS WITH, Winter 2005, 6 pages

#### What Businesses Need To Know About FDA's Plan To Combat Obesity

By Sarah A. Key, an attorney in the Washington, D.C. office of the law firm Morgan Lewis LLP. LEGAL OPINION LETTER, January 28, 2005, 2 pages

#### FDA Must Reform Its Arbitrary Drug Name Review Process

By Jeffrey N. Gibbs, a director at the Washington, D.C. law firm Hyman, Phelps & McNamara. LEGAL BACKGROUNDER, January 28, 2005, 4 pages





By Kevin E. Grady, an antitrust partner in the Atlanta office of the law firm Alston & Bird LLP; Marc J. Scheineson, a food and drug partner in the firm's Washington, D.C. office and a former FDA Associate Commissioner; and Stewart F. Alford IV, an associate in the trial practice and antitrust groups of the firm's Atlanta office.

LEGAL BACKGROUNDER, December 3, 2004, 4 pages

#### CMS Advises On Reimbursement For Off-Label Use Of Drugs

By David Price, Senior Vice President for Legal Affairs of the Washington Legal Foundation. COUNSEL'S ADVISORY, October 15, 2004, 1 page

#### State Fraud Suits Over Drug Clinical Trial Results Tread On Free Speech Rights

By Mark E. Nagle, a partner in the Washington, D.C. office of the law firm Sheppard, Mullin, Richter & Hampton LLP, who, immediately prior to joining the firm, served as Chief of the Civil Division in the United States Attorney's office for the District of Columbia. LEGAL BACKGROUNDER, September 17, 2004, 4 pages

#### Medicare Drug Reimbursement Reform Presents Challenges And Opportunities

By Glenn G. Lammi, Chief Counsel of the Washington Legal Foundation's Legal Studies Division.

LEGAL OPINION LETTER, August 20, 2004, 2 pages

#### Senate Proposal On Drug Importation Treads On Constitutional Rights

By **Burt Neuborne**, John Norton Pomeroy Professor of Law at New York University Law School, where he has taught Constitutional Law, Federal Courts, Civil Procedure and Evidence for more than thirty years.

LEGAL BACKGROUNDER, July 9, 2004, 4 pages

#### NIH Invites Public Comment On Petition Seeking Drug Price Controls

By **David Price**, Senior Vice President for Legal Affairs of the Washington Legal Foundation. COUNSEL'S ADVISORY, June 25, 2004, 1 page

#### Drug Importation: A Prescription To Put Biotech On Life Support

By David M. McIntosh, a former Congressman from Indiana, and currently a partner in the Washington office of the Washington law firm Mayer, Brown, Rowe & Maw LLP. LEGAL BACKGROUNDER, June 11, 2004, 4 pages

**Debate Over "Generic Biologics" Poses Unique Challenges For Policy Makers** By Alvin J. Lorman, a partner in the Washington, D.C. office of the global law firm of Mayer, Brown, Rowe & Maw LLP. LEGAL BACKGROUNDER, May 14, 2004, 4 pages

#### Unique California Laws Imperil Speech On "Off-Label" Use Of Drugs

By Lisa M. Baird and Michael K. Brown, partners in the international law firm of Reed Smith LLP who specialize in litigation involving the pharmaceutical and medical device industries. LEGAL BACKGROUNDER, May 14, 2004, 4 pages





#### Altering Patent Suit Proof Burden Would Chill Innovation

By Michael J. Shuster, co-chair of the law firm Fenwick & West's Bioscience Industries Group, Dan Flam, an intern with the firm, and Sasha Blaug, an analyst with the firm. LEGAL BACKGROUNDER, April 16, 2004, 4 pages

### Better Late Than Sorry: Medicare Reform Ushers In New Rules On Generic Drugs

By Alan R. Bennett, a partner with the law firm of Ropes & Gray LLP in the firm's Washington, D.C. office and X. Joanna Wu, Ph.D., an associate with the law firm in the Boston office. LEGAL BACKGROUNDER, March 19, 2004, 4 pages

#### Appeals Court Opens Door To Suits On Medicare Agency Decisions

By **David Price**, Senior Vice President, Legal Affairs, of the Washington Legal Foundation. COUNSEL'S ADVISORY, March 5, 2004, 1 page

#### **Does Reprocessing Of Medical Devices Tread On Trademark Rights?** By **James Dabney Miller**, a partner with the law firm King & Spalding LLP. LEGAL BACKGROUNDER, March 5, 2004, 4 pages

## FDA Guidance for "DTC" Ads Strives To Advance Consumer Understanding By Rosemary C. Harold, a partner with the Washington, D.C. law firm Wiley Rein & Fielding LLP, and John F. Kamp, of counsel to the firm.

LEGAL OPINION LETTER, February 20, 2004, 2 pages

#### Patent Harmonization Through The UN: International Progress Or Deadlock? By The Honorable Gerald J. Mossinghoff, Senior Counsel, Oblon, Spivak, McClellan, Maier & Neustadt; Cifelli Professorial Lecturer, The George Washington University Law School; and former Assistant Secretary of Commerce and Commissioner of Patents and Trademarks. LEGAL BACKGROUNDER, December 19, 2003, 4 pages

Avoiding Collisions At The Intersection Of Antitrust And Intellectual Property Laws By Scott P. Perlman and Lily Fu Swenson, partners in the Washington, D.C. office of the law firm Mayer, Brown, Rowe & Maw LLP. CONTEMPORARY LEGAL NOTE, December 2003, 38 pages

#### European Court Issues Encouraging Ruling On Intellectual Property

By Howard Fogt, a partner in the Washington, D.C. office of the law firm Foley & Lardner and Sophie Lignier, of counsel in the firm's Brussels office. LEGAL OPINION LETTER, October 31, 2003, 2 pages

#### Accurate Drug Price Reporting: A Modest Proposal

By Grant Bagley, John Bentivoglio, and Rosemary Maxwell, members of the healthcare and pharmaceutical regulatory practice in the Washington, D.C. office of the law firm Arnold & Porter.

LEGAL BACKGROUNDER, October 17, 2003, 4 pages

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By Marc J. Scheineson, a partner in the law firm of Reed Smith, LLP and Robert J. Kaufman, a third year law student at Harvard Law School. LEGAL BACKGROUNDER, October 17, 2003, 4 pages

#### FDA Should Propose Rule On Federal Preemption Of Failure To Warn Lawsuits

By James Dabney Miller, a partner with the law firm King & Spalding LLP in its Washington, D.C. office.

LEGAL BACKGROUNDER, September 19, 2003, 4 pages

#### **Research Grants And Fraud Laws: The Need To Separate Sales And Science** By David Hoffmeister, a partner with the law firm Wilson Sonsini Goodrich & Rosati.

LEGAL BACKGROUNDER, July 18, 2003, 4 pages

#### **Compliance Planning For "Voluntary" Guidelines On Drug Marketing Practices**

By Susan B. Geiger, a partner at the law firm Preston Gates Ellis & Rouvelas Meeds LLP in its Washington, D.C. office, Brian K. McCalmon, an associate at Preston Gates Ellis & Rouvelas Meeds LLP, and Francie Makris, Esq., Washington D.C. CONTEMPORARY LEGAL NOTE, July, 2003, 23 pages

#### FDA Lacks Authority To Force Over-The-Counter Drug Switch

By Andrew S. Krulwich, a partner in the Washington, D.C. law firm Wiley Rein & Fielding LLP. LEGAL BACKGROUNDER, June 27, 2003, 4 pages

States' Use Of Lawsuits To Regulate Drug Pricing Threatens Patients' Health By James M. Spears and Terry S. Coleman, partners in the Washington office of Ropes & Gray. LEGAL BACKGROUNDER, June 27, 2003, 4 pages

The High Cost Of Low Cost Drugs: Why The "Canadian Model" Is No Panacea For Pricing By Monte Solberg, the Canadian Alliance Member of Parliament for Medicine Hat Alberta currently serves as Vice Chair of the House of Commons Standing Committee on Human Resources Development.

LEGAL OPINION LETTER, June 6, 2003, 2 pages

#### FDA "Trans Fat" Labeling Proposal Treads On Commercial Free Speech

By Christopher A. Brown, an associate with the law firm of Sonnenschein Nath & Rosenthal in its Washington, D.C. office.

LEGAL OPINION LETTER, June 6, 2003, 2 pages

New CME Bias Standards Will Reduce Quality Of Medical Education By Alan R. Bennett and Dr. Gregory J. Glover, partners with the law firm Ropes & Gray in its Washington, D.C. office. LEGAL OPINION LETTER, June 6, 2003, 2 pages



HHS Expanded Use Of Fraud Law's "Corporate Death Sentence" Is Legally Suspect By Ronald H. Clark, a Member of Arent Fox Kintner Plotkin & Kahn, PLLC in its Washington, D.C. office; Gabriel L. Imperato, the Managing Partner of Broad and Cassel's Fort Lauderdale office and head of the firm's White Collar/Health Care Criminal and Civil Fraud Practice; and Robert Salcido, a partner at Akin Gump Strauss Hauer & Feld, L.L.P., in its Washington, D.C. office.

LEGAL BACKGROUNDER, June 6, 2003, 4 pages

#### **Commercial Speech And The Limits Of Federal Anti-Kickback Laws**

By **Rosemary Maxwell**, a member of the health care and pharmaceutical regulatory practice in the Washington, D.C. office of the law firm Arnold & Porter. WORKING PAPER, May 2003, 27 pages

#### FDA Limits On Dual Trademarks Tread On Patient Safety And Law

By Marc J. Scheineson, a partner in the law firm of Reed Smith, LLP in Washington, D.C. where he heads the firm's food and drug practice. LEGAL BACKGROUNDER, April 25, 2003, 4 pages

#### Michigan High Court Upholds Drug Product Liability Reform

By Thomas J. Foley, a founder of the Detroit area law firm of Foley, Baron & Metzger, PLLC. COUNSEL'S ADVISORY, April 25, 2003, 1 page

#### FDA Must Clarify Drug Makers' Ability To Publicly Defend Products

By Kathleen M. Sanzo and Stephen Paul Mahinka, partners in the Washington, D.C. office of the law firm of Morgan Lewis, LLP. LEGAL OPINION LETTER, February 28, 2003, 2 pages

#### Dramatic Changes To CME Accreditation Process Compel Scrutiny And Comment

By **Richard Samp**, Chief Counsel of the Washington Legal Foundation. COUNSEL'S ADVISORY, February 14, 2003, 1 page

#### Pharmacist's Crime Shouldn't Expose Businesses To Liability

By **Thomas P. Redick**, a partner in the St. Louis law firm Gallop, Johnson & Neuman, L.C. LEGAL OPINION LETTER, January 31, 2003, 2 pages

#### Mixed Results For Free Speech In FDA Health Claims Guidance

By George W. Evans, Associate General Counsel to Pfizer, Inc., and Arnold I. Friede, Senior Corporate Counsel to Pfizer. LEGAL OPINION LETTER, January 17, 2003, 2 pages

#### Vaccine Liability Law Clarification Protects Lives And Resources

By Victor E. Schwartz, chairman of the Public Policy Group at the law firm Shook, Hardy & Bacon L.L.P., and Leah Lorber, of counsel to the firm. LEGAL BACKGROUNDER, January 10, 2003, 4 pages





Biting The Hand That Feeds?: Generic Drugs And Abuse Of The Hatch-Waxman Law By Robert D. Bajefsky, a partner of the intellectual property law firm of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., in Washington, D.C., and Gregory Chopskie, an associate in the firm's Bio/Pharmaceutical Practice Group. LEGAL BACKGROUNDER, December 6, 2002, 4 pages

#### Federal Court Ruling Impacts FDA Suppression Of Medical Speech

By George W. Evans, an Associate General Counsel, Pfizer Inc., and General Counsel–Pfizer Pharmaceuticals Group, and Arnold I. Friede, a Senior Corporate Counsel at Pfizer Inc., who formerly served in the FDA Chief Counsel's Office. LEGAL OPINION LETTER, November 15, 2002, 2 pages

#### FDA Limits On Print Drug Ads Violate First Amendment

By Richard L. Frank, a principal at the Washington, D.C. law firm Olsson, Frank and Weeda, P.C., and Tish Eggelston Pahl, a senior associate at Olsson, Frank and Weeda, P.C. LEGAL BACKGROUNDER, October 4, 2002, 4 pages

#### FTC Administrative Judge Rejects Commission's View Of Drug Patent Settlements

By Geraldine M. Alexis and Zorah Braithwaite, a partner and an associate, respectively, with the law firm Bingham McCutchen LLP in its San Francisco office. LEGAL BACKGROUNDER, October 4, 2002, 4 pages

#### In The Eye Of The Storm: Tips For Managing An FDA Recall

By David M. Hoffmeister, a partner with the law firm Wilson Sonsini Goodrich & Rosati, and Wayne L. Pines, President of Regulatory Services and Healthcare at APCO Worldwide. LEGAL BACKGROUNDER, September 6, 2002, 4 pages

#### FTC, Not FDA, Should Regulate Online Food Information

By Lawrence S. Ganslaw, an associate, and Kathleen M. Sanzo, a partner, in the Washington, D.C. office of the law firm Morgan, Lewis & Bockius LLP. LEGAL BACKGROUNDER, September 6, 2002, 4 pages

#### An FDA Q&A: How Does The First Amendment Limit Its Regulatory Power

By Alan R. Bennett, a partner in the Washington, D.C. office of the law firm Ropes & Gray, and Kenneth P. Berkowitz, President of KPB Associates, a Washington, D.C. consulting firm specializing in the regulation of medical communications. LEGAL BACKGROUNDER, August 23, 2002, 4 pages

#### Proposed Limits On Prescription Drug Ads: A Constitutional Analysis

By Bert W. Rein and Rosemary C. Harold, partners at the Washington, D.C. firm Wiley, Rein & Fielding, and John F. Kamp, of counsel to the firm. WORKING PAPER, July 2002, 40 pages

#### Drug Ads Enhance Health By Empowering Patients

By Richard L. Manning, PhD, Director of Economic Policy Analysis at Pfizer Inc. LEGAL OPINION LETTER, May 10, 2002, 2 pages



#### Recent Patent Ruling Intrudes On Key Antitrust Immunity Doctrine

By Christopher Sipes and James R. Atwood, partners in the Washington, D.C. office of the law firm Covington & Burling.

LEGAL BACKGROUNDER, April 26, 2002, 4 pages

#### New FDA Policy On Warning Letters A Sensible Move Towards Due Process

By Larry R. Pilot, a partner in the Washington, D.C. office of the law firm McKenna Long & Aldridge.

LEGAL OPINION LETTER, January 25, 2002, 2 pages

#### Forcing Drugs To "OTC" Status Treads On Law And Patient Safety

By Richard F. Kingham, a partner with the Washington, D.C. law firm Covington & Burling practicing for nearly thirty years in the areas of food and drug law and regulation. LEGAL BACKGROUNDER, November 2, 2001, 4 pages

#### New Commissioner Must Adapt FDA To A New Security Role

By Alan Slobodin, Senior Oversight Counsel at the House Energy and Commerce Committee. LEGAL BACKGROUNDER, October 19, 2001, 4 pages

#### **Priorities For A New FDA Commissioner**

By John W. Bode, a partner with the Washington, D.C. law firm Olsson, Frank and Weeda, P.C. and a former Assistant Secretary of Agriculture. LEGAL BACKGROUNDER, October 5, 2001, 4 pages

#### Innovative Reforms Could Reduce Time And Cost Of Drug Approvals

By Henry I. Miller, a fellow at the Hoover Institution and the Competitive Enterprise Institute. LEGAL OPINION LETTER, June 15, 2001, 2 pages

#### **Excessive FDA Scrutiny Of DTC Ads Undermines Speech Rights**

By Sandra J. P. Dennis, a partner, and Lawrence S. Ganslaw, an associate, in the Washington D.C. office of Morgan Lewis LLP in the FDA/Product Regulation Practice Group. LEGAL BACKGROUNDER, May 18, 2001, 4 pages

Activists Use Mad Cow Scare To Advance Ideological Agendas

By **David Martosko**, Director of Research for The Guest Choice Network. LEGAL BACKGROUNDER, May 4, 2001, 4 pages

#### Does Junk Science Influence FDA Decisions On Drug Recalls?

By Carl W. Hampe, a partner with the international law firm Baker & McKenzie. LEGAL BACKGROUNDER, February 9, 2001, 4 pages

#### Federal Court Blocks Maine Drug Price Control Law

By Richard A. Samp, Chief Counsel to the Washington Legal Foundation. COUNSEL'S ADVISORY, November 17, 2000, 1 page

#### Proposal To Deny Tax Deduction For Drug Ad Expenses Unconstitutional

By John F. Kamp, Of Counsel to the Washington, D.C. law firm Wiley, Rein & Fielding. LEGAL OPINION LETTER, October 23, 2000, 2 pages



#### FDA's Restitution "Authority" Relies Upon Flawed Court Ruling

By Jeffrey N. Gibbs, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara. LEGAL OPINION LETTER, October 6, 2000, 2 pages

#### Maine Drug Price Control Act Vulnerable To Legal Challenge

By Glenn G. Lammi, Chief Counsel to Washington Legal Foundation's Legal Studies Division. LEGAL OPINION LETTER, July 14, 2000, 2 pages

#### FDA And DTC Advertising: Changes, Challenges & Constitutional Scrutiny

By Sandra J. P. Dennis, a partner in the Washington D.C. office of Morgan Lewis LLP CONTEMPORARY LEGAL NOTE, October 1999, 28 pages

#### **Court Again Nullifies FDA Policies Restricting Health Care Information**

By George M. Burditt, a partner with the Chicago law firm Bell, Boyd & Lloyd. LEGAL OPINION LETTER, September 17, 1999, 2 pages

#### **Court Ruling Frustrates Access To Off-label Drug Information**

By Mark Boulding, General Counsel and Vice President, Regulatory Affairs for Medscape Inc. LEGAL OPINION LETTER, April 30, 1999, 2 pages

#### **Court Suppresses FDA Censorship Of Health Product Information**

By George M. Burditt, a partner with the Chicago law firm Bell, Boyd & Lloyd. LEGAL OPINION LETTER, November 4, 1998, 2 pages

#### FDA "Draft Guidance" Suppresses Critical Health Care Information

By Marc J. Scheineson, head of the food and drug practice at the law firm Reed Smith from its Washington, D.C. office, and a former FDA Associate Commissioner for Legislative Affairs, and Katherine Chen, a food and drug associate at the firm. LEGAL BACKGROUNDER, April 3, 1998, 4 pages

#### Public Comment Can Shape FDA Guidance On TV Advertising

By Mark E. Boulding, General Counsel & Vice President, Regulatory Affairs for Medscape Inc. LEGAL OPINION LETTER, September 12, 1997, 2 pages

#### Ten Questions For The Next FDA Commissioner

By **Daniel J. Popeo**, Chairman and General Counsel to the Washington Legal Foundation. LEGAL BACKGROUNDER, April 4, 1997, 4 pages

#### Federal Appeals Court Finds State Food Labeling Law Unconstitutional

By Steven J. Rosenbaum, a partner and Sarah E. Taylor, Of Counsel, in the Washington, D.C. offices of Covington & Burling.

LEGAL OPINION LETTER, December 6, 1996, 2 pages.

#### Federal Court Must Strike Down FDA Censorship Of Advertising

By **David S. Versfelt**, a partner with the New York office of the law firm Kirkpatrick & Lockhart LLP.

LEGAL BACKGROUNDER, November 1, 1996, 4 pages





#### FDA Regulation May Inhibit Positive Uses Of The Internet

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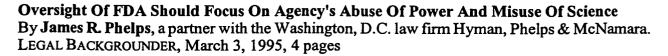
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### **ACTIVITIES REPORT**

to the

### WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

### **REFORMING THE AMERICAN LEGAL SYSTEM**

July 31, 2006

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### ACTIVITIES REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

JULY 31, 2006

### **REFORMING** THE AMERICAN LEGAL SYSTEM

The ideals upon which America was founded – individual freedom, limited government, a free-market economy, and national security – are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. Adherence to those principles is essential to maintaining America's position as the possessor of the finest and fairest legal system in the world.

Throughout its 29 years, WLF has devoted a significant portion of its resources to bringing about fundamental reforms in the American legal system. Those law-reform efforts have focused on protecting the civil liberties of the business community; seeking to rein in the excesses of the plaintiffs' bar; ensuring that environmental laws are properly balanced by protecting our natural resources without unnecessarily undermining the health of the economy; ensuring that class action lawsuits are not used as a means to extort unwarranted settlements from deep-pocketed defendants; working to prevent the award of excessive punitive damages in tort suits; and ensuring that economic development is not stifled by excessive litigation.

WLF has worked to achieve those objectives through its precedent-setting litigation, its involvement in government regulatory proceedings, its publication of timely articles on legal reform-related issues, and its tireless advocacy for free-market solutions in the news media and other public forums. This report provides an update on current WLF efforts and highlights some of the more significant WLF legal reform-related activities of the past five years.

### I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF's public interest programs. The Foundation litigates across the country before state and federal courts and administrative agencies. WLF represents only those who are otherwise unable to retain counsel on their own. Its clients have included numerous individuals and advocacy groups who have turned to WLF for assistance when their economic rights were threatened by government bureaucrats or unscrupulous plaintiffs' lawyers.



#### A. Protecting Business Civil Liberties

#### **1.** Commercial Free Speech Rights

There are any number of regulators and activists who believe they can make the world a better place by gagging companies that they dislike, or by forcing those companies to put out government-mandated messages. WLF believes freedom of speech is for everyone – as does the U.S. Supreme Court. Accordingly, WLF has been at the forefront of fighting for the right of business enterprises to engage in truthful and non-misleading speech.

Doe v. Wal-Mart Stores, Inc. On May 5, 2006, WLF filed a brief in U.S. District Court in Los Angeles, urging the Court to dismiss a lawsuit brought against Wal-Mart by activists who are critical of Wal-Mart's overseas labor practices. In response to such criticisms, Wal-Mart issued statements denying that it purchases products manufactured overseas under "sweat shop" conditions. The activists responded by filing suit against Wal-Mart under California's infamous "unfair competition" law, claiming that Wal-Mart's denials are false and constitute unfair competition. WLF's brief urged dismissal on the ground that the First Amendment fully protects Wal-Mart's right to speak out on issues of public importance, such as international labor conditions. WLF also urged dismissal of the plaintiffs' claims that overseas labor practices used by Wal-Mart's suppliers violate international human rights laws because they constitute "slavery." The court heard oral arguments in the case on July 24, 2006.

In re Tobacco Cases II. On September 14, 2005, WLF filed a brief in the California Supreme Court, urging the court to uphold the dismissal of tort claims filed against tobacco companies for having run truthful advertising that allegedly overglamorized smoking. WLF argued that such claims are barred both by the First Amendment and by federal law – regardless of the plaintiffs' claim that glamorous advertisements induce minors to buy cigarettes in violation of California law. WLF argued that cigarette advertising is already heavily regulated at the federal level (by the Federal Cigarette Labeling and Advertising Act and by oversight conducted by the Federal Trade Commission), and at the State level by State regulators (by virtue of the Master Settlement Agreement entered into between tobacco companies and State attorneys general). WLF argued that there is no reason to permit an additional level of advertising regulation, in the form of tort suits filed under State law.

Physicians Comm. for Responsible Medicine v. General Mills. On September 2, 2005, WLF filed a brief in the U.S. District Court for the Eastern District of Virginia, urging the court to dismiss a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. WLF argued that the suit threatens to undermine manufacturers' commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled as manufacturers become increasingly unwilling to comment on such issues. The suit targets a recent milk industry advertising campaign that advocates increased consumption of dairy products as a method of losing weight. The Physicians Committee for Responsible Medicine (PCRM) challenges the validity of the scientific studies that form the basis for the industry's advertising. PCRM argues that the weight-loss claim is false and violates Virginia's consumer protection and false advertising laws. Their principal request is that the

court issue an injunction against any further promotion of the weight-loss claims. WLF argued that Virginia law does not permit individuals to obtain injunctions against speech. WLF also argued that such suits raise serious First Amendment issues because of their potential to chill truthful speech on issues of public importance, such as whether increases in consumption of dairy products are good for one's health.

**R.J. Reynolds Tobacco Co. v. Shewry.** On February 21, 2006, the U.S. Supreme Court declined to review an appeals court decision that rejected a First Amendment challenge to an advertising campaign conducted by the State of California. The Court's action, made without comment, was a setback for WLF, which filed a brief urging the Court to review the appeals court ruling. WLF argued that the First Amendment prohibits a State from forcing a company to pay for advertisements that vilify the company. California imposes a special fee on the tobacco industry and then uses it to finance a \$25 million per-year ad campaign that repeatedly portrays tobacco companies as liars and "public enemies." WLF argued that the First Amendment protection against compelled financial support of speech to which one objects has been recognized repeatedly by the courts and applies just as strongly when the speaker is the government as it does when the speaker is a private party. WLF also filed briefs in the case when it was before the appeals court.

Petition Regarding Restrictions on Speech About Part D Plans. On April 4, 2006, WLF petitioned the federal Centers for Medicare and Medicaid Services (CMS) to lift restrictions on commercial speech imposed by CMS's marketing guidelines for carriers offering Medicare prescription drug benefit plans. The guidelines prohibit carriers from making truthful and non-misleading statements comparing their plans to other plans. WLF's petition asserted that the speech restrictions are beyond the scope of CMS's authorizing regulations and violate the First Amendment rights of carriers and consumers.

Johanns v. Livestock Marketing Ass'n. On May 23, 2005, the U.S. Supreme Court ruled that the federal government may force beef producers to provide financial support for advertising with which they disagree, because the government at least nominally supervises the advertising. The 6-3 decision was a setback for WLF, which filed a brief urging the Court to strike down the advertising program. WLF argued that the First Amendment protects not only the right to speak but also the right not to speak, and that forcing someone to provide financial support for private speech with which he disagrees violates his First Amendment rights. Johanns was a challenge to a Department of Agriculture program that requires all beef producers and importers to fund a generic advertising campaign administered by a committee of producers. Many producers object to the advertising campaign, particularly to advertisements indicating that beef is fungible. These producers contend that their beef is superior to other beef on the market. The Court held that so long as the speech in question originates with the government, the First Amendment does not prohibit the government from forcing small groups of people to fund the speech against their will.

Nike, Inc. v. Kasky. On June 26, 2003, the U.S. Supreme Court decided not to review a California court decision that threatens to impose severe restrictions on the right of corporations to speak freely on matters of public importance. The Court initially agreed in January to review the case. On the last day of its 2002-2003 term, the Court changed its mind and dismissed as "improvidently granted" its original order granting review. As a result, the case returned to the California courts for further proceedings. WLF filed two briefs in the case: one in November 2002 urging the Court to hear the case and a second in February 2003

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urging the Court to overturn the lower court decision. WLF argued that the California court effectively held that *all* corporate speech – even speech on matters of great public importance – is entitled to reduced levels of First Amendment protection.

Trans Union LLC v. Federal Trade Comm'n. On June 10, 2002, the U.S. Supreme Court declined to review a lower-court decision that denies full First Amendment protection to truthful speech deemed by the court not to "relate to matters of public concern." WLF argued in a brief urging review that all truthful, noncommercial speech should be entitled to full First Amendment protection. In this case, the lower court upheld an FTC order prohibiting companies from transmitting truthful, noncommercial lists of names and addresses of consumers.

Gerawan Farming, Inc. v. Kawamura. On June 3, 2004, the California Supreme Court issued a decision accepting WLF's argument that mandatory fees for state agriculture marketing programs must be given searching scrutiny to ensure they do not violate freedom of speech. WLF had filed a brief in the Court on September 9, 2002, urging the Court to strike down a California law that compels farmers to pay for advertisements that promote plums on a generic basis. WLF argued that forcing plum growers to pay for advertising with which they disagree violates the California Constitution. The dissenting farmers have invested heavily in developing distinctive, high-quality plums, while the advertisements produced by the State promote the message that all California plums are of uniformly good quality. WLF argued that free speech rights must include not only the right to speak freely but also the right not to speak. The California Supreme Court sent the case back to the lower courts for further factfinding.

People of the State of California v. R.J. Reynolds Tobacco Co. On June 9, 2004, the California Supreme Court issued an order declining to review a lower court decision that imposed significant sanctions on a company for engaging in nonmisleading commercial speech. The decision was a setback for WLF, which had filed a brief urging that review be granted. WLF argued that the First Amendment protects a company's right to engage in such advertising and that tobacco companies have never agreed to waive such rights. California sued R.J. Reynolds Tobacco Co. for allegedly "targeting" youth with its advertising, based on evidence that Reynolds places advertising in magazines (such as *Sports Illustrated*) with up to 25% youth readership. WLF argued that Reynolds may not be sanctioned for its advertising in the absence of evidence it purposely intended to target youth; mere knowledge that some youth would see its ads is not sufficient to sanction non-misleading speech, WLF argued.

Federation of Advertising Industry Representatives v. Chicago. On October 6, 2003, the U.S. Supreme Court without comment denied WLF's petition for review in this commercial speech case. WLF's July 2003 petition had urged the Court to reinstate a challenge to commercial speech restrictions imposed by the City of Chicago. WLF represents a group of advertisers that has been fighting in federal court since 1997 against a Chicago ordinance that restricts outdoor advertising. In April, a federal appeals court dismissed the case as moot simply because Chicago repealed the ordinance after it became apparent that WLF was about to win the case. In its petition asking the Supreme Court to review that decision, WLF argued that a suit is never rendered moot simply because a defendant voluntarily ceases its objectionable conduct, except in very rare cases in which it is absolutely clear that the conduct will not recur. WLF argued that to dismiss a suit as moot under these circumstances would leave a government free to re-impose its speech restrictions at any time.

Lorillard Tobacco Co. v. Reilly. On June 28, 2001, the U.S. Supreme Court overturned Massachusetts regulations that banned outdoor advertising of tobacco products while imposing virtually no restrictions on other products' advertising. The decision was a victory for WLF, which had filed a brief arguing that the regulations were unconstitutional. The Supreme Court agreed with WLF that the regulations could not be upheld, in the face of a First Amendment challenge, as a measure reasonably designed to reduce underage smoking. The Court held that states could achieve that same objective by stepping up enforcement against merchants who violate the ban on sales to minors without interfering with speech. The Court also agreed with WLF that the Massachusetts regulations are preempted by a federal statute that severely limits states' power to regulate cigarette advertising.

United States v. United Foods, Inc. On June 25, 2001, the U.S. Supreme Court handed WLF a victory by striking down a federal program forcing farmers to contribute to generic advertising with which they disagree. The Court agreed with WLF that compelled *commercial* speech deserves no less constitutional protection than other forms of compelled speech. This case arose from a constitutional challenge brought to overturn certain provisions of a federal law that requires mushroom growers to fund generic advertising. In its brief filed with the Supreme Court, WLF had urged the Court to adopt the most searching standard of judicial review – strict scrutiny – in cases where a governmentally mandated subsidy program is challenged on free speech grounds. WLF asserted that the mandatory subsidy in this case could not survive that test.

Washington Legal Foundation v. Henney. On February 11, 2000, the U.S. Court of Appeals for the District of Columbia Circuit dismissed the Food and Drug Administration's appeal from a district court decision that struck down FDA regulations that severely restricted the flow of truthful information regarding off-label uses of FDA-approved drugs and medical devices. The decision was a major victory for WLF in its long-running battle against FDA speech restrictions. The appeals court did not actually address the merits of the First Amendment issues over which the parties have fought. Rather, the court dismissed FDA's appeal - thereby leaving the district court's decision substantially intact - on the basis of concessions made by FDA at oral argument in the case. The overturned restrictions threatened severe sanctions against manufacturers who distributed medical textbooks or peer-reviewed journal articles to doctors. Despite WLF's victory, FDA maintains that it retains some authority to sanction manufacturers who distribute medical texts or journal articles. In April, WLF asked the district court to order FDA to rescind such statements. On November 30, 2000, the district court declined to issue such an order, declaring that it had no on-going jurisdiction in the case. Nonetheless, as a result of WLF's victory, FDA has not initiated enforcement actions against any of the manufacturers who have exercised their First Amendment rights to disseminate truthful information. WLF stands prepared to file a new lawsuit against FDA should it take enforcement action in violation of the decision in this case.

"DDMAC Watch." In June 2005, WLF inaugurated its "DDMAC Watch" program, designed to monitor federal regulation of prescription drug advertising. WLF has determined that the Food and Drug Administration (FDA), acting through its Division of Drug Marketing, <u>Advertising</u>, and Communications (DDMAC), has been using letters to industry to advance questionable legal theories and request remedial actions that the agency could not require under law. Under the DDMAC Watch program, when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF *immediately* sends back a letter of our own to DDMAC identifying the specific ways in which this is so. The goal of the



program is to alert the press and public to abuses occurring at DDMAC. As of July 2006, WLF had responded to 29 letters from DDMAC and related agencies; those letters were sent to Eli Lilly, Endo Pharmaceuticals, MedImmune Vaccines, Dutch Ophthalmic USA, Hoffman, LaRoche, Abbott Laboratories, Pfizer, Actelion, SuperGen, Allergan, Alcon Research, Nephrx, ISTA Pharmaceuticals, Gen Trac, Medicis Pharmaceutical, Sankyo Pharma, Duramed Pharmaceuticals, Biogen Idec, Mayne Pharma, ZLB Behring, Palatin Technologies, InterMune, VaxGen, Bioniche Pharma Group, Boehringer Ingelheim Pharmaceuticals, Sandoz, Wyeth Pharmaceuticals, PrimaPharm, and GlaxoSmithKline.

Oversight of Criminal Investigations into Improper Drug Promotion. On March 24, 2005, WLF filed a petition with the U.S. Department of Justice (DOJ), urging DOJ to remove the Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetic Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF said that OCL has simply rubber-stamped whatever criminal investigation local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal investigation. WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal investigations of promotional activities have the potential to adversely affect the nation's health care delivery system.

Word-of-Mouth Marketing. On February 2, 2006, WLF filed with the FTC a response in opposition to a petition seeking an investigation of word-of-mouth, or "buzz," marketing programs. The petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert claimed in its petition that programs inviting consumers (without compensation) to tell their peers about new products are deceptive if the consumers do not also disclose that they are participating in a marketing program. WLF argued in its response that such communications are not deceptive and that there is no basis for requiring the disclosures sought by Commercial Alert.

Union of Concerned Scientists Campaign Against Auto Emissions Ads. On September 26, 2005, the FTC announced its decision not to take action on a letter-writing campaign of the Union of Concerned Scientists (UCS), in which UCS and its supporters asked the FTC to punish a trade association for an issue advocacy ad. WLF had filed comments on May 17, 2005, arguing that issue advocacy ads are constitutionally protected. The ad in question, which the Alliance of Automobile Manufacturers placed in Capitol Hill publications such as Congress Daily, called attention to improvements in auto emissions. UCS's campaign disputed the ad's claim that today's cars are "virtually emissions free" because they emit carbon dioxide. The FTC agreed with WLF's view that the ad was protected speech.

Comments on Proposed Regulation of Television Product Placements. The Federal Trade Commission issued an opinion letter on February 10, 2005, rejecting a petition from an activist group urging greater regulation of product placement on television. The pro-regulatory petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. The FTC's ruling was a victory for WLF, which was the only public interest organization to file comments in opposition to the Commercial Alert proposal. In its comments filed on March



26, 2004, WLF pointed out that the FTC had rejected a similar petition targeting film product placement in 1992 on the basis of a lack of consumer injury, and WLF observed that Commercial Alert gave no reason to overturn that determination. WLF further argued that even if Commercial Alert could show some harm from product placements, the proposed regulations would violate freedom of speech, as defined in U.S. Supreme Court cases.

Comments on Ban of Alcohol Serving Facts. On September 26, 2005, WLF filed comments with the Alcohol and Tobacco Tax and Trade Bureau (TTB) requesting the TTB to revoke its ban on truthful alcohol labeling that discloses basic information to the consumer. WLF contended that such a ban violates sound public policy and the First Amendment commercial free speech rights of the alcohol industry. In its submission, WLF argued that proposed labels on alcoholic beverages that contain so-called "Serving Facts" (listing the serving size of the beverage, the number of servings per container, and the amount of alcohol per serving) benefit consumers, are in the public interest, are truthful and not misleading, and are constitutionally protected by the First Amendment. WLF's comments were filed as part of a larger rulemaking proceeding where TTB is soliciting public comments on a wide range of alcohol labeling and advertising issues.

Comments on Constitutionality of Proposed Tobacco Legislation. On September 24, 2003, WLF submitted to U.S. Senator Jeff Sessions its analysis of proposed legislation that would impose severe federal controls on tobacco advertising and marketing. WLF completed the analysis at Senator Sessions's request. WLF concluded that the bill violates the First Amendment because it would prohibit vast amounts of truthful advertising yet it is not narrowly tailored to achieve its stated goals - reduction of tobacco use by youth and adults. The bill would write into law 1995 FDA tobacco restrictions that were never enforced because the courts determined that FDA was not authorized to issue them. WLF noted that a 2001 Supreme Court decision that struck down Massachusetts tobacco advertising restrictions on First Amendment grounds made clear that many provisions in the 1995 FDA regulations (provisions that were incorporated into the 2003 legislation) were unconstitutional.

FDA Requests for Comments on First Amendment Issues. FDA has lost several major First Amendment lawsuits in recent years, including WLF v. Henney. FDA responded in 2002 by requesting public input on whether any current FDA policies violate the First Amendment. On September 13, 2002, WLF filed extensive comments, citing a broad array of FDA regulatory activities that violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. On October 28, 2002, WLF filed a second round of comments, responding to arguments (made by several U.S. Senators in connection with the initial round of comments) that public health concerns justify exempting FDA from First Amendment constraints applicable to other government entities. WLF criticized the contention of those Senators that consumers are likely to misuse truthful information. FDA has pledged to address these First Amendment concerns, but recent events suggest that FDA is considering further restrictions on speech rights. FDA conducted hearings on November 1 and 2, 2005, at which it considered proposals to restrict direct-to-consumer (DTC) advertising. Many hearing witnesses advocated severely limiting drug ads, calling them inherently biased and misleading. WLF attorneys countered by testifying that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options. WLF asserted that FDA officials need to rein in their efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers.

Comments on Labeling of "Alcopops." On July 23, 2001, WLF filed comments with BATF, expressing strong opposition to a request from the Center for Science in the Public Interest (CSPI) that BATF revoke existing labels for sweet-tasting malt-based alcoholic beverages (referred to by CSPI as "alcopops"). WLF argued that CSPI failed to identify any portion of such labeling that is in any way misleading to consumers or is otherwise in violation of BATF regulations. WLF also argued that any effort to prohibit "alcopop" manufacturers from disseminating non-misleading product labeling would violate their First Amendment rights to engage in truthful commercial speech.

#### 2. Property Rights of Businesses and Landowners

One of the highest responsibilities of civil government is the protection of persons and property. But what happens when the government itself seeks to invade the property rights of businesses and citizens? The Fifth Amendment to the U.S. Constitution answers this question with its guarantee that "private property" shall not "be taken for public use, without just compensation." WLF works to keep this guarantee alive by litigating in property rights cases across the country.

*MacPherson v. Dep't of Admin. Svcs.* On February 21, 2006, the Oregon Supreme Court issued a decision upholding the legality of a ballot measure adopted by the voters for the protection of landowners' rights. The decision reversed a trial court ruling that found the ballot measure to be a violation of the Oregon Constitution. WLF had filed a brief in the state Supreme Court supporting the ballot measure on December 5, 2005. The case was a challenge to the constitutionality of Ballot Measure 37, an Oregon ballot measure protecting landowners who suffer a loss in the value of their property on account of land use regulations. After the passage of the measure in 1994, a state trial court held it invalid under various provisions of the Oregon Constitution. In its brief, WLF argued that the trial court had erred in its ruling under the Equal Privileges and Immunities Clause of the Oregon Constitution; the state Supreme Court agreed.

Franklin Savings v U.S. On March 28, 2005, the U.S. Supreme Court declined to review a lower court decision that adversely affects the property rights of businesses that are heavily regulated by the government. The decision was a setback for WLF, which had filed a brief urging the Court to grant review. The appeals court ruled that since the savings industry is heavily regulated, the government may effectively take over a private institution and deplete its assets without having to pay compensation to its owners under the Takings Clause of the Fifth Amendment. WLF's brief argued that if the decision were allowed to stand, it would threaten the property rights of many other heavily regulated businesses and industries. WLF also argued that the appeals court decision was at odds with Supreme Court precedent, including decisions that grant Takings Clause protections to wireless telephone spectrum licenses – even though such licenses are heavily regulated by the federal government.

San Remo Hotel v. City and County of San Francisco. On June 20, 2005, the U.S. Supreme Court upheld an appeals court decision that essentially bars assertion of Takings <u>Clause claims in the federal courts and relegates such claims to state court</u>. The decision was a setback for WLF, which had filed a brief urging that property owners be given a right to insist that their Fifth Amendment claims at some point be heard in federal court. WLF filed its brief on behalf of the Chamber of Commerce of the United States. A silver lining in the decision: a

concurring opinion signed by four Justices indicated that they may well be willing to overrule the 1985 decision that forces Fifth Amendment claimants to file their initial suit in state court. In this case the California Supreme Court had voted 4-3 to deny a hotel owner's state-law claim that San Francisco improperly seized more than \$500,000 of his property. The U.S. Supreme Court upheld the federal appeals court's determination that the hotel owner's loss in state court barred him from filing a new suit in federal court – even though the hotel owner was raising his federal constitutional claim for the first time in the federal proceedings. WLF argued that the appeals court decision contradicts the strong federal policy of permitting litigants to assert their federal constitutional rights in a federal forum.

**RUI One Corp. v. City of Berkeley.** On January 10, 2005, the U.S. Supreme Court declined to review a lower court decision that upheld a Berkeley, California ordinance that imposed huge new liabilities on a company that operates a restaurant on land owned by Berkeley. The decision was a setback for WLF, which filed a brief urging the Court to grant review in order to prevent governments from adopting laws that impose increased costs on their lessees, above and beyond the costs imposed by the lease agreement. WLF argued that the ordinance violated the U.S. Constitution's Contract Clause, which prohibits state and local governments from passing any laws that "impair the obligation of contracts." WLF argued that before imposing the liabilities on the restaurant, Berkeley had signed a binding contract in which it agreed not to adopt laws imposing additional costs on the restaurant beyond those specified in the lease.

GDF Realty Investments v. Norton. On June 3, 2005, U.S. Supreme Court declined to review and reverse a court of appeals decision that gives the Department of Interior's Fish & Wildlife Service essentially unlimited authority to regulate local land development across the country in the name of protecting endangered species, including plants and bugs, that are local in nature and do not affect interstate commerce. The decision was a setback for WLF, which filed a brief urging that review be granted. In this case, the Fish & Wildlife Service denied a permit to GDF Realty to develop its property and threatened the company with criminal prosecution because it might disturb various species of beetles that live only in certain nearby caves in Texas. The bugs spend their entire lives underground and have absolutely no commercial value.

*Esplanade Properties v. City of Seattle.* On June 16, 2003, the U.S. Supreme Court declined to hear a case that raised the issue of whether property owners generally are entitled to compensation when government environmental regulations prevent them from making any economically productive use of their property. The one-sentence order declining review was a setback for WLF, which on April 7, 2003 filed a brief urging the Court to hear the case and to overturn a lower-court decision declining to award compensation. The case involved an effort by the City of Seattle to prevent further development of its waterfront. WLF argued that if Seattle wishes to prevent development, the costs should be borne by all citizens rather than by a few unlucky landowners.

Rogers Machinery, Inc. v. City of Tigard. On March 10, 2003, the U.S. Supreme Court denied review in this important takings case. On December 17, 2002, WLF filed a brief urging the Court to review a lower court ruling upholding the imposition of development impact fees. The City of Tigard, Oregon, imposed a so-called traffic impact fee (TIF) of approximately \$32,000 upon Rogers Machinery as a condition for granting the company a building permit to construct a new office building next to its current headquarters to relieve



overcrowding. The TIF fee is designed to help the city and county fund road improvements for traffic that would be generated by the new building; however, because no additional employees were hired by Rogers, the construction of the building did not generate any new, traffic. In its brief, WLF argued that the same judicial scrutiny should apply to development fees as is applied in land dedication or easement exaction cases.

McQueen v. South Carolina Department of Health and Environmental Control. On November 3, 2003, the Supreme Court declined to hear this case. On July 28, 2003, WLF filed a petition for writ of certiorari in the U.S. Supreme Court seeking review of an adverse ruling by the Supreme Court of South Carolina. That court ruled that even though a land use regulation had the effect of destroying all economic value of private property, the government is not subject to the Takings Clause of the Fifth Amendment because the property is allegedly held in the "public trust." In so ruling, the Court accepted arguments made by regulators and activist environmental groups, and rejected arguments made by WLF on behalf of its client that the Fifth Amendment and U.S. Supreme Court precedent requires just compensation when a regulation destroys all economic value and use of the property.

**Phillips v. WLF.** On March 31, 2003, the U.S. Supreme Court vacated a decision from the U.S. Court of Appeals for the Fifth Circuit, which had given WLF a major victory in its long-running battle against the Texas IOLTA (Interest on Lawyers' Trust Accounts) program. The Supreme Court remanded the case to the Fifth Circuit for reconsideration in light of the Court's March 26 decision in *Brown v. Legal Found. of Washington*, which upheld the Washington State IOLTA program. IOLTA is a program under which states require attorneys to put client funds into special IOLTA accounts, with the interest generated by the accounts being used to finance legal activist organizations; nearly \$150 million is raised each year in this manner for legal aid groups. In a landmark 1998 decision, the Supreme Court ruled in this case that interest earned on IOLTA accounts is the private property of the clients whose funds generated the interest. That victory still stands. On October 30, 2003, the Fifth Circuit granted WLF's request that the case be dismissed.

**Brown v. Legal Found. of WA.** On March 26, 2003, the U.S. Supreme Court upheld Washington State's IOLTA (Interest on Lawyers' Trust Accounts) program, rejecting by a 5-4 vote WLF's claim that the program violated the Fifth Amendment's Taking Clause. Under IOLTA programs, client funds held in trust by attorneys and real estate professionals must be placed into special IOLTA accounts, with interest generated by the accounts being paid to a variety of legal aid organizations. The Supreme Court's ruling leaves open another ground upon which WLF had challenged the program: that the program violates the First Amendment rights of those who are forced to contribute to causes with which they disagree.

Tahoe Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency. On April 23, 2002, the U.S. Supreme Court ruled that a government is not automatically required to provide compensation to property owners when it prohibits all use of property, so long as the prohibition is only temporary. WLF had argued that the Fifth Amendment's Takings Clause requires government to provide just compensation whenever it takes private property, and it does not contain an exception for takings that are only temporary. Declining to overturn a decision from the U.S. Court of Appeals for the Ninth Circuit that denied compensation to Lake Tahoe property owners, the Supreme Court ruled that compensation claims filed in response to temporary moratoria on land use should be judged on a case-by-case basis.



Machipongo Land and Coal Co., Inc. v. Commonwealth of Pennsylvania. On May 30, 2002, the Pennsylvania Supreme Court reversed a lower court decision and rejected a takings claim filed by a coal company alleging that restrictions on coal mining constituted a regulatory taking entitling the company to just compensation under the Fifth Amendment. WLF had filed a brief with the Court on June 29, 2001, urging the Court to affirm the lower court decision. WLF argued that the court ought to affirm that Pennsylvania owes compensation to coal owners whose property was declared "unsuitable for mining." WLF noted that the U.S. Supreme Court has reinvigorated the Takings Clause by limiting the discretion of land use authorities to regulate property without paying compensation.

San Remo Hotel v. City and County of San Francisco. On March 4, 2002, the California Supreme Court rejected arguments by WLF that a government regulation requiring hotel owners to pay exaction fees to ease the shortage of low-income housing in San Francisco constituted a taking of private property requiring just compensation. On April 11, 2001, WLF had filed a brief with the California Supreme Court, arguing that the Constitution's Takings Clause obligates San Francisco to compensate a hotel owner for a \$500,000 exaction the city imposed when it required hotel owners to pay for the privilege of renting a greater portion of its rooms to tourists than it rented out as of a certain date in 1979. WLF argued, first, that U.S. Supreme Court decisions interpreting the Takings Clause have considerably reduced the deference owed to local land use authorities. WLF further demonstrated that monetary exactions, such as the one imposed under the "hotel conversion ordinance" at issue in this case, require heightened judicial scrutiny. And WLF argued that San Francisco cannot evade its constitutional duty to compensate the hotel owners simply by redefining the owners' property rights out of existence.

Palazzolo v. Rhode Island. On June 28, 2001, the U.S. Supreme Court handed WLF a victory when it held that a state may not regulate property into uselessness without paying compensation, simply because the owner acquired the property after the regulation became effective. In addition, the Court held that an owner need not submit his constitutional claim for "just compensation" for endless rounds of bureaucratic review in order for that claim to be "ripe" for adjudication. This case arose from Anthony Palazzolo's efforts over more than 40 years to develop his coastal land. The state government blocked those efforts by denying him permission to build, because it deemed most of his property wetlands. Mr. Palazzolo then took his case to court, claiming that the state's denial of permission had the effect of "taking" his property without "just compensation," in violation of the Fifth Amendment to the Constitution. In its brief filed with the Supreme Court, WLF had argued that the Court should consider revisiting a major part of its Takings Clause jurisprudence by largely abandoning its reliance on a property owner's "reasonable investment backed expectations" in determining when a taking has occurred.

#### 3. Confiscation of Trade Secrets and Other Intellectual Property

Today, a company's most critical assets almost always include its intangible intellectual property – its trade secrets, its patents, its confidential business records, and more. The protection of these interests against unlawful confiscation by government agencies or in civil courts is a growing component of WLF's docket.

*Metro-Goldwyn-Mayer Studios v. Grokster.* On June 27, 2005, the U.S. Supreme Court held that a company whose file-sharing software allows others to illegally copy and disseminate copyrighted music and films on the Internet also itself violates the copyright law. The decision addressed several important and previously undecided copyright law issues. WLF had filed a brief in November 2004, urging the Court to address these issues. Copyright laws protect owners of the copyrighted work from having their music or films downloaded without paying the owner a royalty fee. Grokster enables computer users to share music and film files between each other utilizing so-called "peer-to-peer" services, usually violating the copyright laws. Consequently, major motion picture studios and record companies sued Grokster, instead of the users, to stop the service that allows the illegal file sharing on the theory that Grokster is guilty of contributory infringement rather than direct copyright infringement. The Court ruled against Grokster but in a manner unlikely to inhibit developers of innovative software products.

Frankl v. Goodyear Tire & Rubber Co. On July 28, 2004, the New Jersey Supreme Court affirmed the reversal of a trial court decision that had ordered the release of internal corporate documents belonging to Goodyear. The decision was a victory for WLF, which filed a brief arguing that internal documents do not become fair game for public release simply because they have been made available to the opposing party in a lawsuit. The trial court had ordered release of 14 documents on the ground that Goodyear had made an insufficient showing that the documents contained trade secrets. In affirming the appeals court's reversal of that decision, the New Jersey Supreme Court agreed with WLF that the public has no right of access to documents that have not been introduced as evidence in a court proceeding. Rather, such documents remain fully private even after being produced in connection with litigation, and even the opposing party may not disclose the document if it is subject to a courtimposed protective order.

Consumers Union v. Suzuki Motors Corp. On November 3, 2003, the U.S. Supreme Court let stand a 2002 appeals court decision that reinstated a product disparagement suit filed by a car manufacturer against the magazine Consumers Report. The appeals court had ruled that a business is entitled to bring tort claims to protect its good name from false reports, and the Supreme Court declined to review that ruling. The Supreme Court decision was a victory for WLF, which filed a brief in the case in support of the plaintiff, Suzuki Motor Corp. In allowing the case to proceed, the appeals court agreed with WLF that a product disparagement plaintiff need not\_present evidence directly demonstrating that\_the defendant acted with actual malice; rather, it is sufficient to present evidence (as did Suzuki) from which malice can be inferred.

**Philip Morris, Inc. v. Reilly.** On December 3, 2002, the U.S. Court of Appeals for the First Circuit in Boston enjoined enforcement of a Massachusetts law that would have entailed the confiscation of trade secrets worth billions of dollars. The decision was a victory for WLF, which filed several briefs in the case, urging that the law be overturned. The court agreed with WLF that because Massachusetts is unwilling to pay for the property it is attempting to confiscate, its actions violate the Takings Clause of the Fifth Amendment. The case involves the State's efforts to obtain a detailed list of additives in each tobacco product sold in the State and then release the list publicly – thereby destroying the trade secret.

J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc. On December 10, 2001, the U.S. Supreme Court ruled that genetically modified seed is eligible for patenting

under federal law. The Court agreed with WLF that in adopting the patent law, Congress intended to permit patenting of a broad range of inventions, including living organisms.

Chicago Tribune Co. v. Bridgestone/Firestone, Inc. On August 28, 2001, the U.S. Court of Appeals for the Eleventh Circuit ruled that courts may not order the release of a company's trade secret documents based solely on the news media's argument that the public may have a strong interest in seeing the documents. The decision was a victory for WLF, which had filed a brief in the case opposing disclosure. Overturning a trial court order requiring disclosure, the appeals court agreed with WLF's argument that internal company documents are not fair game for public release simply because they have been made available to the opposing party in a lawsuit – unless the documents become evidence in a public trial. WLF had also argued that to the extent that public safety requires the release of company documents, the release should be ordered by the appropriate government regulatory agency – not at the behest of plaintiffs' attorneys who hope to use those documents to bring additional lawsuits.

#### 4. Unlawful Government Regulation and Taxation

When government regulators and taxing authorities take action outside the law – in violation of their statutory mandate or in violation of constitutional limits on congressional authority – WLF is a voice for respecting the law. WLF presents a public interest perspective in such cases when there is a significant public policy interest at stake.

*McLane Western, Inc. v. Department of Revenue.* On June 12, 2006, WLF filed a brief in the U.S. Supreme Court, urging it to review (and ultimately overturn) a court decision upholding a Colorado excise tax that imposes higher taxes on out-of-state companies than on Colorado companies. WLF argued that taxes, such as the Colorado tax at issue here, that discriminate against interstate commerce violate the Constitution's Commerce Clause. WLF also argued that such taxes interfere with the unrestricted flow of commerce and can damage the national economy. The petitioner in this case purchases the products subject to the tax fairly late in the distribution chain, from an out-of-state distributor. The "tax base" used in computing the excise tax is the purchase price paid by whichever distributor first brings the products into Colorado. Thus the petitioner pays a higher tax than when the same products are brought into the State at an earlier stage of the distribution chain (before all distribution mark-ups have been added to the price).

Kiley v. Calif. Dep't of Alcoholic Beverage Control. On May 24, 2006, the California Supreme Court issued an order declining to review the dismissal of a suit designed to impose significant restrictions on flavored malt beverage (FMB) sales by increasing taxes and prohibiting their sale in convenience and grocery stores statewide. The decision was a victory for WLF, which had filed a brief urging that review be denied because the appeals court had acted properly in dismissing the suit. WLF argued that California's long-standing policy of classifying FMBs as "beer" for regulatory purposes fully complies with California law. WLF further argued that the appeals court properly deferred to the Department of Alcoholic Beverage Control's (ABC) interpretation of relevant statutes. WLF argued that further review of the case was particularly unwarranted in light of the California legislature's ongoing review of FMB sales regulations; WLF argued that it makes little sense for the Court to review the ABC's compliance with existing statutes given that those statutes may be amended in the near



future. WLF also argued that there is no evidence that sales of FMBs are targeted to those under 21.

DaimlerChrysler Corp. v. Cuno. On May 15, 2006, the U.S. Supreme Court overturned an appeals court ruling that had struck down a state program of tax incentives for economic development. The decision was a victory for WLF, which filed a brief asking that the appeals court decision be overturned. The appeals court held that an Ohio tax incentive program violated the Constitution's "dormant" Commerce Clause because it provided benefits to companies doing business in Ohio but not to those operating outside the state. The Supreme Court did not reach the merits of the Commerce Clause issue. Rather, it held that the appeals court should never have considered the issue because the plaintiffs (Ohio taxpayers) lacked "standing" to raise it. WLF's brief had challenged the plaintiffs' standing and had also argued that the Ohio program is constitutional because it does not in any way penalize companies that choose to do business outside the state.

United States v. Rx Depot, Inc. On February 22, 2006, the U.S. Court of Appeals for the Tenth Circuit in Denver declined an opportunity to prevent FDA from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, affirming FDA's authority to seek a massive damage award against an internet pharmaceutical distributor, was a setback for WLF, which had filed a brief urging the court to deny FDA that authority. In its brief, WLF argued that FDA has no power to seek disgorgement or restitution from companies alleged to have violated federal drug laws. WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that disgorgement and restitution are not among them. WLF argued that FDA, throughout most of its history, never asserted a right to seek disgorgement; WLF charged that FDA only recently began asserting that power, to have a big club with which to intimidate manufacturers who might otherwise seek to challenge FDA. The case involves a company accused by FDA of brokering illegal purchases by American consumers of prescription drugs from Canadian pharmacies. The case now returns to the trial court, where FDA is seeking disgorgement of profits as a remedy; the several million dollars sought to be disgorged vastly exceeds the maximum fine permitted under the FDCA.

United States v. Lane Labs-USA, Inc. On October 21, 2005, the U.S. Court of Appeals for the Third Circuit in Philadelphia issued a decision virtually identical to the Tenth Circuit's-decision-in Rx Depot (see above). The court's decision, upholding a massive \$109 million restitution award against a dietary supplement manufacturer, was a setback for WLF, which had filed a brief urging the court to overturn the award. WLF had argued that FDA has no power to seek restitution from manufacturers alleged to have violated the Federal Food, Drug, and Cosmetic Act (FDCA). WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that restitution is not among them. The Third Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief. The case involved a dietary supplement manufacturer accused by FDA of improperly promoting its products as a treatment for cancer; it was ordered to refund to consumers all money used to buy its products.

National Cable & Telecomm. Ass'n v. Brand X Internet Services. On June 27, 2005, the U.S. Supreme Court ruled that the Federal Communications Commission (FCC) could properly decide not to impose burdensome regulatory requirements on the delivery of

broadband Internet access by cable companies. The decision was a victory for WLF, which filed a brief with the Court supporting the FCC's position. The case arose from a decision by the FCC to treat cable modem service as an "information service" rather than a "telecommunications service." The decision meant that cable modem providers (local cable television companies) would not be required to share their lines with other providers of Internet. In its January 18, 2005, brief before the High Court, WLF argued that the FCC's decision was sound policy because the broadband market is a competitive battlefield between cable companies and local telephone companies (providers of DSL service) and that further competition is on the horizon in the form of new technologies for broadband service.

Alliant Energy Corp. v. Bridge. On January 12, 2004, the U.S. Supreme Court declined to hear a challenge to a Wisconsin state law that regulates the investments and stock sales of non-Wisconsin companies. WLF had filed a brief supporting the petition for review, arguing that the law violates the Commerce Clause of the U.S. Constitution by regulating the out-of-state activities of out-of-state corporations. In its brief, WLF argued that state laws such as Wisconsin's that directly control extraterritorial commerce – commerce occurring wholly outside the state's borders – are per se invalid under the Commerce Clause.

Overfelt v. McCaskill. On August 12, 2002, the Missouri Court of Appeals affirmed a lower court ruling that upheld a proposed ballot initiative to raise taxes on tobacco products, despite finding that the State Auditor failed to conduct a study of the fiscal impact of the initiative upon local governments as required by Missouri's initiative and referendum law. Under Missouri law regarding the certification of ballot initiatives, the State Auditor is required to conduct a fiscal impact of the measure and prepare a fiscal note describing that impact, and also prepare a fiscal note summary, which is a component of the ballot title. Missouri law requires the State Auditor to assess the fiscal impact of the measure on both state and local governments. The Auditor neglected altogether to assess the initiative's impact on those local jurisdictions that impose a local tax on cigarettes in addition to the state tax.

Washington Legal Foundation v. U.S. Dep't of Labor. On March 7, 2001, the U.S. House of Representatives handed WLF a noteworthy victory when it invoked the never-beforeused Congressional Review Act to repeal the Occupational Safety and Health Administration's (OSHA) ergonomics standard. Agreeing with WLF, the proponents of this repeal measure argued that the ergonomics rule was poorly tailored to protect workplace safety and represented a boon to plaintiffs' lawyers, who were expected to take full advantage of the vague and ambiguous language of the rule to bring lawsuits against a wide range of businesses. WLF filed a lawsuit against OSHA on December 7, 2000, charging that the ergonomics standard was improperly promulgated. OSHA's ergonomics standard would have required virtually every employer in the country to establish a program designed to guard against employee injuries caused by repetitive motions, such as lifting objects or typing on a keyboard. Among other things, the standard would have also required employers to give paid leave to employees complaining that repetitive workplace motions were causing them pain.

Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA. On December 11, 2002, the U.S. Court of Appeals for the Fourth Circuit ruled that companies adversely affected by the Environmental Protection Agency's (EPA) designation of second-hand smoke as a Group A ("known human") carcinogen do not have the right to seek judicial review of that designation. The court held that EPA's designation was not "final agency action" subject to review under federal law. WLF had filed a brief in the case in support of the plaintiffs,



arguing that individuals and businesses can be severely damaged by a federal government designation that their product causes cancer and thus ought to be permitted judicial review of the propriety of such designations.

#### **B.** Environmental Law Project

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Environmental extremist groups, activist courts, and the media foster the false notion that the environment is always threatened by economic activities. WLF's Environmental Law Project seeks to strike a rational, proper balance between environmental protection and economic growth/property rights. The Foundation's goal: to help create a body of law that will serve as a precedent for those seeking to protect their rights to operate their businesses without undue governmental interference.

#### 1. Abusive Criminal and Civil Enforcement

WLF believes that use of the criminal laws to enforce environmental rules should be reserved for those who flout well-known rules, knowing full well the potential for significant environmental harm. WLF regularly opposes over-zealous prosecutors who seek to criminalize good-faith disagreements over the meaning of obscure regulations. WLF also opposes activist groups that seek to use the courts to expand the scope of environmental laws beyond that intended by Congress.

Rapanos v. United States. On June 19, 2006, the U.S. Supreme Court ruled that the U.S. Army Corps of Engineers may not assert federal jurisdiction over certain wetlands that have only a tenuous hydrological connection to navigable waterways. Its reversal of a lower court decision upholding jurisdiction was a victory for WLF, which filed a brief urging the Court to reject the federal government's claim that it has regulatory authority under the Clean Water Act (CWA) over isolated "wetlands" located over 20 miles away from any navigable waterway. However, because the Court's principal opinion was supported by only four justices, with a separate opinion and rationale for reversal by Justice Kennedy providing the fifth vote for reversal, the full ramifications of the decision will be litigated in future cases. The Court's decision reins in to some extent federal regulators, who had seemingly ignored a 2002 Supreme Court ruling that Congress intended the Clean Water Act's jurisdiction to extend only over wetlands that are adjacent to navigable waterways, not over isolated wetlands that are otherwise subject to local control.

Connecticut v. American Electric Power Company. On March 2, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit in New York, urging the court to reject an appeal filed by several states and environmental groups claiming that global warming is a public nuisance and that the courts should order the major power companies to restrict their carbon dioxide emissions. The States of Connecticut, New York, California, Iowa, New Jersey, Rhode Island, Vermont, and Wisconsin filed the suit in federal court in New York City claiming that global warming constitutes a legal and actionable public nuisance under federal common law. WLF argued in its brief that the district court was correct in dismissing the case or political question grounds because the policy issues involved in the case should be resolved by the political branches rather than by a federal court. WLF argued that Congress has repeatedly rejected proposed legislation and the Kyoto Treaty that would impose mandatory



caps on carbon dioxide emissions on U.S. power companies while leaving countries such as China and India free from any constraints.

New York v. EPA. On March 17, 2006, the U.S. Court of Appeals for the District of Columbia Circuit struck down the Environmental Protection Agency's (EPA) Equipment Replacement Provision (ERP) under the New Source Review (NSR) program. As a result, many existing facilities may now be forced to install expensive retrofit technology or shut down, thereby jeopardizing thousands of jobs and reliable energy supplies. The decision was a setback for WLF, which filed a brief in the case in support of EPA's position – the only pro-free enterprise public interest organization to do so. EPA's ERP regulations were challenged by a group of states, environmental groups, and U.S. Senators. The regulations required existing manufacturing and power generating facilities to comply with the time-consuming and costly NSR procedures only when the facility underwent major modifications as opposed to routine maintenance and repair. The appeals court disagreed, holding that federal law requires compliance with NSR procedures even when routine repairs are undertaken.

Northern Alaska Environmental Center v. Norton. On July 8, 2005, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, urging the court to affirm a lower court ruling that upheld the Final Environmental Impact Statement (FEIS) for the oil and gas leasing program for the Northwest Planning Area of the National Petroleum Reserve in Alaska. The Northwest Planning Area consists of 8.8 million acres. WLF argued that the FEIS was more than sufficient to satisfy environmental laws, and noted that the oil and gas production would disturb less than 2,000 acres of the surface area of the Northwest Planning Area. Significant measures would also be taken to mitigate any harm to wildlife and the environment. WLF argued that domestic oil exploration and production are vital to our national security inasmuch as the United States imports over 60 percent of its oil from foreign countries, up from 36 percent after the oil crisis of 1973.

Riverdale Mills Corp. v. United States. On November 1, 2004, the U.S. District Court in Massachusetts dismissed this suit by Riverdale Mills Corporation (RMC), ruling that the EPA was not liable for malicious prosecution under the Federal Tort Claims Act. At the same time, the court excoriated the EPA for the unprofessional manner in which it conducted its investigation of RMC. In a parallel proceeding, the U.S. Court of Appeals for the First Circuit ruled in December 2004 that EPA agents did not violate the Fourth Amendment rights of the company and its owner for its warrantless search of the company's premises. WLF's initial complaint, brought under the Federal Tort Claims Act, included claims for the malicious prosecution of RMC and Knott, stemming from charges brought against them in late 1997 for allegedly violating the Clean Water Act. RMC, located in Northbridge, Massachusetts, is an environmental award-winning, energy-efficient facility that manufactures wire mesh used for lobster traps, aquaculture, erosion control, and other commercial purposes. After an EPA raid on the business by 21 armed EPA agents, the company and its owner were indicted on two felony counts. In the course of the criminal proceedings, review of EPA's investigation log revealed that a lawful pH reading of 7 had been altered to look like a 4, and that other sevens had been altered to look like twos. Faced with evidence of its own misconduct, the government dropped all criminal charges just before trial.

**Blandford v. United States.** On February 23, 2004, the U.S. Supreme Court denied a petition for review filed by WLF on behalf of three seafood importers and dealers who were sentenced to up to *eight years* in prison for importing "illegal" seafood. In a case that has



ramifications for all regulated businesses, the seafood dealers were prosecuted and convicted under the Lacey Act for importing lobster tails from Honduras because they allegedly violated several obscure Honduran regulations, such as one requiring that frozen seafood be shipped in cardboard boxes instead of clear plastic bags. Because the seafood was shipped in plastic bags, the dealers were also charged with "smuggling," even though the shipments regularly went through Customs and FDA inspections. Because the importers paid the exporter for the seafood, they were all charged with money laundering. The Honduran government took the extraordinary step of filing a brief in the Supreme Court supporting WLF's position that the Honduran regulations were invalid. As a result of the Supreme Court's denial of review, the defendants were ordered to begin serving their prisons terms in June and July 2004. In addition to representing the defendants, WLF coordinated the filing of numerous amicus curiae briefs in their support by prominent business groups. Further legal actions may include filing a petition for Presidential commutation of sentence, if the pending habeas petition is denied.

*Massachusetts v. EPA.* The U.S. Court of Appeals for the D.C. Circuit ruled on July 19, 2005, in favor of WLF's position that the EPA cannot be required to regulate carbon dioxide as a pollutant under the Clean Air Act. Had the court ruled in favor of the petitioners, the EPA would have been required to regulate so-called "greenhouse gases" produced by automobiles, manufacturing facilities, and other sources of carbon dioxide that petitioners claim are causing global warming. Such a ruling would, in effect, have implemented the unratified Kyoto Treaty regulating greenhouse gases. In its brief, WLF argued that the issue of global climate change and its causes has been the most prominent energy and environmental issue of recent years. WLF argued that Congress would certainly have been explicit when it enacted the Clean Air Act if it had wanted to give the EPA authority to initiate a massive regulatory program for greenhouse gases. In June 2006, the U.S. Supreme Court agreed to review the case; WLF will file a brief in the Supreme Court in the fall of 2006, again urging rejection of the claim that carbon dioxide is a "pollutant."

Petition on Improper Assessment of Cancer Risks. On March 21, 2006, WLF requested that the Environmental Protection Agency (EPA) reconsider its February 2006 decision to decline to hear a WLF petition to eliminate "junk science" from the process by which EPA determines whether a substance is likely to cause cancer in humans. In a petition filed pursuant to the Information Quality Act (IQA) in August 2005, WLF had argued that EPA guidelines for determining human carcinogenicity violate the IQA because they are not based on sound science but rather on an EPA policy judgment that extreme caution should be adopted in connection with substances that pose any possible cancer risk. EPA's response asserted that because its guidelines constitute a "policy" document, they are not subject to the IQA. WLF's March 21 reconsideration petition explains why EPA policy documents are not exempt from the IQA. In a June 27, 2006 letter to WLF, EPA said that it will respond to the reconsideration request within 90 days. WLF filed its initial petition and its reconsideration request on behalf of itself and the American Council on Science and Health ("ACSH"). ACSH recently published a study, America's War on "Carcinogens," that is extremely critical of EPA's guidelines for determining cancer risks.

National Audubon Society v. Dep't of the Navy. On September 7, 2005, the U.S. Court of Appeals for the Fourth Circuit in Richmond ruled that the Navy should be permitted to go forward with planning for construction of a new North Carolina airfield, even as it prepares a new environmental impact statement (EIS) for the airfield. The decision was a victory for WLF, which had filed a brief urging the court to lift a district-court injunction



against all site-preparation and planning work. The airfield, desperately needed for pilots being trained to land planes on aircraft carriers, has been blocked by questions over the adequacy of the initial EIS. The appeals court held that a new EIS was required. But it agreed with WLF that the district court erred in blocking all work on the airfield while the new EIS is being prepared. The appeals court agreed with WLF that the district judge acted improperly in second-guessing the Navy's determination that building the base is vital for national security.

United States v. Hansen. On June 16, 2002, the U.S. Supreme Court declined to review this important environmental case. WLF had filed a brief with the Court urging the High Court to review a dangerous court of appeals decision on criminal liability. On August 24, 2001, the United States Court of Appeals for the Eleventh Circuit in Atlanta, Georgia, affirmed the convictions and unprecedented prison sentences of two officers and the plant manager of a chemical facility for violating the Resource Conservation and Recovery Act (RCRA) and the Clean Water Act (CWA). WLF had filed a brief with the court of appeals in 1999, urging it to overturn the convictions and draconian prison sentences. Several years after the plant shut down, the officers were indicted and convicted of knowing endangerment, even though no employee was ever injured. The defendants were convicted under the "responsible corporate officer" theory of liability. The court sentenced 72-year-old Christian Hansen to prison for an unprecedented term of 108 months (nine years); his son Randall was sentenced to 46 months; and the plant manager was sentenced to 78 months. The Hansens later filed habeas corpus petitions, seeking post-conviction relief; those petitions were denied in May 2004.

United States v. Alcan Aluminum Corporation. On January 12, 2004, the U.S. Supreme Court denied review in this important case. On December 15, 2003, WLF filed a brief in the Court in support of a petition for review filed by Alcan Aluminum Corporation (Alcan) seeking review and reversal of a ruling by the U.S. Court of Appeals for the Second Circuit, which required Alcan to pay \$13 million in cleanup costs for two EPA Superfund sites in upstate New York. Alcan's allegedly "hazardous substance" was essentially nothing more than water. Based on this precedent, all businesses could now be subject to costly cleanups if their wastes have even trace levels of a hazardous substance. WLF also filed a brief in the court of appeals, on behalf of numerous congressional and major business clients, including the U.S. Chamber of Commerce and the National Restaurant Association.

Kootenai Tribe of Idaho v. Veneman; State of Idaho v. U.S. Forest Service. On December 12, 2002, the U.S. Court of Appeals for the Ninth Circuit, in a 2-1 decision, overturned a district court injunction against implementation of the Roadless Area Conservation Rules. On June 26, 2001, WLF had filed a brief with the court of appeals urging the court to uphold the district court ruling. Those rules, promulgated by the Clinton Administration on January 12, 2001, prevent road construction, timber harvesting, and other activities in over 25 percent of the National Forest System, or about 50 million acres of

forests. The rules as promulgated are seriously flawed and will have catastrophic environmental impacts, such as increased risk of insect infestation and forest fires, and will needlessly prevent public access to the forests.

**Rancho Viejo, LLC v. Norton.** In March 2004, the U.S. Supreme Court declined to review a court of appeals decision that would effectively remove any Commerce Clause limits on Congress's power to regulate development. In *Rancho Viejo, LLC v. Norton*, the U.S. Court of Appeals for the District of Columbia Circuit upheld the application of the Endangered Species Act to a small residential developer, which had erected a fence on its property. The Department of Interior claimed that the fence would interfere with the southwestern arroyo toad, a federally listed engandered species which is located only in California and only ranges about one mile from the streams in which it breeds. In its brief, WLF argued that the court of appeals decision would effectively undermine the Supreme Court's Commerce Clause jurisprudence. In landmark rulings, including *United States v. Lopez*, the Supreme Court has ruled that the power to regulate interstate commerce does not include the power to regulate local activity that does not substantially affect interstate commerce.

Solid Waste Agency of Northern Cook County (SWANCC) v. U.S. Army Corps of Engineers. WLF scored a major victory when the U.S. Supreme Court ruled on January 9, 2001, that Congress did not give authority to the U.S. Army Corps of Engineers under the Clean Water Act to regulate the filling of isolated wetlands. In doing so, the Court did not find it necessary to address the additional issue of whether Congress has authority under the Commerce Clause to regulate such isolated wetlands simply because migratory birds were observed on the parcel. In its brief filed in 2000, WLF argued that the Corps' so-called "migratory bird rule" exceeds the authority conferred on the federal government under the Commerce Clause. The actual or potential presence of migratory birds on private property does not involve commercial transactions or economic activity, WLF argued.

#### 2. "Environmental Justice" and Title VI

Title VI of the Civil Rights Act of 1964 prohibits federal fund recipients (such as state governments) from intentionally discriminating on the basis of race. Some environmental activists have attempted to expand Title VI to cover any action that has any sort of disparate racial impact, even impacts that are wholly unintended. Those activists then try to use Title VI as a club for their version of "Environmental-Justice" – they argue that manufacturing facilities may never be built in a minority community because doing so would have a disparate impact on racial minorities. WLF regularly goes to court to oppose the "Environmental Justice" movement's distortion of Title VI.

South Camden Citizens in Action v. New Jersey Department of Environmental Protection. On December 17, 2001, the U.S. Court of Appeals for the Third Circuit overturned a trial-court decision which found that the State of New Jersey had violated federal civil rights laws even though it never intended to discriminate against any protected class of citizens. The trial court had blocked operation of a cement factory in Camden, New Jersey on the grounds that allowing the plant to operate would violate Title VI of the Civil Rights Act of --1964-(which-prohibits racial discrimination by federal fund recipients) because it would have a greater impact on Camden's minority population. In reversing, the appeals court agreed with WLF that private individuals are not permitted to sue to enforce regulations promulgated under Title VI. Rather, the court held that any enforcement of the regulations must come from the



government itself. The U.S. Supreme Court later declined to review the decision, thereby leaving WLF's victory intact.

Alexander v. Sandoval. On April 24, 2001, the U.S. Supreme Court overturned a ruling that the State of Alabama had violated federal civil rights laws even though it never intended to discriminate against any protected class of citizens. The Court held that claims brought under Title VI of the Civil Rights Act of 1964 are untenable in the absence of evidence that the defendant *intended* to discriminate. The decision was a victory for WLF, which had filed a brief in the case in support of Alabama. The case was a challenge to Alabama's policy of giving its driver's license tests in English only, but has implications for Environmental Justice cases which are also based on Title VI.

Comments on Interim Guidance for Environmental Justice Complaints. On August 28, 2000, WLF filed its comments opposing the EPA's Draft Revised Guidance for Investigating Title VI Administrative Complaints Challenging Permits. Although the guidance ostensibly provides a framework for processing complaints filed under the EPA's discriminatory effect regulations, the entire concept of enforcing "environmental justice" under the EPA's Title VI regulations is legally flawed because Title VI prohibits only intentional discrimination. WLF argued that the interim guidance is also likely to cause a significant, unjustified shifting of permit decision-making authority from the states to the federal government. WLF requested that since the guidance was legally flawed, procedurally improper, unwise, and unworkable as a matter of policy, it should be withdrawn. WLF is reviewing the EPA's so-called Environmental Justice "Toolkit" for businesses issued in December 2003, and is monitoring other recent developments in EPA's Environmental Justice Program.

#### C. Reining in the Plaintiffs' Bar

Many of the problems with the civil litigation system in this country can be traced to plaintiffs' lawyers filing too many frivolous cases, and then demanding excessive attorney fees as the price for dropping their claims. WLF has litigated to ensure that court-awarded fees are kept within reasonable limits, that public funds are not used to support unwarranted litigation, and that appropriate sanctions are imposed on attorneys who file frivolous suits or otherwise abuse the public trust.

#### 1. Opposing Excessive Attorneys' Fees

The fuel that has caused the litigation explosion is the award of excessive attorneys' fees to plaintiffs' attorneys and activist groups. In class actions and other major cases, plaintiffs' attorneys routinely seek and receive huge awards that translate into rates of \$10,000 an hour and more, while class members receive worthless coupons or small awards. WLF is in the forefront of filing objections to the award of excessive attorneys' fees in class actions and other cases. In addition, WLF has petitioned the Federal Trade Commission (FTC) and State Bar associations to regulate and curb this abusive practice.

Chance v. United States Tobacco Co. On April 3, 2006, WLF filed a brief in the District Court of Seward County, Kansas, opposing a fee request by plaintiffs' attorneys for

\$22.5 million for settling a class action lawsuit where users of smokeless tobacco products will receive only coupons toward the purchase of future products. WLF argued that the coupon settlement was highly inflated, and that the court should base any fee on the hourly rate – which plaintiffs estimate would result in a \$4.6 million fee, and which defendants estimate to be more like \$3.6 million. WLF argued that a coupon settlement is worth little to consumers if few consumers actually redeem them. WLF cited cases where coupon redemption rates were only in the 3 to 6 percent range, and where part of the attorneys' fees were ordered to be paid in coupons. The recent federal Class Action Fairness Act, as well as the law in Texas, provide that fees should be based on the amount of coupons actually redeemed.

In re iPod Cases. On July 28, 2005, WLF filed objections in the Superior Court of California in San Mateo County urging the court to reject an attorneys' fee award request of \$2.7 million in a consumer class action lawsuit against Apple Computer on behalf of purchasers of Apple's iPod Digital Music Player. The plaintiffs claim that those who purchased or obtained the iPod before May 31, 2004 may have experienced problems with the battery's capability to hold a charge. The settlement calls for class members to receive a \$25 check or a coupon worth \$50 in store credit for those who file claims by September 30, 2005. On behalf of WLF's client, who owns an iPod and is a class member, WLF filed objections to the fee and class member incentive payments of \$1,500 each. WLF also argued that no fees should be paid until after all claims have been filed so the court can determine the value of the benefits to be distributed. On September 6, 2005, the court approved the settlement, but requested further documentation to justify the attorneys' fees application. After receiving the information, the court approved the fee application for lead counsel and reduced the fees requested by counsel for one of the lead plaintiffs.

Graham v. Daimler Chrysler Corp. On December 1, 2004, the California Supreme Court affirmed a lower court's rationale for awarding a consumer group attorney fees under the so-called "catalyst theory" of awarding such fees. However, the Court remanded the case to the lower court to determine the actual amount that should be paid to the activist group for filing a short-lived consumer lawsuit against a company by taking into account certain clarifications of the catalyst theory. On November 12, 2003, WLF filed a brief in the California Supreme Court urging it to review and reverse a dangerous lower court decision that could subject all companies to costly activist litigation. The lower courts upheld a huge attorneys' fees award to a consumer group for filing a lawsuit against an automobile company because of an-inadvertent misprint in the-owner's manual about the vehicle's towing capacity. Because the company began to change the misprint in the manual well before the suit was filed, and even offered to repurchase any vehicle, the activists' suit became moot, no relief was awarded, and the case was dismissed less than three weeks after it was filed. Nevertheless, the group was awarded almost \$800,000 simply for filing the lawsuit.

Azizian v. Federated Department Stores. On March 8, 2005, U.S. District Court Judge Saundra Armstrong of the Northern District of California approved a class action settlement among consumers, cosmetic manufacturers, and department stores that would provide class members with \$175 million worth of cosmetics; the court previously rejected an unusual "first-come, first-served" giveaway proposal. She also awarded the plaintiffs' attorneys \$24 million in fees, the full amount that they requested with no questions asked, despite her previous position that an award should only be made after the giveaway program had been completed – such a delay would have enabled the court to assess the program's effectiveness and the reasonableness of the fee risk in light of that effectiveness. On March 26, 2004, WLF

had filed objections in this class action case on behalf of a group of 33 objectors to a proposed settlement that offered class members only a chance to get a "free" item of cosmetics allegedly valued between \$18-\$25 during a one-week giveaway period if they had purchased so-called "high end" cosmetics or fragrances over the last 10 years. WLF filed further objections on June 1, 2004; during later hearings before a Special Master, WLF argued that the parties should provide more effective notice to the class about the case, and that cash or coupons would be preferable to a product giveaway. WLF further argued that the attorney fees request of \$24 million was excessive.

LiPuma v. American Express. On February 14, 2005, WLF filed a brief in federal court in Miami objecting to a proposed class action settlement against American Express Company, including \$11 million in attorney fees. The suit claimed that American Express improperly assessed and disclosed adjustments to foreign currency conversions for cardholders who used their American Express card overseas during the previous five years. The adjustments, or surcharge, amounted to 1-2 percent of the currency conversion rate. In its objections filed on behalf of a class member from Atlanta, WLF argued that the settlement was not fair, reasonable, or adequate, arguing that class members' accounts should be automatically credited without the necessity of their submitting claim forms since the account information is readily available to American Express. More importantly, WLF objected to the proposed \$11 million attorney fee as excessive, particularly because the suit appeared to be a copycat suit, filed only after a California trial court ruled against Visa and MasterCard for similar conduct. WLF also opposed so-called "incentive payments" of \$10,000 to the lead plaintiffs. On December 22, 2005, the court approved the terms of the settlement, but reserved ruling on the application for attorney fees.

*Court Reporting Services, Inc. v. Compaq Computer Corp.* On June 2, 2003, WLF filed objections in federal court in Texas on behalf of a consumer to the proposed award of up to one million dollars in attorney fees in a class action case where the class members will essentially receive no compensation. WLF argued that the requested fees were excessive in comparison to the relief obtained on behalf of the class members. WLF also reserved the right to file supplemental objections once the attorneys file more detailed pleadings justifying their fee request. The gist of the complaint is that Compaq's advertising and promotional literature for "Presario" computers failed to disclose certain aspects about the partitioning of the hard drives of those computers; and with respect to certain models, failed to provide backup and restoration software. The court finalized the settlement on December 31, 2004.

In re Vitamin Cases/Philion v. Lonza. The California Supreme Court announced on June 11, 2003, that it will let stand a class action settlement in which the plaintiffs' lawyers are to receive millions in fees, while consumers – their purported clients – will receive nothing. WLF had filed a brief in May 2003 in support of the objecting class members, arguing that the settlement violated California law and urging the High Court to grant review. The lower court in the case, the Court of Appeal of California, First Appellate District, had upheld the settlement, in which the consumers will have no opportunity to seek compensation of any kind. Instead, the so-called *cy pres* settlement of \$38 million was to be paid to governmental and nonprofit organizations; the plaintiffs' attorneys were to receive an award of \$16 million in fees.

In re Magazine Antitrust Litigation. On May 5, 2003, WLF filed its initial objections on behalf of itself and several consumers to the proposed award of \$1.1 million in attorney fees in a class action case where the class members will receive no compensation. WLF argued that the requested fees are excessive compared to the relief obtained on behalf of the class members. WLF also reserved the right to file supplemental objections once the attorneys file more detailed pleadings justifying their fee request. This class action lawsuit was filed in October 2000 in the U.S. District Court for the Southern District of New York against the Magazine Publishers of America (MPA) and fourteen magazine publishing companies alleging that there was an agreement among the defendants since 1996 to set a minimum price of or maximum discount on magazine subscriptions through the enactment of an MPA guideline. In February 2004, WLF scored a victory when the Court denied the award of any attorney fees for the plaintiffs' attorneys because they obtained no monetary or other relief for the class members. Rather, the plaintiffs' attorneys merely required the defendants to comply with existing antitrust law.

Simon v. Schwartz. On May 7, 2003, the U.S. Supreme Court denied review in this important attorney's fee case. WLF had filed a brief with the Court, urging it to review the case, which involved the proper standard for use by trial courts in awarding attorney fees in class action settlements. WLF argued that the fees awarded in this case, which were about five times the normal hourly rate of the attorneys, were excessive; rather, the fee should have been capped at the normal hourly rate according to Supreme Court precedent. The case was a class action filed against Citibank on behalf of credit card holders claiming that the company violated the federal Truth-in-Lending Act by not crediting payments made by the card holders in a timely manner. Approximately a year after suit was filed, the parties proposed a settlement whereby the class members would share in a fund of \$18 million, injunctive relief would be granted, and the defendant would pay up to \$9 million to the attorneys, an amount later reduced to \$7.2 million. The fee award compensates the attorneys at approximately five times their normal hourly rate. Class members received checks in the mail for as little as two cents.

In re Compact Disc Minimum Advertised Price Antitrust Litigation. On June 13, 2003, the U.S. District Court of Maine upheld a proposed settlement of a nationwide class action case where the attorneys were seeking \$12.5 million in fees. The underlying lawsuits, which were filed across the country by state attorneys general and private attorneys and consolidated in the federal court in-Maine, sought antitrust damages against the distributors of music compact discs (CDs) and certain retailers for engaging in a Minimum Advertised Price (MAP) program that allegedly had the effect of maintaining higher retail prices of CDs. WLF had urged the court, in a brief filed on behalf of consumer objectors, to reject the fee request as excessive. The attorneys sought \$12.5 million in fees to share with several State attorneys general. WLF argued on behalf of a group of objecting class members that the award of \$12.5 million in fees was grossly excessive due to the fact that the Federal Trade Commission (FTC) and the State attorneys general had already investigated the matter thoroughly.

Gisbrecht v. Barnhart. On May 28, 2002, the U.S. Supreme Court issued a decision that declined to restrict the size of attorney fees that can be collected from disabled Americans who win-suits-claiming\_entitlement\_to\_disability\_benefits\_under the Social Security Act. WLF unsuccessfully argued that Congress intended to limit attorney fees in such cases to "reasonable" fees because attorneys often collect an unconscionably high fees based on a percentage of the disability benefits awarded. WLF also had argued that such "contingency

fee" awards ought to be barred and that fees ought to be awarded under the "lodestar" method – under which the number of hours an attorney worked is multiplied by a reasonable hourly rate. The Court concluded, however, that lawyers may charge a contingency fee equal to 25 percent of the benefits awarded, if that was the amount the client had originally agreed to pay.

Wilson v. Massachusetts Mutual Ins. Co. WLF filed formal objections on March 2, 2001, with the First Judicial District Court of Santa Fe County, New Mexico, to the award of attorney fees of approximately \$8 million in a case where the class members were to receive no compensation whatsoever. Shortly after WLF filed its objection, the attorney withdrew his fee request. In this case, a Santa Fe lawyer filed suit against the insurance company on behalf of policyholders claiming that the company failed to disclose fully the amount of additional payments charged when policyholders choose to pay their premium on a monthly, quarterly, or semi-annual basis rather than on an annual basis. The company initially agreed not to oppose the award of an attorney fee of 1) \$5 million in cash; 2) \$250,000 annual annuity for 20 years; and 3) a \$3 million life insurance policy for the attorney. In addition, the lead plaintiff (an attorney himself) was to receive \$250,000 as an "incentive" payment for participating in the suit.

Vizcaino v. Microsoft Corp. On April 16, 2001, the U.S. District Court for the Western District of Washington in Seattle upheld the award of \$27 million in attorney fees in this class action case. WLF had filed formal objections with the court on January 24, 2001, on behalf of several class members opposed to the proposed fee award. The court initially ordered the plaintiffs' attorneys to submit more detailed information justifying their fee. On March 29, 2001, WLF filed a response, arguing that the fee was not justified. The attorneys sought 28% of the common settlement fund of approximately \$98 million. This amounted to approximately \$27 million in fees. This lawsuit was originally filed against Microsoft in late 1992 on behalf of employees of Microsoft who were classified as temporary employees or independent contractors.

In re American Family Publishers Business Practices Litigation. On September 13, 2000, the U.S. District Court for the District of New Jersey approved the final settlement and modified the attorneys' fee award in this class action case. On May 8, 2000, WLF had filed formal objections to the proposed settlement, on behalf of a class member. In particular, WLF objected to the proposed payment of up to \$11,750,000 in attorney fees and costs as unreasonable considering that class members were to receive payments as small as \$5.00. This class action case began in 1998 when several plaintiffs filed both state and federal class actions against American Family Publishers and their related companies for direct mail solicitation of magazine subscriptions. The plaintiffs alleged that the marketing materials sent to consumers misleadingly suggested that it was either necessary to purchase magazine subscriptions to win sweepstake prizes, or that purchasing the subscriptions or other merchandise enhanced their chances of winning a prize.

In re Synthroid Marketing Litigation. On April 15, 2003, a federal appeals court overturned a WLF victory by reversing a lower court ruling that had significantly reduced (from 29% to 10%) a requested fee award in a nationwide class action. WLF, along with WLF's Economic Freedom Law Clinic at George Mason University School of Law, had filed formal objections to the fees request on behalf of two class members. The underlying lawsuit alleged that advertising associated with Synthroid inaccurately suggested the superiority of Synthroid over other products used to treat certain thyroid disorders, thereby deterring



consumers from purchasing less expensive alternatives to Synthroid. Under the proposed settlement agreement, the company would pay approximately \$87 million into the settlement fund for the benefit of the class members. However, the attorneys sought 29 percent of that amount, or approximately \$26 million in fees, even though the average class member would receive less than \$100. WLF objected to the requested fee as excessive.

Citizens for a Better Environment v. The Steel Company. On April 23, 2001, the U.S. Supreme Court declined to review a lower court ruling that favored plaintiffs over defendants in environmental cases. The decision was a setback for WLF, which had filed a certiorari petition seeking Supreme Court review of the case. WLF's petition argued that defendants should not be discriminated against in the award of attorney fees. On October 17, 2000, the U.S. Court of Appeals for the Seventh Circuit ruled against WLF's client, holding that companies virtually never are permitted to recover their attorney fees even when they successfully defend environmental suits brought against them. WLF's petition to the Supreme Court argued for a stop to the practice of routinely granting large attorney fee awards to environmental groups that prevail in lawsuits they file against private companies, while routinely denying fees to the companies when the environmental groups lose. Environmental groups can file what are often frivolous lawsuits with little risk of sanction, knowing that the high costs of litigation will force most defendants into quick settlements, no matter how meritorious their defenses.

Petition on Regulation of Contingency Fees at the Federal Level. On August 14, 2001, WLF filed a petition urging the FTC to crack down on abuses of the contingency fee system by attorneys. WLF argued that contingency fee practices routinely engaged in by attorneys constitute "unfair trade practices" within the meaning of the FTC Act. WLF said that FTC action was necessary because the legal profession and state bar authorities have demonstrated their unwillingness to address the contingency fee scandal, under which lawyers are pocketing billions of dollars of their clients' funds, often for minimal work. In July 2002, the FTC published a booklet for consumers advising them on how to retain an attorney, and noting that contingency fee rates are negotiable. The FTC is continuing to review the issue of contingency fees.

#### 2. Opposing Abusive Litigation Tactics

WLF opposes litigation tactics by activists and plaintiffs' lawyers that undermine the integrity of the judicial process. WLF cases range from those involving improper pressures and influences on the judiciary, to potential manipulation of stock market prices by the collaboration between short-sellers and class action attorneys.

Rhode Island v. Lead Industries Assoc. On June 2, 2006, the Rhode Island Supreme Court said that it would defer its ruling on whether the State's Attorney General acted improperly in retaining plaintiffs' lawyers on a contingency fee basis to bring a nuisance action against companies that decades ago manufactured lead-based paint. WLF had filed a brief urging the Court to act immediately to bar such arrangements. WLF argued that such fee agreements create an inherent conflict of interest and constitute an improper delegation of a ---State's-police powers.--In its June 2 ruling, the court noted that an appeal from the underlying litigation, which alleges that the continued presence of lead paint on Rhode Island houses represents a public nuisance, is expected to reach the Supreme Court in due course. Although the court last year agreed to address the attorney retention issue on an expedited basis, the June

2 ruling said that consideration of the issue was premature until the appeal of the underlying litigation reaches the court. The court said that its review of the attorney retention issue would be assisted if it had before it, at the time of the review, the entire trial record.

Lincoln Property Co. v. Roche. On November 29, 2005, the U.S. Supreme Court overturned an appeals court decision that had made it much more difficult for out-of-state defendants to move their lawsuits from state court to federal court. The decision was a victory for WLF, which filed a brief urging that the lower court decision be overturned. The Supreme Court agreed with WLF that the lower court improperly deemed the defendant corporation a citizen of the state in which it was being sued. As a result, the corporation had been barred from "removing" the case to federal court from state court, because parties generally may invoke the federal courts' "diversity jurisdiction" only when the plaintiffs and defendants are not citizens of the same state. WLF had argued that the ability to remove a case to federal court often is crucial for obtaining a fair trial; corporations in particular often feel the need to move lawsuits to federal courts. The Supreme Court agreed with WLF that the appeals court's analysis was faulty in numerous respects. The Court held, for example, that for purposes of determining diversity jurisdiction, it is never appropriate to take into account the citizenship of parties who could have been named as defendants but were not.

American Home Products, Inc. v. Collins. On April 18, 2005, the U.S. Supreme Court issued an order declining to review an appeals court decision that makes it much more difficult for out-of-state defendants to move their lawsuits from state court to federal court. The decision was a setback for WLF, which had filed a brief urging the Court to review (and ultimately overturn) the lower court decision. The suit at issue is one filed against all the major childhood vaccine manufacturers, and threatens to drive even more manufacturers out of the market. WLF argued that the lower court defined "fraudulent joinder" in an unnecessarily narrow manner. WLF argued that plaintiffs' lawyers regularly join fraudulent defendants to their lawsuits in an effort to prevent out-of-state corporations from moving lawsuits to federal court, which are generally considered less hostile to out-of-state corporations than are state courts. WLF argued that the appeals court decision frustrates the will of Congress that cases of this sort be removable to federal court as a means of ensuring that out-of-state defendants can have their cases heard in an impartial forum.

*Fullerton v. Florida Medical Association.* On July 11, 2006, a Florida appellate court reinstated a defamation lawsuit filed by a doctor against the Florida Medical Association (FMA) and several other doctors, based on the defendants having instigated professional peer review of the plaintiff's expert testimony in a medical malpractice suit. The defendants had begun their investigation because they did not believe that the opinions expressed by the plaintiff doctor in his expert testimony demonstrated professional competence. The decision was a setback for WLF, which filed a brief in the case, urging that the trial court's dismissal of the case be upheld. WLF argued that both Florida law and a federal statute (the Health Care Quality Improvement Act of 1986) provide immunity from money damages to doctors who criticize their peers in connection with peer review proceedings. In reinstating the defamation lawsuit, the appeals court ruled that immunity extends only to complaints regarding a doctor's competence in treating an actual patient, not to competence in expert testimony. WLF entered the case in the trial court in 2004 because the lawsuit presented an important legal issue regarding peer review of expert testimony. Improper expert testimony is a concern of the business community, particularly in asbestos litigation, where studies have indicated that

most claims of asbestos-related diseases are backed by unfounded "expert" interpretations of screening X-rays.

In re Kensington International. In 2003 and 2004, WLF filed a total of three briefs in bankruptcy court and in the U.S. Court of Appeals for the Third Circuit, urging that a federal judge overseeing a contentious asbestos bankruptcy (filed by Owens Corning in the face of a massive number of asbestos claims) be disqualified from hearing the case because of an appearance of partiality. WLF charged that the judge hired two advisors with an impermissible conflict of interest. The highly compensated advisors were attorneys who represent asbestos claimants in other bankruptcy proceedings; WLF charged that the close relationship between the judge and his advisors created an appearance of partiality that requires the judge's disqualification. WLF won a partial victory in December 2003, when the Third Circuit directed the judge to decide no later than January 2004 whether to disqualify himself. When he declined to do so, the case returned to the appeals court. In May 2004, the Third Circuit granted WLF a major victory by disqualifying the judge, and reassigning the case to a different judge.

Stephens v. Evans. On October 14, 2004, the U.S. Court of Appeals for the Eleventh Circuit voted 8-2 to reject a challenge – brought by U.S. Senator Edward Kennedy and others – to President Bush's recess appointment of former Alabama Attorney General William Prior to a seat on the Eleventh Circuit. The decision was a victory for WLF, which filed a brief in the case in support of Judge Prior's appointment. The Court agreed with WLF that the appointment did not exceed the President's authority under the Recess Appointments Clause of the Constitution. WLF's victory became final on March 21, 2005, when the U.S. Supreme Court denied Senator Kennedy's request that it review the case.

G-1 Holdings, Inc. v. Baron & Budd. On December 11, 2001, the U.S. District Court for the Southern District of New York declined to dismiss a damages suit against attorneys who are alleged to have abused the legal process in connection with their handling of asbestos liability cases. The decision was a partial victory for WLF, which had filed a brief in the case in support of the plaintiff, a company that was driven into bankruptcy by the large number of asbestos claims filed against it. The court upheld the plaintiff's right to proceed on two grounds, including a claim that the attorneys tortiously interfered with the plaintiff's efforts to enter into economically advantageous agreements with other manufacturers. WLF argued in - its-brief that the complaint filed against the defendants (three plaintiffs' law firms that have dominated asbestos litigation, plus six lawyers at those firms) amounted to an allegation that they had engaged in a massive conspiracy to undermine the American judicial system. G-1 Holdings (formerly known as GAS Corp.) alleges that the law firms have been inducing potential claimants to commit perjury in order to allow the continued filing of massive numbers of nonmeritorious asbestos suits.

Southern Christian Leadership Conference v. Supreme Court of Louisiana. On May 29, 2001, the U.S. Court of Appeals for the Fifth Circuit handed WLF a victory by unanimously approving restrictions placed by the Supreme Court of Louisiana on the filing of disruptive lawsuits by activist law school clinics in Louisiana. In particular, the Fifth Circuit found that the state court's rule governing the authority of law students to represent clients in litigation was a viewpoint-neutral rule that posed no violation of the First Amendment. WLF had filed a brief in March 2000 urging the Fifth Circuit to uphold the restrictions.

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### **D.** Class Action Reform

Plaintiffs' lawyers often bring nationwide class actions as a means of coercing a settlement, without regard to the merits of the suits. In many instances, inappropriate class certifications are forcing defendants to pay large settlements – because the risk of facing an allor-nothing verdict presents too high a risk, even when the likelihood of an adverse judgment is low. Consumers, of course, ultimately pay the price of such settlements. When the lawsuits do go to trial, they tend to be totally unmanageable, because class members typically have widely varying damages claims, and different sets of laws often apply to class members from different states. WLF has participated in numerous class action cases to present a public interest perspective in favor of reasonable limits on class actions.

Avery v. State Farm Mut. Ins. Co. On August 18, 2005, the Illinois Supreme Court overturned a massive \$1.2 billion judgment against auto insurer State Farm, which (when issued) was the largest judgment ever rendered in Illinois. The decision was a victory for WLF, which had filed three separate briefs over the course of the previous seven years, seeking to overturn the judgment. The case involved charges that State Farm defrauded its customers by requiring them to use generic parts (rather than parts manufactured by the original manufacturer) when having their cars repaired. Most consumer groups and many states favor use of generic parts as a way of holding down repair costs. In its briefs, WLF had argued that State Farm had done nothing wrong and that the suit was unlikely to benefit any consumers but could result in huge fees for the attorneys masterminding the litigation. The Illinois Supreme Court agreed with WLF that the case never should have been certified as a nationwide class action and that, in any event, the plaintiffs failed to establish breach of contract or consumer fraud. WLF's victory became final on March 6, 2006, when the U.S. Supreme Court issued an order declining to review the case.

Merrill Lynch v. Dabit. On March 21, 2006, the U.S. Supreme Court reversed a lower court's restrictive interpretation of the Securities Litigation Uniform Standards Act of 1998, or "SLUSA." The decision was a victory for WLF, which filed a brief urging that the appeals court decision be overturned. In adopting SLUSA, Congress acted to curb abusive class action claims in state court for securities fraud. The appeals court in this case read a restriction into the statute's preemption provision, holding that it allows suits to proceed in state court on behalf of persons who merely hold, rather than purchase or sell, securities. In reversing, the Supreme Court agreed with WLF that SLUSA's language preempts "holder" claims as well as purchaser and seller claims. WLF noted that SLUSA was intended to protect the federal policy of encouraging efficient securities markets by preventing circumvention of Securities Litigation Reform Act of 1995. WLF's brief also argued that a broad reading of SLUSA is consistent with principles of federalism.

Kircher v. Putnam Funds Trust. On June 15, 2006, the U.S. Supreme Court held that securities-law class action defendants do not have the right to appeal from rulings that keep securities class action cases in state courts rather than federal courts. The decision was a setback for WLF, which filed a brief urging the Court to recognize such a right of appeal. The case arises under the Securities Litigation Uniform Standards Act of 1998 (SLUSA), in which Congress acted to curb abusive class action claims for securities fraud. Congress enacted SLUSA to make federal courts the exclusive venue for most securities fraud class action litigation involving nationally-traded securities. The plaintiffs here filed security class actions

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in Illinois state court against mutual fund companies. The defendants sought to have the cases removed to federal court as provided by SLUSA, but the federal district court ruled that it had no jurisdiction and sent the claims back to state court. While acknowledging that the decision to send the case back to state court likely was incorrect, the Supreme Court held that the decision could not be appealed. A silver lining in the Court's decision was its statements that the defendants were entitled to raise their SLUSA defenses in state court, defenses that almost surely will result in dismissal of this case.

In re Simon II Litigation. On May 6, 2005, the U.S. Court of Appeals for the Second Circuit in New York overturned a district court decision that certified a nationwide class action on behalf of smokers seeking punitive damages against the cigarette industry. The decision was a victory for WLF, which had filed a brief arguing that the suit would be wholly unmanageable if it proceeded as a class action on behalf of millions of smokers, each of whose claims depended on a unique set of facts. The Court agreed with WLF that certification of the class violated federal court rules. WLF also argued that certification violated the constitutional rights of both absent class members and the defendants; the appeals court did not reach that issue. WLF filed its brief on behalf of itself and the National Association of Manufacturers.

Engle v. Liggett Group, Inc. On July 6, 2006, the Florida Supreme Court rebuffed efforts by plaintiffs' lawyers to reinstate a \$145 billion punitive damages judgment against the tobacco industry, awarded by a trial court to a class consisting of all Florida smokers who have contracted diseases caused by cigarettes. The decision was a victory for WLF, which filed a brief urging that the judgment, which had been reversed by an intermediate appellate court, not be reinstated. The Supreme Court agreed with WLF that the punitive damages award was improper because it had been entered without any determination that the approximately 700,000 plaintiffs had a valid basis for recovery: there were no factual findings with respect to causation, reliance, comparative negligence, and damages. Moreover, the court said that such factual determinations are necessarily individualized and thus cannot be made on a class-wide basis – thereby precluding further use of class-action proceedings in this case. WLF filed its brief on behalf of itself and the National Association of Manufacturers.

Dura Pharmaceuticals v. Broudo. On April 18, 2005, the U.S. Supreme Court unanimously reversed an appeals court ruling that had applied a very relaxed pleading standard for attorneys filing securities class action cases against publicly-held companies. The decision was a victory for WLF, which filed a brief urging that stricter pleading standards be applied in securities fraud cases. The ruling is likely to curb abusive securities fraud cases; because such suits are very expensive to defend, corporations often make substantial payments to settle even frivolous claims. The Supreme Court ruled that plaintiffs in such cases must establish "loss causation"; that is, they must demonstrate that the drop in price of the security they held was actually caused by public disclosure of the untruthfulness of statements previously made by the defendant company. The Court noted that there may be many reasons, unrelated to the disclosure of alleged misstatements, why the price of a company's stock may drop. The Court agreed with WLF that when Congress enacted the Private Securities Litigation Reform Act in 1995, it intended to prevent class action attorneys from filing securities fraud cases based on little more than a drop in a company's stock price.

Dukes v. Wal-Mart Stores. On December 8, 2004, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit in San Francisco, urging the court to overturn a lower court decision that certified a massive class action against retailer Wal-Mart. The suit was

filed by a small number of female Wal-Mart employees who claim that the company denied them equal pay and opportunities for promotion. But the trial court has certified them as representatives of a class of 1.6 million current and former female employees. WLF argued that the plaintiffs failed to demonstrate that the case could manageably be tried as a class action. WLF was particularly critical of the trial court's decision to rely on the testimony of the plaintiffs' "expert" witness; WLF argued that the plaintiffs failed to establish that the testimony met the standard of "scientific reliability."

Aspinall v. Philip Morris. On August 13, 2004, the Supreme Judicial Court of Massachusetts upheld a trial judge's decision to certify a massive class action based on claims of fraud. The trial judge in the case had ruled that the plaintiffs could seek damages based on phrases like "light" or "low-tar" in cigarette advertisements, even where the cigarette brand did have lower tar under Federal Trade Commission standards, and without any evidence that individual consumers were defrauded. WLF filed a brief in the Supreme Judicial Court on January 23, 2004, arguing that Massachusetts law requires individualized evidence to determine whether individual plaintiffs were, in fact, misled by the allegedly deceptive phrases. WLF further argued that under the "commonality" requirement of Massachusetts class action law, plaintiffs who have not been injured cannot be lumped together into a class with plaintiffs who were injured. Finally, WLF argued that by sweeping aside any requirement of individual causation, the plaintiffs' theory would have disastrous effects, as it would allow the bootstrapping of essentially any fraud action into a mammoth statewide class action.

Stetser v. TAP Pharmaceutical Products Inc. On July 6, 2004, the North Carolina Court of Appeals imposed strict limits on certification of nationwide class action lawsuits, in which the plaintiff seeks to sue on behalf of himself and every similarly situated person throughout the nation. The decision was a victory for WLF, which filed a brief urging that nationwide certification be overturned in this case. WLF argued that lawyers often bring nationwide class actions as a means of coercing a settlement, without regard to the merits of the suits. Such suits tend to be totally unmanageable, because class members will often have widely varying damages claims, and different laws apply to class members from different states. The trial judge in this case tried to avoid these problems by decreeing that all claims would be judged under North Carolina law. The court of appeals agreed with WLF that applying North Carolina law violated the due process rights of the vast majority of litigants who had no connection with North Carolina.

Howland v. Purdue-Pharma, L.P. On December 15, 2004, the Ohio Supreme Court overturned a lower court's decision to certify as a state-wide class action a product liability suit brought by three individuals who claim they were injured due to their use of the defendant's pain-relief medication. The decision was a victory for WLF, which filed a brief urging that the class be decertified as well as an earlier brief urging the Ohio Supreme Court to review the case. WLF argued that personal injury product liability suits are virtually never appropriate for class action treatment because the claims of each class member are unique – for example, each plaintiff must separately establish such elements of his/her tort claim as inadequacy of warning, reliance, causation, and damages. The court agreed with WLF that when, as here, individual issues of fact and law predominate over common issues, class action treatment is rarely appropriate, and that the trial court had given inadequate consideration to the "predominance" issue when it certified the class.

Wilson v. Brush-Wellman, Inc. On November 18, 2004, the Ohio Supreme Court overturned a lower-court decision that certified a class action consisting of thousands of individuals who worked at an Ohio manufacturing facility over the past half-century. The decision was a victory for WLF, which filed a brief in the case urging that the class be decertified. The court agreed with WLF that certification of the class was wholly inappropriate given the widely disparate claims of each of the class members. The case involves workers at an Ohio plant used for producing beryllium alloy; the plaintiffs have no symptoms of disease but want the plant owner to pay to establish a medical monitoring program for all those who have ever worked at the plant. The court ruled that certification was even less appropriate under Rule 23(b)(2) (class actions seeking injunctive relief) than under Rule 23(b)(3), the more commonly invoked class action rule. The court agreed with WLF that a case may be maintained as a class action only if the class is "cohesive"; i.e., common issues of fact and law "predominate" over issues unique to individual class members. The court also agreed that the appeals court erred when it held that the cohesiveness requirement is inapplicable to proposed class actions in which the relief requested is primarily injunctive in nature.

State Farm Mut. Automobile Ins. Co. v. Lopez. On December 6, 2004, the Texas Supreme Court issued a decision that clamps down on the excessive number of class action lawsuits being certified by state trial courts. The decision was a victory for WLF, which filed a brief urging the court to overturn an unwarranted class certification. WLF argued that many defendants are being forced by such certifications to pay large settlements, even though in many instances the suits are nonmeritorious and the cases are wholly inappropriate for class action status. In reversing the certification order, the court agreed with WLF that trial courts should not be permitted to certify a plaintiff class without simultaneously issuing a "trial plan" that explains how they intend the trial to proceed. The court said that the certification order, involving tens of thousands of insurance policy holders with conflicting interests, reflected a "certify now and worry later" approach that it deemed unacceptable. The plaintiffs allege that a mutual insurance company should have rebated a larger percentage of its profits to policyholders, rather than retaining the profits as a reserve against future losses. WLF argued that the case is frivolous, that class action certification was wholly inappropriate, and that the only people that can hope to benefit from class certification are the plaintiffs' lawyers.

Gilchrist v. State Farm Mut. Automobile Ins. Co. On November 18, 2004, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta threw out a lawsuit involving antitrust claims brought on behalf of 70 million car insurance policy holders nationwide. The lower court had certified the case as a nationwide class action; the appeals court held that the case never should have been allowed to go forward at all. The decision was a victory for WLF, which filed a brief urging that the trial court decision be overturned. The appeals court agreed with WLF that the suit was essentially frivolous. But instead of merely decertifying the plaintiff class, the appeals court dismissed the case altogether. The appeals court held that the plaintiffs' antitrust claims involved the "business of insurance," a subject over which Congress has prohibited federal courts from exercising jurisdiction. The named plaintiffs (several Florida residents) had challenged an insurance industry practice of specifying use of parts manufactured by sources other than the original equipment manufacturer ("non-OEM parts") when adjusting claims for damage to insured vehicles. The insurers assert that by retaining the option to specify non-OEM parts, they encourage competition in the automobile repair parts industry and thereby reduce costs to consumers. The plaintiffs alleged that this practice violated the antitrust laws.

*Peterson v. BASF Corp.* On February 18, 2004, the Minnesota Supreme Court declined an opportunity to impose limitations on the certification of nationwide class action lawsuits – suits in which the plaintiff seeks to sue on behalf of himself and every similarly situated person throughout the nation. The decision was a setback for WLF, which had filed a brief urging the Court to limit the certification of nationwide class action lawsuits. The decision did not set an unfavorable precedent, however. Rather, the court invoked a complex procedural rationale for declining to consider the class action issue. This case involves claims by farmers who objected to the manner in which BASF Corp. marketed its herbicides. The trial judge tried to avoid manageability problems by decreeing that all claims would be judged under New Jersey law. WLF argued that applying New Jersey law to all claims violated the due process rights of the vast majority of litigants who have no connection with New Jersey. WLF's loss may yet be overturned: on May 2, 2005, the U.S. Supreme Court vacated the Minnesota decision and remanded the case to the Minnesota courts for reconsideration in light of a recent Supreme Court decision on federal preemption of state law.

*Ysbrand v. DaimlerChrysler Corp.* On November 6, 2003, the Oklahoma Supreme Court declined to reconsider its earlier decision establishing a rule that encourages widespread certification of nationwide class action lawsuits (in which the plaintiff seeks to sue on behalf not only of himself but also on behalf of every similarly situated person throughout the nation). The decision was a setback for WLF, which filed a brief urging the court to grant reconsideration. This case involves a claim by two Oklahoma residents that the minivans they purchased from Daimler-Chrysler were defective because they included air bags that could injure small children due to their rapid deployment. The trial judge sought to avoid unmanageability problems by decreeing that all claims would be judged under Michigan law, the state in which the manufacturer has its headquarters. WLF argued that applying Michigan law violates the due process rights of the vast majority of class members who have no connection with Michigan. Since class members come from all 50 states, WLF argued that the class should be decertified because any trial involving the application of the laws of all 50 states would be too cumbersome. On June 28, 2004, the U.S. Supreme Court declined a petition to review the case.

Green Tree Financial Corp. v. Bazzle. On June 23, 2003, the U.S. Supreme Court overturned a South Carolina court ruling that superimposed class action procedures onto arbitration proceedings despite the absence of any agreement among the parties to proceed in that manner. The decision was a victory for WLF, which in February filed a brief urging that the South Carolina ruling be overturned. WLF argued that allowing arbitrations to proceed as class actions would undermine the effectiveness of arbitration as an efficient alternative to litigation. The Court agreed with WLF that it is up to the arbitrator, not the state courts, to decide whether the parties in an arbitration proceeding actually agreed that their dispute could be decided on a class-wide basis. The Court further agreed that a court's role is limited to determining whether the parties have agreed to arbitration; once that determination is made, all further issues of contract interpretation are to be decided by the arbitrator.

Dow Chemical Co. v. Stephenson. On June 9, 2003, the U.S. Supreme Court announced that it was evenly split (4-4) in this important case concerning class action lawsuits. The result is that the lower court decision remains intact. On December 19, 2002, WLF filed a brief in the Court, urging it to prevent absent class members in a class action lawsuit from relitigating final judgments entered in the lawsuit. This case arises in the aftermath of a 1984 class action settlement of all claims by Vietnam War veterans against manufacturers of the



herbicide Agent Orange. After the \$180 million in settlement funds had been fully expended, two Vietnam veterans developed cancer in the 1990s. They alleged that their disease was attributable to Agent Orange exposure and that their claims should not be barred by the 1984 settlement because their interests had not been adequately represented at the time of that settlement. In its brief, WLF noted that the courts that reviewed the settlement in 1984 unanimously concluded that the settlement was fair to all absent class members. WLF argued that when (as here) that issue has been fully and fairly litigated in the trial court and has been affirmed on direct appeal, it may not be raised anew in connection with a collateral attack on the class action judgment. Allowing such attacks would be unfair to defendants who pay out funds in reliance on the finality of a settlement, WLF argued.

Farmer v. Monsanto. On April 7, 2003, the Supreme Court of South Carolina issued a decision that prevents plaintiffs' attorneys from using South Carolina courts as forums for filing unwarranted nationwide class actions against national companies. The decision was a victory for WLF, which filed a brief in the case urging the court to cut back on class actions. WLF argued that plaintiffs' lawyers often bring such nationwide class actions as a means of coercing settlement, without regard to the merits of the suits. The South Carolina Supreme Court agreed with WLF that such suits are prohibited by a South Carolina statute known as the "Door Closing Statute." The court held that in any class action filed against a company with its principal place of business in another state, only South Carolina residents may be included in the plaintiff class.

Lockheed Martin Corp. v. Superior Court of California. On March 3, 2003, WLF scored a major victory when the Supreme Court of California held that a suit for medical monitoring costs could not proceed as a class action. The plaintiffs alleged that they had been exposed to chemicals allegedly disposed of by the plaintiffs. They did not allege that they had been injured; rather, they sought to recover expenses related to medical monitoring because of their fears that they might suffer injury in the future. The Court agreed with WLF that class action status was inappropriate because members of the proposed class had faced widely varying exposure levels and thus the strength of their claims for medical monitoring varied too widely to permit the case to be considered on a class-wide basis.

General Electric Capital Corp. v. Thiessen. On June 17, 2002, the U.S. Supreme Court declined to grant review in this tort reform case, in which the Court was being asked to impose stricter limits on the certification of class action lawsuits in the federal courts. WLF argued that lower courts are certifying class actions too freely, with the result that defendants are compelled to settle claims, even when they believe the cases lack merit. In this case, an appeals court ordered the certification of a class consisting of all workers who may have been discriminated against on the basis of age. WLF also had argued that an employment discrimination claim in which the plaintiff seeks to recover damages is virtually never appropriate for class action status, because each plaintiff's claim is likely to turn on facts that are unique to his circumstances.

America Online, Inc. v. Mendoza. On October 20, 2001, review was denied in this important class action case. On September 24, 2001, WLF filed a brief with the California -Supreme Court urging it to review an important business case that could have ramifications throughout the country. A California Court of Appeal had held that a forum selection clause in a consumer agreement can be voided by California courts on the basis of California's Consumer Legal Remedies Act (CLRA). If the decision is left intact, businesses operating



anywhere in the United States with customers in California can be forced to litigate any consumer complaint in California rather than in the states specified in the agreement. In this case, Mendoza, an AOL customer, brought a nationwide class action in California against the company because of disputed billing practices, despite the fact that the service agreement provides that any litigation shall be brought in Virginia where AOL is based. The Court of Appeal held that the forum selection clause in the contract agreed to by the parties was unenforceable.

*Comments on Proposed Changes to Federal Class Action Rules.* On January 15, 2002, WLF filed comments in support of the Judicial Conference's proposed changes to Rule 23 of the Federal Rules of Civil Procedure, the rule that governs class action litigation. WLF particularly applauded the proposed curb on excessive attorney fee awards. WLF warned, however, that the proposed changes do not go nearly far enough in correcting the rampant class-action abuses engaged in by many plaintiffs' attorneys. WLF urged that the Judicial Conference adopt further Rule 23 changes – particularly language that would make clear that mass tort action generally should not be tried on a class basis. On September 24, 2002, the Conference approved the proposed changes, which took effect on December 1, 2003.

### **E.** Limiting Punitive Damages

Punitive damages are properly awarded to punish particularly outrageous, tortious conduct in those few instances in which regular damage awards are insufficient to punish wrongdoers and to deter similar misconduct in the future. Plaintiffs' lawyers in recent years have sought to distort this limited rationale by seeking huge punitive damages awards in virtually every case. WLF has gone to court repeatedly to limit the circumstances under which punitive damages can be awarded. WLF argues that such awards undermine economic development and often result in valuable consumer products (such as vaccines) disappearing from the marketplace altogether. When state legislatures adopt laws imposing reasonable limits on punitive damages, WLF has repeatedly gone to court to defend such laws from the inevitable assault by plaintiffs' lawyers.

City of Hope National Medical Center v. Genentech, Inc. On January 26, 2006, WLF filed a brief the California Supreme Court urging it to overturn a compensatory damages award of \$300 million along with an unprecedented \$200 million punitive damages award against Genentech, a biotech company. The company was involved in a contract dispute over royalties with City of Hope Medical Center, which held a patent on synthesized DNA material. WLF argued that if the judgment is not overturned on appeal, businesses involved in typical contract disputes risk debilitating lawsuits by plaintiffs' attorneys not only for normal contract damages, but also for multimillion dollar punitive damages awards. WLF also argued that an excessive award cannot be justified simply because a defendant can afford to pay it without being forced into bankrupt. WLF argued that punitive damages are generally awarded only to punish outrageous, tortious conduct and should not be awarded simply because a party is found to have breached a contract. WLF further argued that the damage award unfairly punishes innocent shareholders.--WLF previously filed a brief urging the California Supreme Court to review the case; in February 2005, the court agreed to do so.

Johnson v. Ford Motor Co. On June 16, 2005, the Supreme Court of California rejected a \$10 million punitive damages award in a consumer fraud case, ruling that the trial court had erred by basing the award on the disgorgement of all profits earned by the defendant during its alleged wrongful conduct against consumers who were not involved in the case. WLF had filed a brief on December 9, 2004, opposing the punitive damages award. The lawsuit was filed under California's Song-Beverly Consumer Warranty Act, which requires various disclosures to car buyers and requires various remedies for consumers who experience persistent trouble with a newly-purchased car. The dealer in the case was found to have significantly misrepresented the repair record of a used Ford Taurus. The purchasers of the car brought suit against Ford Motor Co.; at trial, the jury awarded compensatory damages of \$17,811.60 as well as the \$10 million punitive award.

Lowry's Reports Inc. v. Legg Mason, Inc. The parties to this major copyright infringement case settled the appeal on June 17, 2005, after it was argued before the U.S. Court of Appeals for the Fourth Circuit, but before the court issued any decision. WLF had filed a brief in the Court on July 13, 2004, seeking to overturn a massive jury award of approximately \$20 million in punitive fines against Legg Mason simply because a Legg Mason employee forwarded electronic copies of a copyrighted financial newsletter to other employees. WLF argued that the punitive fines, although within the statutory range provided by the copyright law, were nevertheless grossly excessive, and that the fines did not comport with constitutional and procedural standards.

Simon v. San Paolo U.S. Bank Holding Co. On June 16, 2005, the Supreme Court of California reversed a lower court decision that allowed a \$1.7 million punitive damages award in a business tort case where no personal injury occurred and only economic harm was claimed. WLF had filed a brief on October 13, 2004, urging reversal of the lower court decision, arguing that the award violated the Due Process Clause of the U.S. Constitution. The lawsuit was filed by a businessman who tried unsuccessfully to buy an office building in Los Angeles from a bank. After the transaction fell through, the businessman sued for breach of contract and fraud. A jury found that there was no contract, and determined that the plaintiff's out-of-pocket losses were only \$5,000, but nonetheless awarded the heavy punitive damages. The Supreme Court of California said in its decision that the 340-to-1 ration of punitive damages to compensatory damages was "breathtaking." It reduced the punitive damages to \$50,000, or ten times the compensatory damages.

State Farm Mutual Automobile Ins. Co. v. Campbell. On April 7, 2003, WLF scored a major victory when the U.S. Supreme Court struck down a \$145 million punitive damages award as excessive. The Utah courts had imposed the award against State Farm Mutual Automobile Insurance Company based on State Farm's refusal to settle a car accident lawsuit filed against one of its customers. The Court agreed with WLF that the award violated the Due Process Clause because it vastly exceeded any damages suffered by its insured. Indeed, the insured suffered no out-of-pocket damages, because State Farm paid the entire amount of the tort award rendered against the insured. The Campbell decision is extremely important because the Supreme Court has now made clear that punitive damage awards are never permitted to be significantly greater than the plaintiffs' actual damages. Also, if this punitive damages\_award had not been overturned, all policy holders would have <u>suffered</u> by facing increased premiums.



**Ford Motor Co. v. Romo.** On May 19, 2003, the U.S. Supreme Court vacated the \$290 million punitive damages award in this case involving a claim that injuries sustained in a car accident were made worse because the car's roof was not strong enough. In a victory for WLF (which filed a brief in support of the defendant), the Court remanded the case to the California courts for reconsideration in light of the Court's *Campbell* decision. WLF argued that because the plaintiffs suffered at most \$5 million in actual damages (including pain and suffering), a \$290 million punitive damages award was wildly out of line.

Rhyne v. Kmart Corp. On April 2, 2004, the Supreme Court of North Carolina upheld a North Carolina tort reform statute that imposes limits on punitive damages awards. The decision was a victory for WLF, which had filed a brief supporting the law. Designed to control out-of-control punitive damage awards, the law limits punitive damages in any case to the greater of three times the compensatory damages or \$250,000. The court affirmed a favorable ruling last year by the North Carolina Court of Appeals, which overturned a \$23 million punitive damages award imposed on Kmart Corporation in a case where damages were less than \$20,000. WLF also filed a brief in the case when it was before the appeals court. The Supreme Court agreed with WLF that the law is a reasonable legislative response to runaway jury awards and does not interfere with a plaintiffs' constitutional right to a trial by jury.

Cooper Industries, Inc. v. Leatherman Tool Group, Inc. On May 12, 2001, WLF scored a victory when the U.S. Supreme Court held that appellate courts must provide independent or de novo review of a trial court's determination regarding whether punitive damages awarded by a jury are excessive. The Court agreed with WLF that because punitive damages are private fines intended to punish the wrongdoer, both the Due Process Clause and the Excessive Fines Clause of the Eighth Amendment are implicated by such awards. Consequently, these questions of law should be reviewed de novo rather than on a less rigorous abuse-of-discretion standard that is typically used by appellate courts to review factual issues. In this case, Leatherman Tool Group claimed that Cooper Industries had competed unfairly by using a picture of one of Leatherman's products in its promotional literature. Although the jury found that Leatherman had suffered only \$50,000 in actual damages, it awarded a staggering \$4.5 million in punitive damages, an amount that exceeded the compensatory award by a factor of 90. The Supreme Court vacated the judgment and directed the appeals court to give the verdict careful scrutiny.

In re Exxon Valdez. On November 16, 2001, the U.S. Court of Appeals for the Ninth Circuit overturned the \$5 billion punitive damages award imposed against Exxon Corporation as a result of the oil spill that occurred when the Exxon Valdez ran aground in Prince William Sound, Alaska in 1989. The decision was a victory for WLF, which had filed a brief in the case, a class-action lawsuit filed in the aftermath of the spill. WLF successfully argued that the unprecedented punitive damages award could not be justified based on either of the purposes served by punitive damage awards: deterrence and punishment. The court noted that the oil spill has already cost Exxon \$3.5 billion in clean-up expenses, payment of private claims, and fines. The court agreed with WLF that such costs are, by themselves, more than <u>sufficient</u> to prompt Exxon and other oil companies to take all prudent measures to prevent repetition of the spill.



### F. Antitrust Law Reform

Antitrust law provides important protection to consumers against abusive business practices, particularly price fixing. However, all too often antitrust law is abused by plaintiffs' lawyers who invoke the antitrust laws to prevent the very competition that the laws were intended to encourage. WLF regularly appears in federal court proceedings to ensure that antitrust law is not distorted by those bent on destroying competition.

Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co. On June 26, 2006, the U.S. Supreme Court agreed to review a lower-court decision that imposed substantial antitrust liability on a large company for engaging in "predatory buying" (*i.e.*, buying supplies at too high a price), even though the uncontested evidence demonstrated that the company at all times sold its products at prices that exceeded its costs. The decision was a victory for WLF, which filed a brief urging that review be granted. The parties will now file a new round of briefs, with oral arguments scheduled for either December or January. WLF has pledged to file another brief in support of the petitioner, urging that the Court reverse the lower court decision. In its brief urging review, WLF argued that consumers, as well as the economy as a whole, benefit when companies bid up the prices of goods they seek and that companies should not be punished for engaging in buying competition that is good for consumers. WLF argued that the lower court decision, unless reversed on appeal, will chill pro-consumer activity by companies that seek to avoid potential antitrust liability.

Illinois Tools Works, Inc. v. Independent Ink, Inc. On March 1, 2006, the U.S. Supreme Court issued a ruling that limited antitrust actions against intellectual property owners by rejecting a presumption that the owner of a copyright or patent possesses market power under the antitrust laws. The decision was a victory for WLF, which filed a brief in the case on August 4, 2005, urging the Court to reject that presumption. In its brief, WLF argued that intellectual property has no inherent characteristics that justify shifting the burden of proof in antitrust cases onto the owners of that property. WLF argued that the Federal Circuit's burden-shifting rule would encourage frivolous nuisance suits by rendering it much easier for a suit to survive a motion to dismiss, even where the patent or copyright owner possesses no market power whatsoever. WLF also argued that the rule encourages defendants in patent infringement actions to bring antitrust counterclaims, thus bypassing the requirements of the patent misuse defense created by Congress.

Volvo Trucks North America v. Reeder-Simco GMC. On January 10, 2006, the U.S. Supreme Court issued a decision rejecting a broad interpretation of the Robinson-Patman Act. That antitrust statute prohibits certain forms of price discrimination in commercial transactions (such as transactions between manufacturers and retail sellers). The Justices accepted WLF's position that a manufacturer cannot be held liable under the Act for alleged favoritism among dealers unless the dealers were in competition with one another. WLF filed its brief on May 20, 2005, noting that the appeals court's contrary interpretation of the Act would have banned pricing practices that are common and legitimate in competitive bidding situations. WLF also filed a brief in February 2005 urging the Supreme Court to review the case; in a victory for WLF, the Court agreed to do so in April 2005.

Freedom Holdings v. Spitzer. On May 18, 2005, the U.S. Court of Appeals for the Second Circuit in New York City rejected an antitrust challenge to the Master Settlement



Agreement (MSA), the settlement that ended the massive product liability suits filed by many States against the tobacco industry. The decision was a victory for WLF, which filed a brief urging the court to reject the challenge. WLF argued that the MSA was a reasonable means of addressing a significant public health concern and should not be subject to antitrust challenge by small tobacco companies seeking to increase their market shares. The plaintiffs are two tobacco importers that import cigarettes manufactured overseas by companies other than the four major tobacco companies. The importers complain that a fee imposed on them by the MSA is a device concocted by the States and the major tobacco companies to ensure that the major companies can maintain high prices and thus recoup the fees they pay pursuant to the MSA. The plaintiffs contend that in the absence of the fees and several other features of the MSA to which they object, foreign tobacco companies could and would gain considerable cigarette market share by undercutting the prices of the major tobacco companies. The appeals court agreed with WLF that the plaintiffs had failed to establish that they would be irreparably harmed if an injunction against the MSA were denied, and thus that the plaintiffs were not entitled to a preliminary injunction pending trial.

Texaco, Inc. v. Dagher. On February 28, 2006, the U.S. Supreme Court reversed an appeals court decision that expanded the reach of the price-fixing laws with respect to joint ventures. The decision was a victory for WLF, which had filed a brief asking the Justices to reverse the appeals court decision. The litigation involved two joint ventures formed by Texaco and Shell Oil to take over the gasoline wholesaling and retailing operations of those companies in the United States. The "Texaco" and "Shell" names continue to exist as separate brands under the joint ventures. The appeals court ruled that the companies could be held liable for price-fixing because the joint ventures priced Texaco and Shell gasoline the same. The case was important to the business community because the appeals court's decision, by treating a bona fide joint venture as a cartel, created the potential for antitrust liability for joint ventures in a variety of contexts. WLF also filed a brief in January 2005, urging the Court to review the case; it agreed to do so in June 2005.

3M Company v. LePage's, Inc. On June 30, 2004, the U.S. Supreme Court without comment declined to review a lower-court decision that imposed substantial antitrust liability on a large company for engaging in "predatory pricing" (*i.e.*, for selling its products at too *low* a price), even though the uncontested evidence demonstrated that the company at all times sold its products at prices that exceeded its costs. The decision was a setback for WLF, which filed a brief urging that review be granted. WLF argued that consumers benefit when companies lower their prices and that companies should not be punished for engaging in price competition that is good for consumers. The case involved an antitrust case filed against 3M Company, the dominant firm in the market for transparent tape. The suit was brought by a far-smaller competitor whose share of the tape market is about 10%. WLF argued that the lower-court decision, unless reversed on appeal, would chill pro-consumer price cuts by companies that seek to avoid potential antitrust liability.

Andrx Pharmaceuticals, Inc v. Kroger Co. On October 12, 2004, the U.S. Supreme Court declined to review a lower-court ruling that agreements to settle patent disputes can amount to per se violations of the antitrust laws. The decision not to hear the case was a setback for WLF, which filed a brief in the case, urging that review be granted. WLF argued that parties ought to be encouraged to settle their patent disputes. By raising the possibility that settlements will be subjected to per se condemnation under the antitrust laws, the federal appeals court in Cincinnati is unnecessarily discouraging settlements, WLF argued. The case

involves the settlement of a patent dispute between Hoechst Marion Roussel (HMR) and Andrx Pharmaceuticals, a generic drug manufacturer that wished to market a generic version of one of HMS's patented drugs.

Valley Drug Co. v. Geneva Pharmaceuticals. On September 15, 2003, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta rejected claims that agreements to settle patent disputes can amount to per se violations of the antitrust laws. The decision was a victory for WLF, which filed a brief in the case urging against blanket condemnation of such agreements. The appeals court explained that patents are intended to provide holders with the power to exclude competition; the court agreed with WLF that agreements that settle patent disputes by simply confirming patent holders' power to exclude do not violate the antitrust laws. The appeals court reversed a district court decision that had condemned a patent settlement as a per se antitrust violation. The case involves the settlement of a patent dispute between Abbott Laboratories (which held a patent to manufacture the drug Hytrin) and several companies that wished to manufacture generic equivalents of Hytrin. In October 2004, the U.S. Supreme Court denied a request to review the Eleventh Circuit's decision, thereby leaving in place a conflict between the Eleventh Circuit's decision and the Sixth Circuit's decision in Andrx Pharmaceuticals (see above).

In the Matter of Schering-Plough Corp. On March 8, 2005, the U.S. Court of Appeals for the Eleventh Circuit overturned a ruling by the Federal Trade Commission that would have imposed antitrust liability on two drug companies based on the settlement of a patent dispute. WLF had filed a brief on June 9, 2004, encouraging the court to overturn the FTC's ruling. The settlement agreement (involving Schering-Plough Corp., Upshur-Smith, and American Home Products) settled a dispute involving generic drug companies who wished to manufacture a drug for which Schering-Plough claimed patent rights. The FTC held that the settlement unreasonably restrained trade because the generic companies agreed to delay their entry into the market. In its brief, WLF argued that the FTC's view of patent settlements between drug companies is commercially unrealistic and counter to federal antitrust law. WLF further argued that the FTC's position would deter settlement of patent disputes. WLF also filed a brief when the matter was before the FTC. WLF's victory became final on June 19, 2006, when the U.S. Supreme Court denied the FTC's petition for review of the Eleventh Circuit's decision.

United States Tobacco Co. v. Conwood Co. On January 6, 2003, the U.S. Supreme Court declined to review the largest damages award ever granted in the history of antitrust law enforcement: \$1.05 billion. WLF had argued in its brief urging the Court to grant review that the plaintiff used "junk science" to calculate its alleged damages in a garden-variety business dispute. The plaintiff, a manufacturer of smokeless tobacco, claimed that unfair business practices allegedly employed by one of its competitors inhibited its sales growth. WLF, filing on behalf of four of the nation's leading experts in using economic models to calculate damages (including a Nobel laureate), argued that the evidence submitted by the plaintiff in support of its multi-billion-dollar damages claim failed to conform to basic norms of economic and statistical analysis.

Verizon Communications, Inc. v. Law Offices of Curtis Trinko, LLP. On January 13, 2004, the U.S. Supreme Court reversed an appeals court's unwarranted expansion of antitrust law to cover claims by a telephone customer that the owner of all telephone lines in New York City (Verizon) was failing to maintain its lines properly. The decision was a victory for WLF,



which filed a brief urging reversal. The customer (a plaintiffs' lawyer) claimed that Verizon was purposely providing poor lines in order to prevent other companies from competing with Verizon in local telephone service. The Court agreed with WLF that antitrust law should not be expanded to cover such claims. WLF had argued that use of the antitrust laws to compel the sharing of facilities would deter competition rather than encourage it, by effectively ordering a taking of a company's property – and thereby would deter that company and its competitors from investing in facilities that might be subject to forced sharing.

USPS v. Flamingo Industries. On February 25, 2004, the U.S. Supreme Court held that the U.S. Postal Service is not a "person" under the antitrust laws, and thus may not be sued under the Sherman Act when it engages in anticompetitive conduct. The decision was a setback for WLF, which filed a brief urging that the Postal Service not be given a special exemption. WLF argued that now that the Postal Service has largely been privatized and has begun competing with firms outside its traditional mail-delivery niche, it should be required to abide by the same antitrust laws that restrain the conduct of other businesses. WLF argued that in 1970, Congress enacted the Postal Reorganization Act, allowing the USPS to "sue and be sued," and intended that the USPS be subject to antitrust laws to the same extent as its private competitors.

In re Stock Exchanges Options Trading Antitrust Litigation. On January 7, 2003, the U.S. Court of Appeals for the Second Circuit in New York City ruled that plaintiffs' attorneys should not be permitted to impose new restraints on the securities industry by bringing antitrust suits against the industry. The decision was a victory for WLF, which filed a brief in the case urging the inapplicability of antitrust law. The court agreed with WLF that the securities industry is already fully regulated under the Securities Exchange Act of 1934 and other securities laws, and that Congress did not intend to permit another layer of regulation that would lead to conflicting rules.

*Microsoft Corp. v. United States.* On October 8, 2001, the Supreme Court declined to hear an appeal in the federal government's antitrust suit against Microsoft. In a brief filed in September 2001, WLF had urged the Court to grant review to consider whether to throw out the judgment against Microsoft, based on misconduct by the original trial judge. Although an appeals court had found that the trial judge acted improperly by, among other things, discussing the case with newspaper reporters while the trial was ongoing; and although it had ordered that the trial judge be removed from the case, the appeals court nonetheless upheld the trial judge's finding that Microsoft had violated the antitrust laws. WLF argued that the court of appeals should have vacated the entire judgment because of the trial judge's repeated and flagrant ethical violations that called into question his impartiality.

#### G. Preemption of State Lawsuits/Regulation

WLF believes that it makes little sense for business activity to be subject to multiple, inconsistent layers of government regulation. Thus, when a business activity is comprehensively regulated at the federal level, it makes little sense to permit states to impose their own regulations -- whether in the form of state statutes or state-law tort actions. Whenever there is any indication that the federal government intends its regulations to "occupy the field," WLF has regularly gone to court to prevent states from second-guessing



federal standards by imposing their own regulations. WLF opposes those who argue that lawsuits do not qualify as "regulations" subject to preemption; WLF argues that no rational business will engage in conduct that will lead to tort liability and thus that the threat of tort liability serves to "regulate" business conduct just as effectively as does a written statute.

Bates v. Dow AgroSciences LLC. The U.S. Supreme Court ruled on April 27, 2005, that buyers of pesticides and herbicides can bring state law tort claims against the product manufacturer even where the product and the product label comply with all federal regulatory requirements. The decision was a loss for WLF, which had filed a brief on November 24, 2004, asking the Court to find that federal law preempts such lawsuits. The lawsuit, brought under Texas law, is based on allegations that the herbicide Strongarm caused crop damage because its label failed to warn against use on high-pH soil. In reaching its decision, while finding some state law claims not preempted by FIFRA, the High Court reaffirmed the principle that FIFRA preempts any state law, regulation, or tort action that would impose a labeling requirement different from those of federal law.

**Buckman Co. v. Plaintiffs' Legal Committee.** On February 21, 2001, the U.S. Supreme Court ruled that plaintiffs' lawyers may not second-guess FDA product-approval decisions by filing state-law suits against the product manufacturer. The decision was a victory for WLF, which had filed a brief with the Court arguing that federal law does not permit such challenges because they undermine FDA's authority to regulate the pharmaceutical industry. The suits here were product liability claims against the manufacturers of orthopedic screws used in spinal surgery; the plaintiffs assert that the screws never should have been permitted on the market and that FDA approved marketing only because manufacturers defrauded the FDA in connection with their product-approval applications. The Court agreed with WLF that because FDA has stood by its decision to permit marketing of the screws, federal law prohibits plaintiffs from filing state-law tort actions that in essence second-guess FDA's approval.

Taylor v. SmithKline Beecham Corp. On March 24, 2003, the Michigan Supreme Court upheld a Michigan statute that precludes design-defect tort actions against the manufacturer of any drug that has been approved for sale by the Food and Drug Administration (FDA). The decision was a victory for WLF, which filed a brief in the case, urging that the statute be upheld. The court agreed with WLF that the Michigan legislature acted properly in adopting the statute and that it did not violate a state constitutional provision that prohibits the legislature from delegating its powers to a federal administrative agency. WLF has argued repeatedly that such measures are necessary to hold down health care costs and to ensure that low-income Americans continue to have access to quality health care.

### H. Barring "Junk Science" from the Courtroom

WLF has gone to court repeatedly in an effort to ensure that scientific testimony is not admitted into evidence in a trial unless the trial judge has first reviewed the testimony and determined that it is based on theories generally accepted within the scientific community. All too often, plaintiffs' lawyers attempt to rely on "junk science" to support claims that the conduct of deep-pocketed defendants caused the plaintiffs' injuries.

Aguilar v. ExxonMobil Corp. ("Lockheed Litigation Cases"). On October 10, 2005, WLF filed a brief in the California Supreme Court asking the court to affirm an appeals court ruling that recognized the need for California trial judges to assess the testimony of expert witnesses for validity. The proceeding involves claims by former workers at a Lockheed aerospace plant that their exposure to five solvent chemicals in the workplace caused them to become sick with cancer. The plaintiffs seek to present an expert witness to testify that their cancer was, in fact, caused by those chemicals. The issue before the California Supreme Court is the admissibility of the testimony of that witness where none of the articles and other materials on which he relies demonstrates a link between the chemicals involved and cancer in humans. In its brief, WLF argued that the decisions of the trial court and the Court of Appeal to exclude this testimony were proper.

Zito v. Zabarsky. On May 16, 2006, the Appellate Division of the New York Supreme Court issued an order declining to reconsider a decision that permits expert testimony to be introduced in a medical malpractice case. The decision was a setback for WLF, which filed a brief urging reconsideration. WLF's brief argued that expert medical testimony must be excluded from court proceedings when it is based on "junk science." WLF argued that the testimony should have been excluded because the medical conclusions reached by the "experts" lacked support in the medical literature. The American Medical Association also urged the appeals court to reconsider its decision. WLF argued that allowing the "expert" testimony in this case was particularly inappropriate because it consisted of a claim that an FDA-drug had caused the plaintiff's disease, yet the drug in question has been marketed for decades without any indication in the medical literature that the drug can trigger that disease.

Kumho Tire Company, Ltd. v. Carmichael. On March 22, 1999, the U.S. Supreme Court handed WLF a victory when it unanimously ruled that the criteria outlined in Daubert v. Merrell Dow Pharmaceuticals (its 1993 decision governing the admissibility at trial of expert testimony involving scientific matters) apply as well to all expert testimony, including the technical and engineering issues that were involved in this product liability case. WLF had urged that interpretation in its August 1998 brief. In this case, the plaintiff filed a product liability lawsuit against a tire manufacturer, claiming the tire failed due to a design or manufacturing defect, even though the tire was worn and had been previously repaired. The expert witness, however, never specified what the defect might be. The Supreme Court ruled that the expert's testimony was properly excluded. The Court agreed with WLF that all expert testimony must be subject to the Daubert standards, which bar admission of expert testimony that is not generally accepted among experts within the field. Otherwise, paid experts can become a roadblock to the jury's search for the truth, the Court held.

#### I. Abuse of the Securities Laws

Through its Investor Protection Program, WLF seeks to counsel federal policymakers and educate the public about the lawsuits that are taking millions of dollars from the assets of investors and placing that money in the hands of plaintiffs' lawyers. Class action lawsuits based on claims of securities fraud have long been a lucrative weapon for class action lawyers. Following a decline in a company's stock price, lawyers file a class action suit alleging that the company's officers knew of the stock decline before it took place and that they fraudulently failed to alert investors to the company's vulnerabilities. The lawsuits are



regularly filed without any supporting evidence. By skillfully playing the media, and by threatening to take a company to trial in America's unpredictable civil justice system, the class action lawyers can wreak havoc on stock prices. WLF is advocating regulatory and judicial reforms to protect employees, pensioners, and investors from stock losses caused by abusive litigation.

Woods v. Fox Broadcasting Co. On June 26, 2005, WLF filed a brief in the California Supreme Court urging the Court to review and reverse a court of appeal decision that would second-guess the everyday business decisions made by corporations, their directors, and majority shareholders by requiring them to maximize the value of stock option holders, even if this were detrimental to the interests of the corporation and other shareholders. In Woods v. Fox Broadcasting Company, the court of appeal held that when a corporation enters into a contract with a holder of stock options, there is an implied covenant of good faith in the option contract to maximize the option holder's return if the company's shareholders choose to sell their stock to a third party, even though (1) the corporation has no ability to control the actions of its shareholders, and (2) the option holder's interests. WLF argued in its brief that the lower court decision has compromised the corporation's, the directors', and the controlling shareholders' ability to fulfill their respective fiduciary obligations. On August 24, 2005, the Court denied review.

Washington Legal Foundation v. SEC. On April 28, 2006, WLF settled this Freedom of Information Act (FOIA) case with the Securities and Exchange Commission (SEC). On June 30, 2005, WLF filed suit in U.S. District Court for the District of Columbia against the SEC for failing to provide certain documents WLF sought under the FOIA relating to abusive class action and short-selling practices. As part of WLF's INVESTOR PROTECTION PROGRAM, WLF has filed several complaints with the SEC requesting an investigation into the often questionable relationship between short-sellers of stock (those who sell borrowed shares of stock, in hopes of profiting if the price of the stock drops) and class action attorneys who later sue the targeted company. Such suits usually cause the stock price to drop, and short-sellers thereby profit at the expense of other stockholders. One complaint filed with the SEC by WLF in 2003 involved the short-selling of stock in J.C. Penney Co. that occurred shortly before and after the filing of a class action lawsuit against Eckerd Drug Store, which was then owned by J.C. Penney Co. WLF's SEC complaint requested that the SEC investigate whether the securities laws and regulations may have been violated with respect to the timing of the lawsuit and the communications between the short-sellers of the company's stock and class counsel suing the company. In connection with settlement of the FOIA suit, the SEC agreed with WLF that it had not conducted a proper search for the documents, and it provided WLF with additional documents in March and April 2006.

**Baxter International Inc. v. Asher.** On March 21, 2005, the U.S. Supreme Court declined to review this case, thereby passing on an opportunity to give real meaning to a 1996 federal law that was intended to limit the liability of corporations that make projections ("forward-looking statements") regarding future sales and earnings. The decision was a setback for WLF, which had filed a brief urging that review be granted. The 1996 law creates a "safe harbor" for forward-looking statements; provided such statements are accompanied by "meaningful" cautions, the safe harbor mandates that the statements cannot be used to hold a publicly held corporation liable to its shareholders for subsequent drops in stock prices, regardless how accurate the statements turn out to be. The appeals court interpreted the safe

harbor so narrowly that it provides virtually no protection to corporations. WLF argued that Congress intended to provide broad protection for forward-looking statements in order to encourage companies to provide such information.

Cypress Semiconductor Corp. v. Yourman. On November 5, 2001, the California Court of Appeal declined to reverse a lower-court decision that may encourage an increase in the filing of frivolous securities class actions by plaintiffs' attorneys. The decision was a setback for WLF, which had filed a brief urging reversal. WLF had argued that the plaintiff – which had been the target of a previous, nonmeritorious lawsuit alleging securities fraud – ought to be permitted to proceed with a malicious prosecution lawsuit against the law firm that filed the non-meritorious suit. WLF argued that the superior court's ruling, if upheld, would give plaintiffs' attorneys license to file frivolous securities class actions against corporations that have committed no wrongdoing.

Complaint on Dissemination of Damaging Information Against Bayer Company. On July 13, 2004, WLF filed a complaint with the Securities and Exchange Commission (SEC) requesting that it conduct a thorough investigation of the facts and circumstances regarding the lawfulness of certain communications by plaintiffs' attorneys designed to depress the stock price of Bayer AG, a German company that is traded on the New York Stock Exchange, in order to pressure the company to settle product liability lawsuits against Bayer over its cholesterol drug Baycol. A noted plaintiffs' attorney was quoted as boasting that, in order to pressure Bayer to settle his questionable lawsuit seeking \$550 million, he was disseminating negative information about Bayer to the media to engender damaging stories, which in turn would drive down the price of Bayer stock.

**Complaint on Short-Selling and Class Actions.** On December 19, 2003, WLF filed a complaint with the Securities and Exchange Commission (SEC), the U.S. Department of Justice (DOJ), and the U.S. Attorney's Office in San Francisco, requesting the federal agencies to investigate whether any federal civil or criminal laws were violated with respect to short selling of the stock of Terayon Communication Systems, Inc. (Terayon), and related conduct in a class action securities fraud lawsuit against the company filed by Milberg Weiss Bershad Hynes & Lerach. WLF's complaint centers around a class action lawsuit (*In re Terayon Communication Systems, Inc. Securities Litigation*) pending in federal court in San Francisco. The lead plaintiffs are short-sellers who undertook a "Game Plan" to drive down the price of the stock. At the hearing to disqualify the lead plaintiffs held on September 8, 2003, the trial judge was clearly troubled by the arrangement. "[It] disturbs me the people who are going to drive the litigation are in fact people who are betting on the stock going down." The judge was also troubled by the fact that the short seller did not disclose its short positions in the stock and the role of Milberg Weiss in the litigation.

Complaint Requesting SEC to Investigate Short-Selling in Class Action Case. On January 21, 2003, WLF filed a complaint with the SEC requesting a formal investigation into possible insider trading violations regarding the short-selling of J.C. Penney Co. stock. Based on a Wall Street Journal article, there is evidence suggesting that short-sellers received and traded on information about the timing of the filing of a major class action lawsuit against Eckerd Drug Stores, which is owned by J.C. Penney Co. WLF argues that if the plaintiffs' attorney tipped off the short-sellers as to when the suit would be filed, that could constitute unlawful insider trading. WLF supplemented the complaint with additional information on January 29, 2003.

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Comments on Hedge Fund Regulation. On April 30, 2003, WLF submitted comments to the Securities and Exchange Commission for its consideration in response to SEC's request for public comment regarding the SEC's Roundtable Discussions Relating to Hedge Funds, which were held on May 14 and 15, 2003. In its comments, WLF reiterated concerns outlined in its earlier submissions to the SEC about the problem of plaintiffs' attorneys disclosing material nonpublic information to short sellers, namely, the timing of the filing of major class action lawsuits against publicly traded companies. Some hedge funds short the stock and reap profits when the filing of the suit causes a drop in the price of the stock. WLF subsequently submitted supplemental comments. In late September 2003, the SEC staff issued its report to the Commission.

Petition for Rulemaking Regarding Disclosure of Contacts Between Plaintiffs' Attorneys and Analysts. On March 24, 2003, WLF filed a formal Petition for Rulemaking with the SEC that would require plaintiffs' attorneys to give pre-notification to the SEC and the public about any contacts or communication between plaintiff's attorneys and financial analysts, short-sellers, and other persons whose recommendation or trading could affect the price of the stock of a publicly-traded company. WLF's petition was based on reports of trial attorneys who file class action cases urging analysts to downgrade the value of a stock, hoping that the targeted company will settle the lawsuit.

Congressional Testimony. On May 22, 2003, WLF testified before the House Subcommittee on Capital Markets, Insurance, and Government Sponsored Enterprises (chaired by U.S. Rep. Richard Baker) of the House Financial Services Committee. WLF was asked to testify on the relationship between trial attorneys and short sellers. WLF testified about cases where plaintiffs' attorneys in class action cases may have provided short sellers with information about the timing of the filing of the lawsuits against publicly traded companies which may constitute unlawful insider trading.

#### J. Abuse of the Federal False Claims Act

The federal False Claims Act (FCA) prohibits anyone from submitting to the federal government a "false" claim for payment. Unfortunately, plaintiffs' lawyers have latched on to the FCA and have expanded it far beyond the anti-fraud statute intended by Congress. The FCA includes a qui tam provision that allows individuals to appoint themselves as "private attorneys general" and to sue companies – supposedly on behalf of the federal government. The result is that plaintiffs' attorneys often file FCA suits based on little more than a policy disagreement with actions taken by a private business. WLF frequently litigates in support of the targets of such suits; WLF argues that the FCA's qui tam provision should be read narrowly to prevent abusive lawsuits.

U.S. ex rel. Gilligan v. Medtronic, Inc. On April 6, 2005, the U.S. Court of Appeals for the Sixth Circuit in Cincinnati dismissed a lawsuit that sought to second-guess decisions of the Food and Drug Administration (FDA) that authorize the sale of drugs or medical devices. The decision was a victory for WLF, which filed a brief in support of the manufacturer whose product was being challenged. WLF argued that permitting such suits to go forward would undermine the integrity of FDA's product-approval system and could result in patients being denied access to life-saving medical products. Although it dismissed the lawsuit, the Sixth



Circuit did so on narrower grounds than WLF had urged. The plaintiffs were suing under the False Claims Act (FCA), a federal law that permits bounty-hunting private citizens to file a suit in the name of the federal government against anyone who makes a "false claim" to the government. They alleged that the defendant, a medical device manufacturer, induced health care providers to falsely claim that the manufacturer's products had been properly approved by FDA. The Sixth Circuit held that the information on which the plaintiffs based their lawsuit was publicly available before they filed suit. The appeals court held that under those circumstances, the FCA suit was barred by the "public disclosure" bar, which eliminates federal court jurisdiction over an FCA claim where the plaintiff is not the original source of the allegations. WLF's victory became final on January 9, 2006, when the U.S. Supreme Court denied the plaintiffs' petition for review of the Sixth Circuit's decision.

U.S. ex rel. Riley v. St. Luke's Episcopal Hospital. On May 28, 2001, the U.S. Court of Appeals for the Fifth Circuit ruled 11-2 that the qui tam provision of the False Claims Act (which allows private citizens to sue as "private attorneys general" in the name of the government) does not violate the Take Care Clause and Appointments Clause of Article II of the Constitution. The decision was a setback for WLF, which had filed a brief urging that the qui tam provision be held unconstitutional. The district court had so held, and a Fifth Circuit panel had agreed; but the full Fifth Circuit, sitting en banc, disagreed and overturned the panel's decision. WLF argued in its brief that private plaintiffs may not bring qui tam suits because they lack standing under Article III of the Constitution. WLF argued that such plaintiffs suffer no economic or other injury when a company allegedly makes a false claim to the federal government, and hence, federal courts lack jurisdiction to hear the case.

#### K. Opposing Excessive Asbestos Litigation

Perhaps the best example of litigation run amuck in our nation's courts is the asbestos litigation fiasco. Hundreds of thousands of personal injury suits have been filed against hundreds of companies – many with only minimal connection to asbestos-containing products – and hundreds of thousands of additional suits are expected over the next several decades. While several thousand individuals contracted deadly forms of cancer as a result of their exposure to asbestos, the vast majority of claimants have suffered no discernable injury. Yet, our nation's courts have proven incapable to date of separating the wheat from the chaff. WLF has repeatedly gone to court in an effort to place limits on the mindless award of damages to uninjured asbestos plaintiffs – damages that have driven scores of major companies into bankruptcy and have significantly undermined the claims of those who actually have suffered serious injury.

In re Congoleum Corp. On June 9, 2006, WLF filed a brief in the U.S. District Court for the District of New Jersey, urging it to uphold a \$9 million sanction imposed by a bankruptcy judge on a Washington, D.C. law firm for its unethical behavior while representing a company that filed for bankruptcy in the face of massive asbestos liability litigation. WLF argued that the law firm of Gilbert Heintz & Randolph (GHR) should be required to disgorge all legal-fees-it was-paid-during-the-course of bankruptcy proceedings. -WLF noted that last year the U.S. Court of Appeals for the Third Circuit kicked GHR off of the case based on its unethical conduct. WLF argued that GHR had done tremendous damage to the bankruptcy system by undermining public confidence in the integrity of that system, particularly with

respect to asbestos-related bankruptcies. WLF argued that disgorgement of fees is an appropriate remedy in that it will provide at least partial compensation for the losses caused by GHR.

Owens Corning v. Credit Suisse First Boston. On March 31, 2005, the federal district judge overseeing the Owens Corning bankruptcy proceedings ruled that all pending and future asbestos claims against the company should be assigned an estimated value of \$7 billion, considerably less than the \$11 billion requested by plaintiffs' lawyers representing asbestos claimants. The decision was a modest victory for WLF, which had filed a brief urging that plaintiffs' lawyers not be permitted to make off with the lion's share of the corporation's assets by inflating the asbestos-related liability claims of their clients. The district court agreed with WLF that pre-bankruptcy asbestos awards issued by state courts are not an accurate gauge of the value of pending and future claims, because past awards were inflated by such questionable practices as: (1) venue shopping, with many plaintiffs filing suit in "friendly" jurisdictions far from their homes; (2) plaintiffs identified through x-ray screenings of large numbers of individuals exhibiting no symptoms of disease; (3) erroneous x-ray readings; (4) over-payment of "unimpaired" claimants; (5) grouping large numbers of plaintiffs in a single suit; (6) "global" settlements of large numbers of cases; and (7) multiple punitive damages awards based on the same alleged misconduct. The court cited those practices as its basis for reducing asbestos claims by nearly 40%.

**Rehm v. Navistar.** On January 6, 2006, WLF, along with a dozen leading industry and insurance trade organizations, urged the Kentucky Supreme Court to affirm a lower court ruling rejecting attempts to circumvent Kentucky workers' compensation program. In *Rehm v. Navistar*, the plaintiff was an employee of a company that installs industrial conveyor systems and machinery. That company was hired as a subcontractor over the years by some 15 different companies to install equipment at their facilities. The plaintiff claims he was exposed to asbestos at those premises and contracted malignant mesothelioma. Under Kentucky law, a contractor becomes a statutory employer, and thus is immune from tort liability, if the work it subcontracted is a "regular or recurrent" part of the work or trade of the contractor. In that circumstance, injured employees are compensated under the state's workers' compensation program and cannot sue the companies separately under tort liability.

Petition for Asbestos Administrative Order. On May 26, 2006, WLF joined with over -a dozen leading industry and trade organizations in urging the Michigan Supreme Court to adopt either of two proposed administrative procedures to help alleviate the asbestos litigation crisis. The crisis is fueled by thousands of lawsuits filed by plaintiffs' attorneys on behalf of individuals who may have been exposed at one time to asbestos but are not sick, forcing companies into bankruptcy while leaving little or no funds to compensate those with significant illnesses. WLF's submission was a follow-up to a similar 2004 filing requesting that the Michigan Supreme Court grant a petition filed by over 60 Michigan asbestos lawsuit defendants that would allow the sickest asbestos claimants to have their cases litigated, and would place most of the other cases where claimants have no illness on an "inactive docket." Those placed on the inactive docket could later reactivate their lawsuits if they develop an asbestos-related disease.

3M Company v. Johnson. On January 20, 2005, the Mississippi Supreme Court overturned a record \$150 million asbestos product liability judgment awarded to six men, none of whom was injured. The decision was a victory for WLF, which had filed a brief arguing

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that the award was a textbook example of the tort system run amok, with damages being freely awarded even in the absence of evidence of exposure to asbestos or negligence on the part of the defendants, proof that any alleged negligence caused the plaintiffs' alleged injuries, or proof that the plaintiffs suffered damages. The Supreme Court agreed with WLF that none of the plaintiffs demonstrated that he had suffered any injury resulting from his use of the defendant's products. The court was particularly critical of the trial court's decision to consolidate numerous claims against numerous defendants into a single trial; the court agreed with WLF that the consolidation deprived defendants of their rights to have defenses adjudged on an individual basis.

Crown Cork & Seal Co. v. Ieropoli. On February 19, 2004, the Pennsylvania Supreme Court voted 4-3 to strike down a Pennsylvania tort reform statute that limited the liability of certain manufacturers that have been unfairly drawn into the asbestos tort litigation morass. The court ruled that the statute violated the state constitution by seeking to change liability rules applicable to pending lawsuits. The decision was a setback for WLF, which filed a brief urging the court to uphold the statute. The statute stated that a Pennsylvania corporation that never manufactured asbestos products could not be brought into asbestos suits simply because it acquired a company that formerly manufactured asbestos products but had ceased doing so long before the acquisition took place. WLF argued that the statute is constitutional and promotes the public interest by limiting liability of such companies.

Norfolk & Western Ry. Co. v. Ayers. On March 10, 2003, the U.S. Supreme Court declined to bar "fear of cancer" emotional distress damage awards to those who have been exposed to asbestos, even in the absence of evidence that they have developed cancer. The 5-4 decision was a setback for WLF, which partnered with former Attorney General Griffin Bell to file a brief in the case. WLF argued that awards to uninjured plaintiffs are becoming all too common in asbestos litigation and are undermining the fairness of the nation's tort system. The Court held that so long as a plaintiff has suffered some physical impairment due to his asbestos exposure (in this case, a mild bronchial condition called asbestosis), he is entitled to recover for whatever emotional injuries are claimed to have been caused by the exposure. In dissent, Justice Kennedy said that the practical effect of the ruling will be to deplete funds that would otherwise be available to compensate the truly injured.

Petitions on Fraudulent Asbestos Claims. In March 2004, WLF launched a nationwide project designed to focus the attention of prosecutors and bar authorities on fraudulent evidence in asbestos cases. In petitions filed in Illinois, Mississippi, Missouri, Texas, Washington, and West Virginia, WLF charged that plaintiffs' attorneys are filing thousands of asbestos lawsuits on behalf of claimants who are neither ill nor physically impaired. WLF charged that attorneys collect plaintiffs through questionable screening programs; it requested that bar authorities investigate the manner in which those programs are conducted. WLF charged that because thousands of asbestos tort suits have been filed on behalf of healthy claimants, more than 30 major corporations have been driven into bankruptcy, yet those truly injured by exposure to asbestos cannot gain speedy access to the compensation they deserve.

### L. Fairness in Government Contracting

The federal government enters into so many contracts with private companies that an entire body of law has developed to govern the rules for such contracts. WLF has participated

in government contracts litigation to ensure that the rules that develop in this area are fair both to taxpayers and to contractors.

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Vietnam Assoc. for Victims of Agent Orange v. Dow Chemical Co. On February 13, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit urging the court to reject a class action lawsuit brought on behalf of Vietnamese nationals, including former North Vietnamese and Viet Cong fighters, against a group of American chemical companies for their role in producing Agent Orange during the Vietnam War. The plaintiffs, the Vietnam Association for Victims of Agent Orange/Dioxin ("VAVAO") and various Vietnamese nationals, claim that the U.S. military's herbicide spraying program during the war was illegal under international law. In its brief, WLF focused on the applicability of the government contractor defense to international law claims, arguing that the defense applies to such claims. WLF noted that allowing tort suits against defense contractors based on alleged violations of the laws of war by U.S. forces would be inequitable and would have serious deleterious effects on military procurement.

Rumsfeld v. United Technologies Corp. On November 10, 2003, the U.S. Supreme Court issued an order declining to review this case, which involved the circumstances under which a party to a government contracts dispute may introduce expert testimony. In a brief filed in August 2003, urging that review be granted, WLF argued that expert testimony is admissible regarding what should be counted as a "cost" under the federal Cost Accounting Standards (CAS). The CAS are a set of rules that govern the accounting practices of government contractors. WLF argued that permitting the testimony of proposed experts (such as, in this case, professors of economics and accounting) would assist trial courts greatly in determining the meaning of the CAS. The U.S. Court of Appeals for the Federal Circuit nonetheless held that such expert testimony is never permissible.

General Motors v. U.S. On October 31, 2003, WLF filed a brief in the U.S. Supreme Court, urging it to review an appeals court decision that could rewrite contracts between the U.S. and its contractors – to the detriment of those contractors. The appeals court held that in many cases, a government contractor is not permitted to charge the government for pension costs directly attributable to the contract, even though federal Cost Accounting Standards appear to provide for such charges. Noting that the disputed charges amounted to more than \$200 million in this one case alone, WLF argued that the appeals court decision is wholly inconsistent with the past practice of the Defense Department. On December 1, 2003, the Supreme Court issued a decision declining to hear the case.

### M. Opposing Creation of New Tort Liability Theories

Plaintiffs' lawyers repeatedly ask courts to create new legal theories under which deeppocketed defendants can be held liable for damages suffered by their clients. WLF repeatedly goes to court to oppose such efforts; WLF believes that the greatest shortcoming in the American legal system is that too many blameless defendants are being dragged into court to defend against extravagant liability theories, not that plaintiffs have been unable to recover damages from blameworthy defendants.

Abdullahi v. Pfizer. On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging it to dismiss claims that a drug company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits asserting that doctors violated international law by allegedly treating patients without first obtaining the patients' informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a law that lay dormant for nearly 200 years before activists recently began seeking to invoke it. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF argued that it has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations.

*Neer v. Pelino.* On May 17, 2006, WLF filed a brief with the U.S. Court of Appeals for the Third Circuit in Philadelphia urging the court to affirm a lower court decision that private litigants do not have the right under Section 304 of the Sarbanes-Oxley Act (SOX) to sue officers and directors of a publicly traded company to disgorge bonuses and profits for alleged errors in the company's accounting statements filed with the Securities and Exchange Commission (SEC). Instead, WLF argued, Congress intended that only the SEC has the authority to enforce the penalty provision. WLF argued that Congress did not manifest any intent to allow private litigants to enforce the penalty provision and that to permit such suits would be contrary to sound public policy. In particular, enforcement of Section 304 would not be uniform and might force blameless officers to disgorge profits simply as a means of avoiding expensive lawsuits. In addition, plaintiffs' attorney fees would be siphoned from disgorged funds that otherwise would have been returned to the company and its shareholders had the SEC instigated the penalty proceedings.

Grisham v. Philip Morris USA, Inc. On March 9, 2006, WLF filed a brief in the California Supreme Court, urging it to uphold the dismissal of tort claims filed against cigarette companies based on allegations that the companies wrongfully addicted the plaintiffs to tobacco. WLF argued that such claims by long-time smokers are barred by the statute of limitations because the plaintiffs knew (or should have known) for decades that they were addicted to cigarettes, yet they waited until 2002 to file suit. WLF urged the court to reject the plaintiffs' contentions that their addiction to tobacco rendered them incapable of recognizing their addiction. The public has known for decades that tobacco is addictive, WLF argued; if there was any doubt on that score, it was eliminated in 1988 when the Surgeon General confirmed that tobacco is addictive. In light of that knowledge, individuals who sue based on claims that they were wrongfully addicted should not be permitted to wait for decades before filing suit, WLF argued.

Balbuena v. IDR Realty LLC. On February 21, 2006, the New York Court of Appeals declined to bar illegal aliens who are plaintiffs in personal injury lawsuits from recovering wages lost as a result of their injuries. The decision was a setback for WLF, which filed a brief in the case, urging that such damages be barred. WLF argued that awarding illegal aliens the wages they would have earned if they had not been injured would be inequitable because it would have been illegal for them to actually earn those wages by taking a job in this country. WLF argued that such awards are preempted by federal law because they undermine federal immigration policy by encouraging more illegal aliens to enter the country and to seek employment. The Court of Appeals rejected WLF's position, contending that to deny



damages for lost wages would encourage employers to reap the economic benefits of hiring illegal aliens. This personal injury tort suit was filed by Gorgonio Balbuena, an illegal alien who was severely injured while working for Taman. Balbuena alleges that his injuries were caused by Taman's negligence. Because Taman no longer exists, Balbuena filed suit against (among others) IDR Realty LLC, which owns the property where the injury occurred. Balbuena's right to recover for his injuries and medical expenses was not challenged; but WLF challenged Balbuena's claim that he is entitled to recover the wages he could have earned in this country had he not been injured.

**Paramount Citrus v. Superior Court.** On January 5, 2006, the California Supreme Court declined to review a trial court decision that allows illegal aliens who file tort actions to seek recovery for damages not yet incurred, and to base those damage claims on an assumption that they will remain in the United States for the remainder of their lives. The decision was a setback for WLF, which filed a brief urging the court to grant review. WLF argued that, because illegal aliens have no right to remain in this country, such damage claims should be limited to the amount of damages that would be incurred if the illegal alien returned to his native country. The case involves an illegal alien who was permanently disabled in a car accident. He seeks recovery of the cost of providing him "life care" for the next 50 years. The present value of such care is \$5.3 million if he remains in the United States, but only \$1.8 million if he returns to his native Mexico. WLF argued that because the plaintiff has no right to remain in this country, he has no right to recover damages computed based on an assumption that he will remain here. WLF also argued that granting the plaintiffs' damage claims would undermine federal immigration policy.

*Philip Morris USA v. Boeken.* On March 20, 2006, the U.S. Supreme Court declined to review a California court decision that imposed a massive liability award against the manufacturer of a "light" cigarette on the ground that the public believes that "light" cigarettes pose less of a health risk than they actually do. The order, issued without comment, was a setback for WLF, which filed a brief urging the Court to review the case. WLF argued that such tort claims are preempted by federal law because cigarette manufacturers already display all the health and safety warnings mandated by the federal government. WLF argued that Congress determined, when it adopted the Federal Cigarette Labeling and Advertising Act, the health warnings that manufacturers must include in advertising and on their labeling. WLF argued that states should not be permitted to second-guess that congressional determination by allowing tort-suits-that would require manufacturers to impose additional warning requirements. WLF argued that Congress has passed a series of laws designed to allow companies in a wide variety of industries to advertise nationwide by imposing a uniform advertising standard and barring States from adopting conflicting standards. WLF argued that the California court decision could have the effect of undermining all such laws.

Bank of China v. NBM L.L.C. On November 15, 2005, the U.S. Supreme Court dismissed this case, thereby preserving the lower court's decision in this important case arising under RICO, the federal anti-racketeering law. The dismissal was a victory for WLF, which had filed a brief urging the Court to affirm the lower court decision and thereby halt the seemingly endless expansion of civil lawsuits brought under RICO. WLF argued that plaintiffs should not be able to recover in a civil RICO action unless they can demonstrate that they "reasonably relied" on the defendant's alleged fraudulent misrepresentations. WLF argued that reliance has always been an element of common-law fraud actions and should be required in RICO actions as well. The case involved loans made by the Bank of China to various



individuals and firms involved in currency trading. The bank alleged that in order to obtain the loans, the defendants submitted false financial information. The defendants responded that the bank's employees and officers were fully aware of their precarious financial position and did not rely on any of the financial information in making the loans. Instead, they alleged, the bank made the loans because it wanted to earn the millions of dollars in fees and interest generated by the loans and was willing to assume the known risks that the loans would not be repaid if the defendants' companies failed – which they eventually did. The appeals court, whose decision stands as a result of the Supreme Court's dismissal, held that the bank could not recover under RICO without demonstrating reliance on the allegedly false financial information.

Dolan v. United States Postal Service. On February 22, 2006, the U.S. Supreme Court ruled that the United States Postal Service (USPS) is not immune from lawsuits under the Federal Tort Claims Act (FTCA) where postal employees' negligence causes physical injuries and property damage to the public. The Court agreed with WLF's argument, set forth in WLF's July 2005 brief, that Congress did not provide USPS with such special immunity and thus should be held liable just as private carriers would be held liable for similar negligent conduct. In this case, a postal carrier delivered postal matter to Mrs. Dolan's home and negligently piled the mail and magazines on the porch by the door where a person leaving the home would likely step. Mrs. Dolan slipped on the mail and was severely injured. The Court agreed with WLF that Congress only intended immunity for damage, loss, or delay of the mail itself, not for physical injuries due to negligence of postal employees.

**Price v. Philip Morris, Inc.** On December 15, 2005, the Illinois Supreme Court overturned a \$10.1 billion award against Philip Morris, Inc., on the ground that the conduct complained of by the plaintiffs – the labeling of some cigarette brands as "light" or "low tar" – was authorized by the Federal Trade Commission. The decision was a victory for WLF, which filed a brief in 2003 on behalf of itself and the Illinois Civil Justice League opposing the lawsuit. The trial judge had levied a \$7.1 billion award for compensatory damages against the company based on claims that the company had fraudulently implied that its low-tar cigarettes are safer than ordinary cigarettes. The trial judge also awarded \$3 billion in punitive damages. On appeal, the Illinois Supreme Court noted that Illinois law does not permit fraud claims based on conduct "specifically authorized" by federal regulators. The Court determined that the FTC had affirmatively-permitted the use-of the descriptions in question in two consent orders.

Brodsky v. Grinell Hauling, Inc. WLF scored a victory on August 9, 2004, when the New Jersey Supreme Court upheld an appellate court ruling that would prevent the jury from being told the particulars of New Jersey's comparative fault statute in a case where a responsible party in a tort action was bankrupt. If the jury were told of the statute, it would likely shift liability to a solvent defendant company in order to compensate the plaintiffs for their injuries. On February 19, 2004, WLF filed a brief in the Court, urging it to maintain an equitable system for allocating tort liability when several defendants are deemed liable for inflicting injury. Under current law, each defendant must pay a share of the damage award based on the jury's findings regarding each defendant's share of the blame. The plaintiffs are asking the court to change that system when one of the defendants has declared bankruptcy and thus cannot pay its share of any judgment; the plaintiffs ask that juries be instructed to allocate damages only among the solvent defendants. WLF argued that it would be extremely



unfair to require a defendant deemed only 5% responsible for the plaintiff's injury to bear 100% of the damages simply because other defendants are bankrupt.

Doe v. Unocal Corp. On April 22, 2003, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, urging the court to rein in suits being filed under the Alien Tort Statute (ATS) – which is being used increasingly by activists to challenge the overseas conduct of U.S. corporations. The ATS – a 1789 law that was intended merely to provide federal court jurisdiction in a limited number of cases involving mistreatment of ambassadors and piracy on the high seas – was held by a Ninth Circuit panel to allow a suit against Unocal Corporation based on Unocal's alleged mistreatment of Myanmar citizens during construction of a pipeline in Myanmar. In urging the entire Ninth Circuit to overturn that Ninth Circuit panel decision, WLF argued that the ATS does not (as the panel held) make alleged violations of international law actionable in federal court. WLF argued that only the Constitution or laws adopted by Congress – not international law – are enforceable in federal court. The parties settled the case in December 2004.

Korea Supply Co. v. Lockheed Martin Corp. On March 3, 2003, the California Supreme Court issued a ruling that significantly reins in abusive lawsuits being filed in California by plaintiffs' lawyers under that State's Unfair Competition Law (UCL). The decision was a victory for WLF, which filed a brief in the case. The court agreed with WLF that the California legislature adopted the UCL as a means of ensuring that victims of unfair or fraudulent business practices can recover their out-of-pocket losses, not as a means of permitting plaintiffs' lawyers to extort large settlements from legitimate businesses in cases where the plaintiff has suffered no real loss. In particular, the court agreed with WLF that a plaintiff that suffered no losses should not be permitted to recover profits the defendant earned as a result of its allegedly unfair trade practices.

Anschutz v. Superior Court. On November 19, 2003, the Supreme Court of California denied a petition to review a lower court decision that permits out-of-state individuals and businesses to be sued in California based solely on the California activities of corporations in which they are shareholders. The decision was a setback for WLF, which in October filed a brief urging the court to grant review. WLF argued that no one should be subject to suit in a state with which he lacks minimum contacts, and that ownership of shares in a company is insufficient to establish such contacts.

Mt. Olivet Tabernacle Church v. Emerson Electric Co. On November 13, 2002, the Pennsylvania Supreme Court upheld a large tort judgment in a case in which the plaintiff destroyed key evidence that prevented the defendant from mounting an effective defense. The decision was a setback for WLF, which filed a brief urging that the judgment be overturned as a sanction for the plaintiff's misconduct. WLF argued that sanctions should be imposed on a party to litigation whenever he is responsible for the destruction of relevant evidence and the opposing party is prejudiced thereby. The case arose in the aftermath of a fire that destroyed a church; the plaintiff alleged that the fire was caused by a defective water heater manufactured by the defendant, but the plaintiff destroyed the fire scene before the manufacturer had an opportunity to inspect it.

**EEOC v. United Parcel Service, Inc.** On September 20, 2002, WLF scored a victory when the U.S. Court of Appeals for the Ninth Circuit ruled that a package delivery company did not violate the Americans with Disabilities Act (ADA) when it required that its truck



drivers meet certain visual acuity standards for safety purposes. The company's standards excluded only those job applicants with severe sight loss (worse than 20/200 vision) in at least one eye. WLF argued in its brief, and the Court agreed, that those who can see well out of one eye generally do not qualify as "disabled" under the ADA and thus may not invoke the law's protections. WLF also argued that there are valid safety reasons for a company not to hire drivers who can only see out of one eye.

Comments on Uniform Commercial Code Revisions. On May 9, 2003, concerned by proposed revisions to Articles 1 and 2 of the Uniform Commercial Code, WLF submitted comments to the National Conference of Commissioners on Uniform State Laws and the American Law Institute. WLF argued against adoption of the proposed changes. WLF argued that the revised Articles 1 and 2 – if adopted by the NCCUSL and ALI and enacted by state legislatures – would create uncertainty in business transactions. The revisions would also introduce new forms of tort-like liability that are properly within the province of tort law.

#### N. Opposing Criminalization of Business Practices

There has been a disturbing trend over the last decade by government regulatory agencies and federal prosecutors to criminalize normal business activities. Even unintentional and minor infractions of any of the thousands of regulations facing the business community are treated as major felonies, when it often would be far more rational to address them administratively. It appears that government regulators and prosecutors think that the free enterprise system is the enemy, and that honest businessmen should be targeted. WLF is at the forefront in the courts opposing this unfair and excessive criminalization of business activities.

Arthur Anderson LLP v. United States. On May 31, 2005, a unanimous Supreme Court reversed the criminal conviction of Arthur Andersen for witness tampering, ruling that the jury instructions did not require a showing of criminal intent. WLF had filed a brief in the Court in February 2005 urging it to reverse a court of appeals decision that would criminalize legitimate business housekeeping activities without prosecutors having to show any criminal intent. In Arthur Andersen LLP v. United States, the U.S. Court of Appeals for the Fifth Circuit upheld the high profile criminal conviction of the accounting firm for willful obstruction of justice. Andersen supervisors had simply reminded company employees to follow the company's legitimate document retention policy prior to the initiation of an investigation of Andersen by the Securities and Exchange Commission (SEC) into the Enron matter. In a brief filed on behalf of itself and the U.S. Chamber of Commerce, WLF argued that the lower court's broad reading of the obstruction of justice statute is not only inconsistent with the rulings of other circuit courts, but also could subject thousands of businesses to criminal prosecution for failing to retain documents that may be subject to future government agency investigations. WLF had also filed a brief in the Court in 2004 successfully urging it to review the case.

United States v. Fanfan; United States v. Booker. On January 12, 2005, the U.S. —Supreme Court ruled that the federal Sentencing Guidelines violate a person's Sixth Amendment right to a jury trial when judges impose a sentence under those guidelines based on aggravating factors not found by a jury beyond a reasonable doubt. But the Court remedied this violation by striking down the provision of the Sentencing Reform Act of 1984 that made



the guideline sentences mandatory for federal judges. The guidelines are now only advisory; that is, although judges should consider them in deciding what sentence to impose in a particular case, they are not strictly bound by them. This decision will greatly diminish the power of overzealous prosecutors who effectively controlled what prison sentences would be meted out, and restore sentencing discretion to experienced and impartial judges. The Court also struck down the so-called "Feeney Amendment" regarding appellate review, thereby giving more discretion to the sentencing judge.

Thurston v. United States. On March 20, 2006, WLF filed a brief in the U.S. Court of Appeals for the First Circuit in Boston urging the court to uphold the district court's threemonth sentence imposed on a business executive for relatively minor misconduct - the same sentence a different district judge had imposed in an earlier sentencing proceeding under the then-mandatory Sentencing Guidelines. The Justice Department is appealing from the sentence, and is asking the appeals court instead to direct that a five-year sentence be imposed. WLF's brief argued that William Thurston deserves no more than three months in federal prison, particularly given the Justice Department's agreement to a plea bargain that allowed a more culpable co-defendant to avoid serving any jail time. WLF argued that the Justice Department, by insisting that the district judge should have followed Sentencing Guidelines provisions that would have resulted in a longer sentence, is in effect arguing that the voluntary Sentencing Guidelines should be deemed mandatory - despite a ruling last year by the U.S. Supreme Court that the Guidelines are unconstitutional and thus are no longer mandatory. In an earlier victory for WLF, the U.S. Supreme Court in 2005 overturned a prior First Circuit decision that had directed the district court to impose a lengthy prison sentence on Thurston. WLF has focused attention on the Thurston case for the past two years as an example of inappropriate federal government efforts to overcriminalize business activities.

Opposing Proposed Regulations Requiring Preservation of Physical Evidence. On March 6, 2006, WLF submitted formal comments to the Chemical Safety and Hazard Investigation Board opposing proposed regulations that would require owners and operators of chemical and other companies to preserve certain physical evidence, including computer records and other information, following an accidental release of a toxic chemical or other hazardous substance into the ambient air. In addition, the proposed rule would trigger civil or criminal referral by the CSB if there is a "knowing failure to comply" with the proposed regulations. WLF argued that the CSB does not have the statutory authority to promulgate the proposed preservation of evidence rule, that the Board had failed to demonstrate that there was any need for the rule, and that the rule would allow the Board to make criminal referrals even if there was no criminal intent on the part of the company or its employees for not complying with the rule.

Attorney-Client Privilege. On March 29, 2006, WLF filed comments with the U.S. Sentencing Commission along with a coalition of business groups, urging the Commission to remove certain language from amendments of the Sentencing Guidelines that, if left intact, would harm the attorney-client privilege. Lawyers for companies and other organizations play a key role in helping these entities and their officials comply with the law and act in the entities' best interests. To fulfill this role, lawyers must enjoy the trust and confidence of managers and boards and must be provided with all relevant information necessary to properly represent the entity. By requiring routine waiver of the attorney-client and work product privileges, the amendment will discourage companies and other organizations from consulting with their lawyers, thereby impeding the lawyers' ability to effectively counsel compliance



with the law, WLF argued. In 2005, WLF urged the Commission to place this issue as a top priority on its agenda for the next round of amendments to the Sentencing Guidelines.

Comments on Corporate Compliance Programs Advisory Committee. On May 19,... 2002, WLF filed comments with the U.S. Sentencing Commission's Advisory Group on Organizational Guidelines, urging it to open its meetings and to provide the public with an opportunity to submit further comments and testimony on specific issues that the Advisory Group will decide to study. In addition, WLF urged the Advisory Group to conduct thorough empirical research on the effectiveness of the criteria the Commission developed for corporate compliance programs, an issue on which the Advisory Group intends to focus its attention. The corporate compliance programs determine the level of fines that a court may impose on a convicted business entity. In general, a more detailed and comprehensive compliance program should result in reduced fine levels for that company, should it be prosecuted and convicted. On March 15, 2004, WLF filed further comments with the Commission opposing the Commission's proposed amendments to the Sentencing Guidelines that would unduly expand the definition of an "effective compliance program" for corporations in order for the company to be eligible for reduced criminal penalties. Under the current guidelines, a company will be deemed to have an effective compliance program if it is designed to reasonably detect and prevent criminal conduct within the company. Under the proposed amendment, however, an effective compliance program must be designed to ferret out and prevent violations of any law or regulation, whether civil or criminal, and whether federal, state, or local. In May 2004, the Commission adopted WLF's suggestion by deleting the reference to non-criminal laws, but added that the compliance program must include an ethical component that requires employees to comply with vague and undefined ethical standards.

Comments on Decriminalization of Regulatory Offenses. On June 6, 2003, WLF sent a critique and proposal to U.S. Attorney Timothy Burgess who heads the Justice Department's Attorney Advisory Group on prosecutorial policies with respect to bringing criminal actions for environmental infractions. This request relates to WLF's proposal in 2001 that DOJ update a 1983 study and report by DOJ's Office of Legal Policy, *Decriminalization of Regulatory Violations*, as a basis for a long overdue reform of our criminal justice system with respect to the criminal prosecution of regulatory offenses. WLF believes that such an effort by DOJ will help to restore the regulated community's and the public's respect for the law and law enforcement, and thus promote the public interest and sound public policy. Our current regulatory system is unquestionably an extensive morass of complicated, confusing, and burdensome statutes, rules, and regulations. This situation is further exacerbated by the fact that many of these laws, rules, and regulations provide for the imposition of criminal penalties upon companies, their officers, and employees for violating them and, in some cases, even if they did so unintentionally.

Comments on Principles of Federal Prosecution. Pending before DOJ is WLF's 2001 request filed on behalf of itself and Business Civil Liberties, Inc., that the U.S. Department of Justice (DOJ) update and publicly recommit itself to adhering to the Principles of Federal Prosecution, especially in white collar crime cases. The Principles contains guidelines meant to channel and limit the powerful force of federal prosecution. Perhaps most importantly, it suggests that federal prosecution is not warranted when (1) no substantial federal interest would be served by prosecution and/or (2) there is an adequate non-criminal alternative to prosecution. WLF argued that the DOJ should recommit itself to these guidelines and eschew prosecution for minor regulatory offenses when administrative or civil remedies would be



more appropriate. By doing so, WLF pointed out, the Department would encourage voluntary compliance with the law.

### **II. CIVIC COMMUNICATION**

WLF recognizes that its litigation and regulatory activities cannot alone suffice if it is to have a significant impact in opposing the efforts of plaintiffs' lawyers and educating the public and policy makers on the damage wrought by excessive litigation. WLF has also sought to influence public debate and provide information through its Civic Communications Program. Through this program, WLF hosts well-attended media briefings featuring experts on a wide range of legal reform-related topics, publishes advocacy advertisements in national journals and newspapers, and participates in legal reform-related symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media – from reporters with general-circulation newspapers to writers at influential trade and legal journals.

### **A. Media Briefings**

The centerpiece of WLF's Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on health-related topics. Recent media briefings (dubbed media "noshes") on legal reform-related issues have included the following:

FDA's Federal Preemption Policy: Implications for Drug Labeling and Product Liability Litigation, March 8, 2006

•Daniel E. Troy, Sidley Austin LLP •Mark S. Brown, King & Spalding LLP

Medical Malpractice Reform: Advances, Stalemates & Prospects for 2006, October 27, 2005

•Richard E. Anderson, M.D., F.A.C.P., The Doctors Company
•Sherman Joyce, American Tort Reform Association
•E. Neil Trautwein, National Association of Manufacturers

**On the '05 Agenda: State and Federal Priorities for Reforming the Legal System, January** 13, 2005

•Patrick M. Hanlon, Goodwin Proctor

•Victor E. Schwartz, Shook, Hardy & Bacon L.L.P.

•James M. Wootton, Mayer, Brown, Rowe & Maw-LLP

#### Copyright Laws & Lawsuits: Seeking a Balance Between Public Domain and Digital Commerce, May 19, 2004

•Stewart A. Baker, Steptoe & Johnson LLP

•Jonathan Potter, Digital Media Association

• Professor Peter A. Jaszi, Washington College of Law

•William F. Adkinson, Progress & Freedom Foundation

Alcohol Use and Promotion: The Next Target for "Regulation by Litigation?", March 24, 2004

•John A. Calfee, American Enterprise Institute

•Jonathan Turley, George Washington University

•John J. Walsh, Carter, Ledyard & Milburn LLP

Do New Legal and Regulatory Challenges Threaten Advances in Agricultural Biotech?, March 17, 2004

•Stanley H. Abramson, Arent Fox PLLC

•Thomas P. Redick, Gallop, Johnson & Neuman, American Soybean Association •Mark Mansour, Morgan Lewis LLP

Civil Justice Reform 2003: Advances, Stalemates, and Prospects for the New Year, December 11, 2003

•The Honorable Dick Thornburgh, Kirkpatrick & Lockhart (Moderator)

•Sherman Joyce, American Tort Reform Association

•Patrick M. Hanlon, Shea & Gardner

•Steven B. Hantler, DaimlerChrysler

Class Action and Asbestos: Is Federal Reform on the Horizon?, August 20, 2003 •John Beisner, O'Melveney & Myers

•Patrick M. Hanlon, Shea & Gardner

State Farm v. Campbell: Punitive Damages Return to the U.S. Supreme Court, December 6, 2002

•Stuart Taylor, Jr., National Journal (moderator)

•Philip K. Howard, Covington & Burling

•Victor E. Schwartz, Shook, Hardy & Bacon L.L.P.

•Evan M. Tager, Mayer, Brown, Rowe & Maw LLP

Can Judges and State Policymakers Rein in Runaway Asbestos Litigation?, July 30, 2002

•Richard O. Faulk, Gardere Wynne Sewell LLP

• Professor David E. Bernstein, George Mason University School of Law

- • Roy Goldberg, Schnader Harrison Segal & Lewis

Torts & Civil Justice Reform: Legal and Public Policy Developments to Expect in 2002, January 29, 2002

•Kathleen L. Blaner, Esq.

•Jonathan R. Yarowsky, Patton Boggs LLP

•Mark A. Behrens, Shook, Hardy & Bacon

•Robert S. Peck, Association of Trial Lawyers of America

Contingency Fees: Can Federal Oversight Protect Legal Consumers from Abuse?, September 5, 2001

•The Honorable Dick Thornburgh, Kirkpatrick & Lockhart, LLP (moderator)

•Victor E. Schwartz, Shook, Hardy & Bacon

• Professor Michael I. Krauss, George Mason University Law School

•Richard A. Samp, Washington Legal Foundation



Tort Reform 2001: New Opportunities and Ongoing Challenges, January 30, 2001

- •Mark A. Behrens, Shook, Hardy & Bacon
- •Robert A. McConnell, Hawthorne & York Intl.
- •Barry J. Nace, Paulson & Nace
- •Robert Peck, Association of Trial Lawyers of America

### **B.** Web Seminars

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WLF Web Seminars, introduced in 2005, present viewers with live webcast analysis and commentary by noted legal experts on current developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF's web site. The speakers for the programs, who provide their insights on a *pro bono* basis, are leading experts in the field of law to be discussed.

Ten Years after BMW v. Gore: Punitive Damages at Trial and on Appeal, April 25, 2006 •Andrew L. Frey, Mayer, Brown, Rowe & Maw LLP •Evan M. Tager, Mayer, Brown, Rowe & Maw LLP

Achieving Civil Justice Reform in Court: How Defendants Can Dismantle Arbitrary, Pro-Plaintiff Common Law Rules, April 13, 2006

•Victor E. Schwartz, Shook, Hardy & Bacon L.L.P.

The Class Action Fairness Act, One Year Later: Mission Accomplished?, March 21, 2006 •John Beisner, O'Melveny & Myers LLP •Jessica Davidson Miller, O'Melveny & Myers LLP

Trial Lawyers' "Enron": Will Indictments & Investigations Expose Bill Lerach and Milberg Weiss to Shareholder Lawsuits?, August 25, 2005 •Paul D. Kamenar, Washington Legal Foundation

The Next Wave of State Tort Litigation?: Liability Risks under Consumer Protection Laws and Public Nuisance Theories, July 27, 2005

•J. Russell Jackson, Skadden, Arps, Slate, Meagher & Flom LLP

•Victor E. Schwartz, Shook, Hardy & Bacon L.L.P.

**Expanding Duties & Liability: Corporate Directors in the Post-Enron Legal Environment**, June 8, 2005

•Richard A. Spehr, Mayer, Brown, Rowe & Maw LLP

•Steven Wolowitz, Mayer, Brown, Rowe & Maw LLP

The Class Action Fairness Act of 2005: Lessons, Opportunities and Challenges, March 10, 2005

•Walter Dellinger, O'Melveny & Myers LLP •Jessica Davidson Miller, O'Melveny & Myers LLP

# CONFIDENTIAL

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# C. Advocacy Ads

In 1998, Washington Legal Foundation began running a series of opinion editorials on the op-ed page of the national edition of *The New York Times* called "In All Fairness." The op-ed has appeared over 100 times, reaching over five million readers in 70 major markets and 90 percent of major newspaper editors. Litigation, the role of plaintiffs' lawyers, and legal reform have been the focus of a number of recent "In All Fairness" columns:

#### Amnesty for Honest Businessmen, May 22, 2006

(Government should ease up on its relentless obsession to criminalize America's free enterprise system)

#### Cartoons Spark Outrage, February 27, 2006

(Anti-business groups threaten frivolous lawsuits against companies for marketing beverages and cereals to children by using cartoon characters)

#### The State of Our Union, January 23, 2006

(Activists misuse the courts to promote their agenda by obstructing homeland security measures and using junk science in novel product liability lawsuits)

# WARNING: Beware of activists, plaintiffs' lawyers, and State AGs who use children and public health to attack free enterprise, November 21, 2005

(Activists harm consumers and violate the First Amendment by attacking commercial advertising)

#### Hurricane Looters in Pinstripes, September 26, 2005

(Trial lawyers seek to exploit tragedy of Hurricane Katrina by suing doctors, nurses, and hospitals who worked heroically to save lives)

#### Political Lawsuit Abuse, July 25, 2005

(Justice Department lawsuit against tobacco industry, repetitive of earlier litigation, is professionally unsound and an abuse of power)

#### Criminalizing Success, June 20, 2005

(Prosecution and eventual acquittal of Arthur Andersen accounting firm shows dangers of letting prosecutors' ambitions drive over-criminalization of business conduct)

#### What's Up With The SEC?, March 28, 2005

SEC should take prompt action on WLF complaints calling for investigation of possible collusion between plaintiffs' lawyers and short sellers)

#### Merchants of Fear, January 24, 2005

(Anti-business ideologues are trying to advance their ends and fill their coffers by promoting the unattainable notion of a risk-free world)

#### Disenfranchised by Lawyers, November 22, 2004

(Trial lawyers and overzealous state attorneys general impose ideological agenda by litigation rather than by democratic legislation)



## Government's Lawsuit Addiction, September 27, 2004

(Department of Justice's lawsuit against tobacco companies is misguided and a waste of valuable resources)

#### The Judges of Madison County, April 21, 2003

(Courts in Madison County, Illinois epitomize America's dysfunctional tort system by sanctioning novel lawsuits and billion dollar awards)

#### An Idiot's Guide to Class Actions, March 10, 2003

(Plaintiff's lawyers who file securities class action lawsuits use questionable tactics to drive down stock prices of targeted companies, force settlements, and reap windfall attorney's fees)

#### Overlooking Stock Manipulation, November 18, 2002

(Plaintiff's class action attorneys improperly urge stock analysts to downgrade a targeted company's rating and stock price to force settlements of lawsuits)

#### The Future of Tort Reform?, October 21, 2002

(Because tort reform has been stalled in Congress, the courts should rein in abusive lawsuits by plaintiffs' lawyers)

#### Litigation, Inc., August 26, 2002

(Plaintiffs' lawyers who file abusive lawsuits to enrich themselves by charging excessive fees should be regulated to protect clients and the public)

## Plundering Free Enterprise, February 15, 2002

(Plaintiffs' lawyers file abusive product liability lawsuits against asbestos manufacturers and other companies, force them into bankruptcy, and reap huge fees for themselves)

## Who Should Pay for Our Legal System?, April 23, 2001

(Plaintiffs' lawyers too often get rich while delivering little or no benefit to their clients; to ensure that the public receives at least some benefit from such abuses, lawyers who receive more than \$500,000 in legal fees from a single case should be charged an excise tax of 15%)

#### The New Policymakers, February 5, 2001

(Professional activist groups and trial lawyers are busy gearing up to keep their outdated and unpopular ideological agenda alive; our elected representatives should head off their strategy of flooding courts with legislation dressed up as litigation)

These and other "In All Fairness" columns are available on WLF's comprehensive web site, <u>www.wlf.org</u>.

# **D.** Public Appearances

WLF attorneys have appeared as featured panelists and speakers on legal reform issues before such organizations as the Food and Drug Administration, the Federal Trade

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Commission, the American Medical Association, the Regulatory Affairs Professional Society, the Federalist Society, the Heritage Foundation, the American Bar Association, the National Association of Mutual Insurance Companies, the Community Financial Services Association, the American Crop Protection Association, the Forest Landowners Association, the Oklahoma Chamber of Commerce, and MedicalAlley. What follows are highlights of the numerous public appearances that WLF attorneys have made in recent years to discuss legal reform issues:

June 8, 2006, Paul Kamenar, WLF's Senior Executive Counsel, was a featured speaker at the inaugural summer speakers program of Rutgers College in Washington for both alumni and undergraduate summer interns. Kamenar discussed WLF's litigation practice and was joined by Tony Mauro, Supreme Court reporter for Legal Times.

June 6, 2006, WLF Chief Counsel Richard Samp was a featured speaker on a teleconference sponsored by Mealey's, regarding FDA's recently announced policy regarding federal preemption of state-law failure-to-warn tort suits against pharmaceutical manufacturers and health practitioners.

April 4, 2006, Samp was interviewed on WBGO-Radio in Newark, New Jersey regarding a recent court decision that held that illegal immigrants who are injured on the job are entitled to recover damages for lost wages – even though they would have had no right to continue to work in this country if they had not been injured.

March 30, 2006, Samp was a featured panelist at the Medical Device Regulatory and Compliance Congress held at Harvard University. Samp discussed manufacturers' First Amendment rights to speak truthfully about FDA-approved medical products.

February 28, 2006, Kamenar appeared on Court TV to discuss the legal issues involved in the Supreme Court case *Marshall v. Marshall*, regarding federal jurisdiction over probate and other state law claims.

December 14, 2005, Samp was the keynote speaker at a breakfast symposium in Minneapolis sponsored by MedicalAlley and MNBIO. Samp's speech focused on recent federal government enforcement actions under the False Claims Act and the anti-kickback statute.

December 6, 2005, Samp was a featured panelist at the Food and Drug Law Institute's Fourth Annual Enforcement and Litigation Conference in Washington, D.C. Samp spoke on the federal government's efforts to obtain restitution/disgorgement as a remedy for violations of the Federal Food, Drug, and Cosmetic Act.

November 15, 2005, Samp testified before the House Judiciary Committee's Subcommittee on Courts, urging Congress to take steps to protect the rights of out-of-state defendants to move their cases from State courts to federal courts.

November 2, 2005, Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer advertising.

October 21, 2005, Samp broadcast an opinion piece on National Public Radio's "Justice Talking" program, decrying tort suits filed against health care providers who worked heroically to assist Hurricane Katrina victims but whose efforts are now being second-guessed.



July 18, 2005, Samp was interviewed on KNX-Radio in Los Angeles regarding the Bush Administration's petition for Supreme Court review in *United States v. Philip Morris*, in which the Administration is seeking to invoke a federal anti-racketeering law (thus far unsuccessfully) to force the cigarette industry to pay hundreds of billions of dollars to the government.

June 28, 2005, Glenn Lammi, WLF Chief Counsel, Legal Studies Division, was interviewed for the Mike Norman Show on BizRadio 1320, KXYZ in Houston, on business criminalization issues.

June 10, 2005, Kamenar was interviewed by KHAL Radio in San Antonio, Texas discussing the Supreme Court's denial of review of *GDF Realty v. Norton*, dealing with whether the federal government has authority to regulate cave bugs found only in a small area in Texas.

May 31, 2005, Kamenar was interviewed on the NBC Nightly News discussing the Arthur Andersen v. U.S. case, in which the U.S. Supreme Court overturned the criminal conviction of the accounting firm for destroying documents that were sought by the government shortly before Enron had collapsed.

May 31, 2005, Samp was interviewed on CNN regarding the U.S. Supreme Court's decision in Arthur Anderson v. U.S.

May 11, 2005, Samp was a featured speaker at a seminar in New York City sponsored by Harvard Business School Publishing. Samp spoke on the corporate community's First Amendment rights to speak out on issues of public importance.

January 27, 2005, Samp was a featured speaker at a conference organized by the Food & Drug Law Institute in Washington, D.C. entitled, "Product Liability for FDA Regulated Products: In What Kind of World Are We Living?" Samp addressed tort liability faced by drug manufacturers for speaking truthfully about their products.

October 29, 2004, Kamenar was a featured panelist at American University Law School Symposium on Overcriminalization along with noted practitioners and law professors. The event was co-sponsored by the Heritage Foundation and the National Association of Criminal Defense Lawyers. Kamenar discussed WLF's recent litigation in this area of the law.

September 20, 2004 Samp was interviewed on KNX-Radio (the CBS affiliate in Los Angeles) regarding the federal government's racketeering lawsuit against the tobacco industry.

September 13, 2004, Kamenar was a featured panelist at a workshop sponsored by the Federal Trade Commission in Washington, D.C., on the topic of class actions and consumer protection. Other panelists included noted federal judges, law professors, and attorneys from the defense and plaintiffs' bar.

June 10, 2004, WLF Senior Vice President for Legal Affairs David Price was a panelist at a forum sponsored by the Cato Institute, together with volunteers from WLF's client, the Abigail Alliance for Better Access to Developmental Drugs. Price discussed WLF's lawsuit on behalf of itself and the Abigail Alliance against the FDA; the suit seeks earlier availability of investigational drugs for the terminally ill.



May 26, 2004, WLF Chairman and General Counsel Daniel Popeo addressed the Washington University's Widenbaum Center Breakfast Meeting in St. Louis. Popeo's speech, "Is Litigation Good for America?," was presented before business leaders, media, professors, and students.

March 31, 2004, Samp was a panelist at a forum sponsored by the Environmental Law Institute in Washington, D.C. Samp addressed the government's obligation to reimburse property owners when it seizes their property in pursuit of environmental goals.

March 3, 2004, Kamenar was the moderator at a seminar co-hosted by WLF, Kirkpatrick & Lockhart, and the Bureau of National Affairs (BNA) on legal and business issues involving Homeland Security. Other speakers included Joseph Whitley, General Counsel of the Department of Homeland Security, and U.S. Senator Pat Roberts, Chairman of the Senate Select Committee on Intelligence.

February 26, 2004, Kamenar was a featured speaker at a conference on lawsuit reform in Oklahoma City. The conference was sponsored by The State Chamber, Oklahoma's Association of Business and Industry, the Manhattan Institute for Policy Research, Oklahomans for Lawsuit Reform, and Pre-Paid Legal Services, Inc. Kamenar discussed WLF's INVESTOR PROTECTION PROGRAM before 600 business leaders.

January 23, 2004, Samp was a featured speaker at the annual meeting in Atlanta of NAAMECC (a trade group for companies that produce continuing medical education symposia), warning against government restrictions on the First Amendment right to speak truthfully regarding medical issues.

November 20, 2003, Samp addressed the American Bar Association's annual pharmaceutical conference in Philadelphia, arguing that expanded use of the False Claims Act as a vehicle for suing drug companies is jeopardizing free speech rights and the ability of drug companies to continue to develop new, life-saving therapies.

September 24, 2003, Popeo was the moderator of the panel, "The Future of Insurance Regulation," at the National Association of Mutual Insurance Companies (NAMIC) annual meeting in New Orleans.

May 13, 2003, Popeo was the keynote speaker at the Ventura County Medical Society's membership meeting in Oxnard, California. Popeo's speech was titled, "What You Can Do About Lawyers: The Future of Tort Reform and the Role that Doctors Must Play."

April 23 and again June 26, 2003, Samp appeared on CNBC to discuss *Nike v. Kasky*, the Supreme Court case that addressed the First Amendment right of corporations to freely discuss matters of public interest.

April 2, 2003, Samp was interviewed on the Pacifica Radio Network regarding the U.S. Supreme Court's decision in Brown v. Legal Foundation of Washington, WLF's challenge to the constitutionality of IOLTA (Interest on Lawyer Trust Account) programs. Samp was interviewed on KING-TV in Seattle on January 15, 2003 on the same topic.



October 25, 2002, Samp was a featured panelist at a symposium organized by the Federalist Society, entitled, "FDA and the First Amendment."

October 11, 2002, Kamenar was a featured panelist at the Annual Conference of the Society of Environmental Journalists in Baltimore. Kamenar discussed key environmental issues, including Environmental Justice.

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October 2, 2002, Popeo was the featured speaker at the Community Financial Services Association's Banking Committee meeting in Washington, D.C.

September 10, 2002, Samp testified before the Federal Trade Commission in connection with the FTC's hearings on "Health Care and Competition."

July 30, 2002, Samp was interviewed on New York radio's "The Barry Farber Show" on the Enron scandal and the need to avoid responding to the scandal by imposing excessive regulations on the business community.

May 28, 2002, Kamenar appeared on MSNBC's "Capital Report" to debate William Schultz, former Clinton FDA official, over FDA's proposal to consider First Amendment implications of FDA regulation.

May 22, 2002, Popeo was the featured speaker at the Annual Meeting of the Medical Device Manufacturers Association (MDMA). At the MDMA Chairman's Luncheon, Popeo discussed the crucial work of WLF in promoting open markets, free enterprise, and competition, and WLF's legal activities challenging excessive regulation by FDA.

March 16, 2002, Kamenar was a featured speaker at the ABA's 31th Annual Conference on Environmental Law in Keystone, Colorado. Kamenar discussed WLF's extensive efforts to prevent unwarranted use of criminal prosecutions by environmental enforcement officials.

February 16, 2002, Samp was a panelist at the University of Virginia Law School's Conference on Public Service and the Law, discussing the so-called Environmental Justice movement.

January 19, 2002, Kamenar was a featured speaker at a Rutgers University conference sponsored by the Society of Environmental Journalists. Kamenar addressed leading court cases raising key environmental issues.

January 11, 2002, Samp testified before the U.S. Commission on Civil Rights in opposition to the Environmental Justice movement's efforts to block industrial development in racial minority communities.

January 7, 2002, Samp addressed a meeting of the Federal Circuit Bar Association regarding an important property rights case in the Supreme Court, *Tahoe Sierra v. Tahoe Regional Planning Association*.

October 29, 2001, Samp spoke before a group of University of Virginia law students in Charlottesville, Virginia regarding limitations on government regulation imposed by the Takings Clause of the Fifth Amendment.



October 10, 2001, Samp appeared on a program sponsored by Maine Public Radio regarding the propriety of States' efforts to impose price controls on prescription drugs.

June 28, 2001, Samp was interviewed on Hearst Television regarding *Lorillard v. Reilly*, a Supreme Court decision that broadly affirmed commercial speech rights. Samp was interviewed on the same subject on KUOW-Radio in Seattle (June 29), C-SPAN (April 24), and AP Radio (April 25).

June 7, 2001, Lammi addressed over 200 corporate counsels and public affairs specialists on public interest legal groups' approach to litigation communications at a Bork & Associates and Fulcrum Information Services conference, "Winning the Reputation War in High Profile Litigation."

February 12, 2001, Popeo was a featured speaker before the Republican State Attorneys General Association's 2001 Winter Conference in Palm Beach, Florida. Popeo spoke on "Managing Public Relations and the Bottom Line."

January 10, 2001, Popeo was the dinner speaker for the St. Louis, Missouri Discussion Club. His topic was "Free Enterprise Public Interest Law and the Role of Communications."

# **III. PUBLICATIONS**

WLF's Legal Studies Division is the preeminent publisher of analytical and carefullyresearched, yet readable, legal policy papers. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDERS covering current developments affecting the American legal system, to comprehensive Monographs providing law-reviewlength inquiries into significant legal issues.

Since its inception 17 years ago, WLF's Legal Studies Division has produced a library of publications on legal reform of considerable size and depth. The areas on which these papers have focused range from substantive explanations of federal and state legislative reform efforts to essential analyses of the most important tort-related court rulings of the day to indepth assessments of specific categories of civil justice law, such as scientific evidence, product liability, the discovery process, punitive damages, and the class action mechanism. Authoring these papers pro bono for WLF are America's leading legal reform and civil justice experts from business, government, the courts, private law firms, and academia. Notable authors include: former U.S. Attorneys General Dick Thornburgh and John Ashcroft; Senator Orrin Hatch; U.S. Court of Appeals Judges Harold DeMoss and Edith Jones; U.S. District Court Judge Shira Scheindlin; Yale Law Professor George Priest; longtime tort reform advocate Victor Schwartz; former Attorney General of Alabama Bill Pryor; and former Solicitor General of the United States Theodore Olson.

WLF legal reform publications have been cited in court rulings, law review articles,
legal briefs, and congressional debates; have provided intellectual firepower to those who are fighting for legislative reform at the federal and state levels; are relied upon by legal and civil justice issue reporters; and are frequently reprinted in influential trade journals and newsletters. Publications during the past five years include:

# CONDENTIAL

Medical Monitoring Claim Pursued In New York State By Sean Wajert, a partner at Dechert LLP. LEGAL OPINION LETTER, June 2, 2006, 2 pages

## **Bilked Asbestos Plaintiffs Sue Florida Bar Association**

By John Stadler, Counsel in the Boston office of the Law Firm Nixon Peabody LLP. COUNSEL'S ADVISORY, May 19, 2006, 1 page

# USG Settlement Reflects Sorry State Of Asbestos Bankruptcies

By Mark D. Taylor, a partner in the Financial Restructuring and Bankruptcy practice of Arent Fox PLLC; and Brandi A. Richardson, an associate at the firm. LEGAL BACKGROUNDER, April 21, 2006, 4 pages

#### Federal Court Finds Medical Monitoring Tort Unavailable In Texas

By Shawn D. Bryant, an attorney with Spriggs & Hollingsworth in Washington, D.C. COUNSEL'S ADVISORY, April 21, 2006, 1 page

An Exaggerated And Ill-Conceived Sense Of Risk: The Ephemeral Nature Of California's Proposition 65 By Thomas H. Clarke, Jr., a senior partner with Ropers, Majeski, Kohn, & Bentley in their San Francisco office.

WORKING PAPER, April 2006, 26 page

#### Federal Court Draws Roadmap For Scrutiny of Attorneys' Fees in "Coupon" Settlements By Thomas M. Smith, Coupsel at McCarter & English, LLP, in the firm's New Y

By Thomas M. Smith, Counsel at McCarter & English, LLP, in the firm's New York office, and Natalie S. Watson, an Associate at the firm's Newark office. LEGAL BACKGROUNDER, April 7, 2006, 4 pages

# Impending Legal Attacks On Food Ads Should Not Be Welcome In Court By Scott A. Elder, a partner, and Anna Aven Sumner, an associate, with Alston & Bird LLP

in the firm's Atlanta office. LEGAL BACKGROUNDER, March 10, 2006, 4 pages

# Regulated Industries Benefit From Illinois Consumer-Protection Ruling

By Victor E. Schwartz, a partner in the law firm of Shook, Hardy & Bacon L.L.P. in Washington, D.C. and Cary Silverman, an associate with the firm. LEGAL BACKGROUNDER, February 10, 2006, 4 pages

Medical Monitoring: Innovative New Remedy Or Money For Nothing? By Steven J. Boranian, a partner in Reed Smith LLP's San Francisco office, and Kevin M. Hara, a litigation associate in the firm's Oakland office. WORKING PAPER, January 2006, 23 pages

# High Courts Reject Premises Liability For Secondhand Asbestos Exposure

By Mark A. Behrens and Andrew W. Crouse, attorneys in the Public Policy Group of the law firm Shook, Hardy & Bacon L.L.P.'s Washington, D.C. office. LEGAL OPINION LETTER, December 16, 2005, 2 pages

CONFIDENTIAL

State Law As Health Hazard: How Prop 65 Undermines National Food Labeling By Gene Livingston, a Shareholder with the law firm Greenberg Traurig, LLP in its Sacramento office, and Lisa L. Halko, an associate at the firm, also in its Sacramento office. LEGAL BACKGROUNDER, December 16, 2005, 4 pages

#### Silica Litigation: Screening, Scheming & Suing

By Nathan A. Schachtman, a partner at McCarter & English LLP in the firm's Philadelphia office whose practice focuses on the defense of products liability suits involving claims of defective drugs and medical devices and toxic exposures. WORKING PAPER, December 2005, 18 pages

#### Would You Like A Prop 65 Warning With Those Fries?

By Ann Grimaldi, a partner with the law firm McKenna Long & Aldridge LLP. LEGAL BACKGROUNDER, November 18, 2005, 4 pages

#### Federal Appeals Courts Rule On Class Action Fairness Act

By Ainsley N. Dietz, former Director of Policy and Outreach of Washington Legal Foundation.

COUNSEL'S ADVISORY, October 7, 2005, 1 page

A Defectively Designed Suit: Deputized Trial Lawyers Twist Tort Law In Rhode Island By Leah Lorber, formerly of counsel in the Public Policy Group in the Washington, D.C. office of Shook, Hardy & Bacon L.L.P. and currently Director of Public Policy - Tort Reform for GlaxoSmithKline.

LEGAL BACKGROUNDER, October 7, 2005, 4 pages

#### **Court Endorses Tort Defenses In Diet Drug Litigation**

By Brennan J. Torregrossa, an associate at Dechert LLP and a member of its Mass Torts & Product Liability practice group.

LEGAL BACKGROUNDER, September 23, 2005, 4 pages

#### **U.S. Judicial Conference Considers E-Discovery Rules**

By Alfred W. Cortese, Jr., Managing Partner of CORTESE PLLC, Washington, D.C., who specializes in developing and advocating strategic legislative, litigation, and regulatory responses to complex public policy issues with particular emphasis on federal and state court procedural rulemaking processes.

LEGAL BACKGROUNDER, September 9, 2005, 4 pages

#### Michigan Court Ruling Advances Trend On Medical Monitoring

By Mark Herrmann, a partner, and Brian Ray, an associate, in the Cleveland office of Jones Day.

LEGAL BACKGROUNDER, August 26, 2005, 4 pages

#### Michigan High Court Rejects Claim For No-Injury Medical Monitoring

By Leah Lorber, of counsel in the Public Policy Group in the Washington, D.C. office of Shook, Hardy & Bacon L.L.P.

LEGAL OPINION LETTER, July 29, 2005, 2 pages



# Federal Court Ruling Undermines Defendants' Ability To Appeal Class Action Certifications

By Donald M. Falk, a partner in the Supreme Court and Appellate Practice Group of the law firm Mayer Brown Rowe & Maw LLP, resident in the Palo Alto office; and Fatima Goss Graves, a former associate in the firm's Washington office, now Counsel, Education and Employment, for the National Women's Law Center. LEGAL BACKGROUNDER, July 29, 2005, 4 pages

# State Class Action Reform: Lessons From Texas

By Pete Schenkkan, a partner with the law firm Graves Dougherty Hearon & Moody, P.C. in Austin, Texas. He participated in the Texas Supreme Court Advisory Committee's work on the new Texas class action rule.

LEGAL BACKGROUNDER, July 29, 2005, 4 pages

# State Consumer Protection Laws Elevate Food Company Liability Risks

By Scott A. Elder and Anna Aven Sumner, associates with Alston & Bird LLP in the firm's Atlanta office. Mr. Elder is a member of the firm's Product Liability and Litigation and Trial Practice groups while Ms. Sumner is a member of the Products Liability group. LEGAL BACKGROUNDER, July 29, 2005, 4 pages

## **Court Dramatically Expands Strict Liability Tort Theory**

By David T. Biderman, a partner with the law firm Perkins Coie LLP in the firm's Santa Monica office, and David R. East, an associate in the firm's Seattle office. LEGAL BACKGROUNDER, June 3, 2005, 4 pages

## **Once Again...Ohio Legislators Approve Comprehensive Tort Reform**

By Kurtis A. Tunnell, Anne Marie Sferra Vorys and Miranda Creviston Motter who have all worked extensively on tort reform efforts in Ohio. Mr. Tunnell is a Partner with Bricker & Eckler LLP and serves as legal counsel to the Ohio Alliance for Civil Justice (OACJ). Ms. Sferra Vorys is a Partner in the firm's litigation department. Ms. Creviston Motter is an Associate in the Firm's government relations department. LEGAL BACKGROUNDER, May 20, 2005, 4 pages

My "Big Fat" Update: Courts Disserve Rule Of Law In Food Lawsuits Decisions By Michael I. Krauss, a professor of law at George Mason University. LEGAL BACKGROUNDER, May 6, 2005, 4 pages

California Ruling Bolsters Suits Against Class Action Counsel By David Price, Senior Vice President for Legal Affairs of the Washington Legal Foundation. COUNSEL'S ADVISORY, April 22, 2005, 1 page

Mississippi High Court Provides Clear Guidance On Mass Torts Through Asbestos Ruling By Margaret Oertling Cupples, a partner in the Jackson, Mississippi office of the law firm Bradley Arant Rose & White LLP. LEGAL BACKGROUNDER, April 22, 2005, 4 pages

Agent Orange Ruling Holds Hidden Hazards For Defense Contractors By David Price, Senior Vice President for Legal Affairs of the Washington Legal Foundation. COUNSEL'S ADVISORY, March 25, 2005, 1 page





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Supreme Court Should Evaluate Impact Of Punitive Damages On Entire Trial Process By James Dabney Miller, a partner with the law firm King & Spalding LLP in its Washington, D.C. office.

LEGAL BACKGROUNDER, March 25, 2005, 4 pages

#### Conversations With: Legal Reform - A View From The States

Features The Honorable Dick Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP, moderating a discussion with Florida Governor Jeb Bush; former Governor of Michigan and current President and CEO of the National Association of Manufacturers John Engler; and Steve Hantler, Assistant General Counsel to DaimlerCrysler and Chairman of the American Justice Partnership. CONVERSATIONS WITH, Spring 2005, 10 pages

#### Conversations With: Legal Reform In Mississippi

Features The Honorable Dick Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP, leading a discussion with The Honorable Haley Barbour, Governor of Mississippi.

CONVERSATIONS WITH, Spring 2005, 6 pages

#### UCC Article 2 Amendments: A Defective Product And A Flawed Process

By Holly K. Towle, a partner with Preston Gates Ellis LLP, a full-service law firm providing legal services from strategic locations in the United States and abroad. LEGAL BACKGROUNDER, February 11, 2005, 4 pages

State High Court Ruling Departs From Tort Principles In Consumer Protection Cases By Victor E. Schwartz, a partner in the law firm of Shook, Hardy & Bacon L.L.P. in Washington, D.C., and Leah Lorber, of counsel to the firm. LEGAL BACKGROUNDER, January 14, 2005, 4 pages

#### Federal "E-Discovery" Rules Proposal Requires Scrutiny And Comment

By Alfred W. Cortese, Jr, of Cortese PLLC, Washington, D.C., who specializes in developing and advocating strategic legislative, litigation, and regulatory responses to complex public policy issues with particular emphasis on court procedural rulemaking processes. LEGAL BACKGROUNDER, December 17, 2004, 4 pages

West Virginia Supreme Court Sets High Bar For Plaintiffs In Medical Monitoring Cases By Sean Wajert, a partner at Dechert LLP and the chair of its Mass Torts & Product Liability practice group. Dechert was part of the team representing the defendants in the *Blankenship*. LEGAL OPINION LETTER, December 17, 2004, 2 pages

## Michigan High Court Ruling Offers Positive Guidance On Challenges To Tort Reform Laws

By Glenn G. Lammi, Chief Counsel of the Washington Legal Foundation's Legal Studies Division and James Chang, an Institute for Humane Studies Fellow at the Washington Legal Foundation during the summer of 2004.

LEGAL BACKGROUNDER, December 17, 2004, 4 pages



A Win For Federalism: Kentucky Court Vacates Punitive Damage Award

By Theodore B. Olson, former Solicitor General of the United States and a partner with the law firm Gibson, Dunn & Crutcher LLP, where he serves as co-chair of the Appellate and Constitutional Law Practice Group and heads the firm's crisis management team; and Thomas H. Dupree, Jr., an associate at the firm.

LEGAL OPINION LETTER, December 17, 2004, 2 pages

# State Appeal Bond Reforms Protect Defendants' Due Process Rights

By Glenn G. Lammi, Chief Counsel of the Washington Legal Foundation's Legal Studies Division, and Justin P. Hauke, an Institute for Humane Studies Fellow at the Washington Legal Foundation during the summer of 2004. LEGAL BACKGROUNDER, November 12, 2004, 4 pages

# Conversations With: Civil Justice Reform

Features The Honorable Dick Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart LLP moderating a discussion with Bernard Marcus, Director Emeritus to and co-founder of The Home Depot, Inc.; Maurice ("Hank") Greenberg, Chairman and CEO of American International Group; and Steven Hantler, Assistant General Counsel for Government and Regulation, DaimlerChrysler Corporation. CONVERSATIONS WITH, Fall 2004, 8 pages

#### "Piggyback" Class Action Suits Don't Merit Exorbitant Fees

By Paul D. Kamenar, Senior Executive Counsel of the Washington Legal Foundation. LEGAL OPINION LETTER, October 29, 2004, 2 pages

#### **Ruling Offers Lesson For Counsel On Electronic Discovery Abuse**

By Thomas Y. Allman, Senior Counsel with the Chicago office of the law firm Mayer, Brown, Rowe & Maw LLP and former Senior Vice President, Secretary, General Counsel and Chief Compliance Officer of BASF Corporation. LEGAL BACKGROUNDER, October 15, 2004, 4 pages

# FBI Arrests Drug Injury Claimants For Filing False Claims

By David Price, Senior Vice President for Legal Affairs of the Washington Legal Foundation. COUNSEL'S ADVISORY, October 15, 2004, 1 page

## A Punitive Damages Primer: Post-State Farm Strategies

By Christina J. Imre, a partner with the San Francisco law firm Sedgwick, Detert, Moran & Arnold LLP. Foreword by Laurel Thurston, Senior Counsel and Assistant Vice President, Republic Indemnity Company. MONOGRAPH, October 2004, 87 pages

Stopping Frivolous Litigation And Protecting Small Businesses By Congressman Lamar Smith, who has represented the residents of the 21<sup>st</sup> Congressional District of Texas since 1987. LEGAL OPINION LETTER, September 3, 2004, 2 pages

Heavyweight Litigation: Will Public Nuisance Theories Tackle The Food Industry? By Charles H. Moellenberg, Jr., a partner in the law firm Jones Day in its Pittsburgh office. LEGAL BACKGROUNDER, September 3, 2004, 4 pages

# CONFIDENTIAL

New California Law Grants State 75% Of Punitive Damage Award By Victor E. Schwartz, Mark A. Behrens and Cary Silverman, attorneys in the Public Policy Group of Shook, Hardy & Bacon, L.L.P. in Washington, D.C. LEGAL OPINION LETTER, September 3, 2004, 2 pages

# Florida High Court Should Reject "Regulation Through Litigation"

By Glenn G. Lammi, Chief Counsel of the Washington Legal Foundation's Legal Studies Division.

LEGAL BACKGROUNDER September 3, 2004, 4 pages

#### **Rulings Strip Away Common-Sense Tort Defense In New York State**

By David Glazer, an associate with the law firm Smith Mazure in New York City. LEGAL OPINION LETTER, August 20, 2004, 2 pages

#### State High Court Strikes Latest Blow Against Tort Reform Nullification

By Thomas J. Foley, a Principal and Founder of the Detroit-area law firm of Foley, Baron & Metzger, PLLC where he heads the Products and Complex Liability Practice Group and Jill I. Zyskowski, an associate with the firm. COUNSEL'S ADVISORY, August 6, 2004, 2 pages

Lawyers Beware: State High Court Ruling Expands Tort Of Malicious Prosecution By Christina Imre, a partner in the Los Angeles office of Sedgwick, Detert, Moran & Arnold LLP, and Douglas Collodel, a special counsel with the firm. LEGAL OPINION LETTER, July 23, 2004, 2 pages

# The End Of The "Sting?" — California Supreme Court To Review Punitive Damage Standards

By David T. Biderman, a litigation partner in Perkins Coie LLC who practices in the San Francisco and Los Angeles offices; and Kyann C. Kalin, an associate in Perkins Coie LLC who practices in the San Francisco office.

LEGAL BACKGROUNDER, July 23, 2004, 4 pages

# "Do-It-Yourself" Tort Reform? — Focus On Medical Experts Could Ebb Tide Of Malpractice Lawsuits

By Dr. Jeffrey Segal, founder and CEO of Medical Justice Services, Inc. and a board certified neurosurgeon and fellow of the American College of Surgeons, and Michael Sacopulos, Counsel to Medical Justice Services, Inc. and a partner in Sacopulos, Johnson, and Sacopulos in Terre Haute, Indiana.

LEGAL BACKGROUNDER, July 23, 2004, 4 pages

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By David E. Dukes, James K. Lehman, Michael W. Hogue, and Jason Sprenkle, attorneys with the South Carolina law firm Nelson Mullins Riley & Scarborough, LLP. Foreword by The Honorable Shira A. Scheindlin of the U.S. District Court for the Southern District of New York. Introduction by Thomas Y. Allman, Senior Vice President and General Counsel, BASF Corporation.

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#### Pennsylvania High Court Ruling Clouds Key Product Liability Issue

By Samuel W. Silver, a partner with the law firm Schnader Harrison Segal & Lewis LLP, resident in its Philadelphia office. Alex Helderman, an associate in the Product Liability and Mass Tort practice group, assisted with this article. LEGAL OPINION LETTER, July 13, 2001, 2 pages

#### High Court Imposes New Standard For Review of Punitive Damages

By Christina J. Imre, an appellate attorney and a director of the law firm Crosby, Heafey, Roach & May in its Los Angeles office.

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By Ian Gallacher, an associate professor at American University's Washington College of Law.

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# **ACTIVITIES REPORT**

to the

# WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

# PROTECTING COMMERCIAL SPEECH RIGHTS

August 15, 2006



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# AUGUST 15, 2006

# ACTIVITIES REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

# PROTECTING COMMERCIAL SPEECH RIGHTS

The ideals upon which America was established — individual freedom, limited government, a free-market economy, and national security — are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. Adherence to those principles is essential to maintaining Americans' high standard of living, and, more important, it is essential to maintaining America's position as the freest nation in the world.

Since its founding in 1977, the Washington Legal Foundation (WLF) has labored to protect the right of all Americans to speak freely. That right has come under increasing attack in recent years, particularly when the speaker is a company in a moment of crisis or in a politically vulnerable industry. All too often, members of the business community have found their right to speak freely being challenged by opportunistic politicians.

Regulators and activists often believe they can make the world a better place by silencing companies they dislike, or by forcing those companies to disseminate government-mandated messages. WLF believes that freedom of speech is for everyone — as does the U.S. Supreme Court. Accordingly, WLF has been at the forefront of fighting for the right of business enterprises to engage in truthful and non-misleading speech.

WLF has worked to achieve those objectives through precedent-setting litigation, involvement in government regulatory proceedings, publication of timely articles on speech-related issues, and tireless advocacy for free-market solutions in the news media and other public forums. This report highlights many of WLF's significant commercial speech-related activities.

# I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF's public interest programs. The Foundation litigates across the country before state and federal courts and administrative agencies. WLF represents only those who are otherwise unable to retain counsel on their own. Its clients have included numerous individuals who have been denied the right to speak freely on business-related issues, as well as other individuals who have been denied access to truthful information that a government bureaucrat does not want them to hear.





Government officials often view advertising and product promotion as a waste of resources that serves only to encourage unwarranted consumer demand for products. WLF strongly disagrees; it believes that truthful advertising has numerous public benefits — particularly increasing public awareness about the types of products available to meet consumer needs. In the medical arena, government officials may become upset when increased consumer awareness leads to increased consumer demand (and thereby may drive up the cost of some government programs), but WLF opposes government efforts to keep consumers in the dark merely to assist in budget-balancing efforts. Accordingly, WLF has battled in the courts and before administrative agencies to lift advertising restrictions, regulations that prevent dissemination of truthful information (such as information on off-label uses of FDA-approved products), and rules that limit discussions at professional gatherings (such as Continuing Medical Education events).

**"DDMAC Watch."** WLF has concluded that the FDA office that regulates prescription drug advertising, DDMAC (an acronym for the Division of Drug Marketing, Advertising, and Communications), routinely has failed to respect the First Amendment rights of pharmaceutical companies whose activities it is monitoring. In response, WLF in 2005 launched its "DDMAC Watch" program, designed to monitor DDMAC's activities. Under the program, when DDMAC sends a regulatory letter to a drug company employing theories that are legally deficient or ill-advised, WLF will *immediately* send back a response letter to DDMAC identifying the ways in which this is so. The goal of the program is to alert the press and public to abuses occurring at DDMAC. As of August 2006, WLF has responded to 27 letters from DDMAC and related agencies; those letters were sent to Ely Lilly, Endo Pharmaceuticals, MedImmune Vaccines, Dutch Ophthalmic USA, Hoffman LaRoche, Abbott Laboratories, Pfizer, Actelion Pharmaceuticals US, SuperGen, Nephryx, ISTA Pharmaceuticals, Gen Trac, Medicis Pharmaceuticals, Sankyo Pharma, Duramed Pharmaceuticals, Biogen Idec, Mayne Pharma (USA), ZLB Behring, Palatin Technologies, InterMune, VaxGen, Bioniche Pharma Group, Sandoz, BIPI, Wyeth Pharmaceuticals, PrimPharm, and GlaxoSmithKline.

Washington Legal Foundation v. Henney. On February 11, 2000, the U.S. Court of Appeals for the District of Columbia Circuit dismissed FDA's appeal from a district court decision that struck down FDA regulations that severely restricted the flow of truthful information regarding off-label uses of FDA-approved drugs and medical devices. The decision was a major victory for WLF in its long-running battle against FDA speech restrictions; WLF had filed suit against FDA in 1994, after FDA rejected a 1993 WLF Citizen Petition asking that the regulations be lifted. In 1998 and 1999, the district court ruled that the regulations violated the First Amendment rights of consumers who wished to learn truthful information about off-label product uses that are widely accepted within the medical community as safe and effective. As a result of WLF's victory, FDA has not initiated enforcement actions against any of the manufacturers who have exercised their First Amendment rights by distributing peer-reviewed journal articles that discuss off-label uses of their products.



FDA Testimony Regarding Direct-to-Consumer Pharmaceutical Advertising. On November 2, 2005, WLF Chief Counsel Richard Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer (DTC) advertising. Samp asserted that FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) needs to rein in its efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers. When FDA announced that it would be holding hearings in November 2005, its announcement suggested that FDA was considering moving in the other direction and imposing additional restrictions on advertising. Many hearing witnesses called for severely limiting drug ads, branding them as inherently biased and misleading. WLF's Samp countered that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options.

In re: ACCME Restrictions on Continuing Medical Education. On January 29, 2003, WLF filed comments with the Accreditation Council for Continuing Medical Education (ACCME), severely criticizing the Council for its proposal to impose draconian restrictions on who may speak at CME activities. WLF argued that the proposed restrictions are an unwarranted infringement on free speech rights. Pre-2003 ACCME standards were designed to ensure unbiased CME presentations by, among other things, requiring speakers to disclose whether they have received any funding from the manufacturer of any of the drugs being discussed. The proposed standards went considerably further; they would have altogether prohibited doctors who had been compensated by a pharmaceutical company from speaking at a CME activity. WLF noted in its comments that most of the top medical authorities in the country are employed in some capacity by one or more of the country's drug companies and thus would no longer be permitted to participate in CME events. WLF argued that without the participation of top doctors, CME would no longer be the important source of new medical information that it is today. WLF attorneys repeatedly voiced their criticisms of the proposed restrictions at several well-attended ACCME-related forums in 2003. The ACCME board of directors approved new rules on April 1, 2004, and they took effect in early 2005. However, in response to criticisms from WLF and others, the ACCME somewhat modified the restrictions such that they are considerably less objectionable than earlier versions had been.

In re: FDA Request for Comments on First Amendment Issues. FDA has lost several major First Amendment lawsuits in recent years, including *WLF v. Henney* (see above). FDA responded in 2002 by requesting public input on whether any current FDA policies violate the First Amendment. On September 13, 2002, WLF filed extensive comments, citing a broad array of FDA regulatory activities that violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. On October 28, 2002, WLF filed a second round of comments, responding to arguments (made by several U.S. Senators in connection with the initial round of comments) that public health concerns justify exempting FDA from First Amendment constraints applicable to other government entities. WLF criticized the contention of those Senators that consumers are likely to misuse truthful information. FDA has pledged to address these First Amendment concerns, but it has yet to do so in a systematic manner.

Citizen Petition Regarding Restrictions on Truthful Speech. Following WLF's victory in



WLF v. Henney (see above), FDA began to suggest that it was not bound by the court's decision in WLF's favor. FDA issued statements to manufacturers, suggesting that they might be sanctioned for engaging in the types of off-label speech that WLF v. Henney had held to be constitutionally protected. Accordingly, on May 23, 2001, WLF filed a Citizen Petition with FDA, urging the agency to repudiate those statements and to announce that it had lifted restrictions on manufacturers' rights to disseminate non-misleading information concerning off-label uses of FDA-approved products. WLF argued that by threatening enforcement action against manufacturers who exercise their freespeech rights, FDA was violating the First Amendment rights of manufacturers who wish to speak in a non-misleading manner about off-label uses of their products, and of those who wish to hear such speech. WLF noted that WLF v. Henney had resulted in a ruling that the First Amendment prohibits FDA from restricting manufacturer dissemination of "enduring materials" (medical texts and reprints of peer-reviewed medical journal articles) that discuss off-label uses of FDA-approved products. WLF charged that FDA was flouting that ruling by threatening enforcement action against manufacturers who disseminate enduring materials. FDA's response to the petition amounted to another WLF victory. Although continuing to argue that the ruling in WLF v. Henney was not as broad as WLF asserted, FDA pledged that in the future (in light of its limited resources) it would not bring enforcement actions based on the types of manufacturer speech described by WLF.

Investigating Efforts to Evade WLF Courtroom Victory. Although WLF established in WLF v. Henney (see above) that the First Amendment protects the right of drug manufacturers, in certain instances, to disseminate truthful information about off-label uses of their products, WLF has become increasingly concerned that various federal officials are seeking to evade that decision. In particular, the United States Attorney's office in Boston has threatened criminal prosecution of companies that disseminate truthful off-label information, while other federal officials have indicated that such conduct may violate the federal False Claims Act or the anti-kickback statute. In the past two years, WLF has been investigating whether such federal officials are violating the terms of the injunction entered in WLF v. Henney. That investigation includes a series of document requests (pursuant to the Freedom of Information Act) directed to (among others) FDA and the Office of Inspector General of the U.S. Department of Health and Human Services.

**Oversight of Criminal Probes Into Allegedly Improper Drug Promotion.** In connection with the investigation described above, WLF quickly concluded that criminal probes into allegedly improper drug promotion are not being supervised effectively by officials from the U.S. Department of Justice (DOJ) in Washington. On March 24, 2005, WLF filed a petition with the DOJ, urging it to remove the Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetic Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal probes are warranted. WLF said that OCL has simply rubber-stamped whatever criminal probe local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal probe. WLF said that it is particularly concerned about the need for effective DOJ



coordination in this area because criminal probes of promotional activities have the potential to adversely affect the nation's health care delivery system. FDA has not yet responded to WLF's petition.

**Proposed Restrictions on Alcohol Advertising and Marketing.** On November 1, 2005, WLF wrote to the Utah Attorney General, who also serves as head of the National Association of Attorneys General Task Force on Youth Access to Alcohol, to object to certain initiatives being undertaken by the Task Force. WLF argued that some of the Task Force's efforts to restrict alcohol advertising violate the First Amendment rights of product manufacturers. WLF argued that the Task Force had no basis for attempting to ban advertising in publications with more than a negligible youth readership; WLF cited Supreme Court decisions that prohibit government from barring truthful commercial speech aimed at adults simply because some children might see the advertisements. WLF also argued that the Task Force's proposed regulations of Flavored Malt Beverages are unwarranted and based on a misunderstanding of the manner in which these products have been marketed.

Tax Deductibility of Drug Advertising. After a U.S. Senator introduced legislation that would deny tax deductibility for pharmaceutical advertising for any drug company that sought to block reimportation of its drugs to the United States, WLF was asked by Capitol Hill officials to provide an analysis of the legislation's constitutionality. In an October 20, 2004 legal memorandum to Senator Charles Grassley and others, WLF concluded that the legislation would violate First Amendment rights. WLF noted that the bill threatened to deny speech-related tax deductions to a small group of companies in a single industry, while it would continue to grant tax deductions to similarly situated companies in other industries. WLF pointed out that the bill's sponsor admitted that the bill's sole purpose was to coerce pharmaceutical companies not to take actions designed to prevent importation of price-controlled prescription drugs. WLF argued that, under those circumstances, the bill could only be deemed speech regulation (not a mere denial of a speech subsidy) and thus could not pass muster under established First Amendment case law. After WLF submitted its analysis, the bill has not advanced out of committee.

WLF Petition Regarding Direct-to-Consumer Advertising of Prescription Drugs. In 1997, FDA adopted substantial revisions to its direct-to-consumer advertising policy. FDA's action was in direct response to WLF's July 20, 1995 Citizen Petition that sought relaxation of FDA restrictions on prescription drug advertising. The petition argued that those restrictions violated the First Amendment rights of drug manufacturers to convey truthful information to consumers, as well as the rights of consumers to receive such information. In particular, WLF asked FDA to eliminate: (1) the "brief summary" requirement, which often renders advertising non-cost-effective by requiring hundreds of words to be added to advertising; (2) the "fair balance" requirement, a totally subjective requirement that permits FDA to reject any advertisement it does not like; and (3) the requirement that advertisements be submitted to FDA for preclearance before being published. FDA's new policy substantially relaxed the "brief summary" requirements with respect to broadcast advertising. As a result of this change, television advertising of prescription drugs has increased substantially over the past eight years, and consumers have received significantly more information about these

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products.

*In re: Television Product Placement.* The Federal Trade Commission issued an opinion letter on February 10, 2005, rejecting a petition from an activist group urging greater regulation of product placement on television. The pro-regulatory petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert petitioned the FTC and the FCC in September, 2003, to adopt new regulations that would mandate a warning for all instances of product placement on television. WLF had filed a response arguing that product placements are not harmful or deceptive. WLF further argued that even if Commercial Alert could show some harm from product placements, the proposed regulations would violate freedom of speech as defined in U.S. Supreme Court cases. Coverage of WLF's response in The Hollywood Reporter and elsewhere raised awareness of the threat to commercial speech rights. The FTC agreed with WLF's position that paid product placement does not mislead or confuse consumers. WLF was the only public interest organization to file comments in opposition to the Commercial Alert proposal.

Greater New Orleans Broadcasting Ass'n v. United States. On June 14, 1999, the U.S. Supreme Court struck down a federal law prohibiting broadcast advertising within Louisiana for gambling casinos that legally operated within the State. The decision was a victory for WLF, which filed a brief urging that the law be struck down. The Court agreed with WLF that the advertising ban served no significant government interest, in light of the fact that casino gambling is legal in all areas where the plaintiffs were seeking to run advertisements. The Court held that the First Amendment virtually never permits a ban on non-misleading advertising for a lawful activity.

44 Liquormart, Inc. v. Rhode Island. On May 13, 1996, the U.S. Supreme Court unanimously struck down Rhode Island's ban on retailer advertising of alcoholic beverage prices as a violation of the First Amendment. The decision was a victory for WLF, which had filed a brief urging the Court to overturn the ban. The Court agreed with WLF that only rarely can truthful commercial speech be banned. The Court held that Rhode Island failed to demonstrate that a ban on truthful price information served any important state interest.

Jakanna Woodworks, Inc. v. Montgomery County. On February 14, 1997, the Maryland Court of Appeals (Maryland's highest court) unanimously struck down on First Amendment grounds a county ordinance that required merchants to obtain a license before advertising a "closing-out" sale. The decision was a victory for WLF, which had filed a brief in the case arguing that the license requirement imposed an unwarranted burden on commercial speech rights. The court agreed with WLF that the ordinance was unconstitutional as applied to truthful advertising; the court held that the county's interest in preventing deceptive advertising could be protected without requiring businesses to get licenses before being allowed to advertise.

**Opposing Regulation of Internet.** On November 10, 2001, FDA responded to an April 12, 2001 WLF Citizen Petition urging the agency to adopt a rule or policy explaining that health claims and other consumer information that appear on a company's website do not constitute "labeling" of that company's product, and thus are not subject to FDA's stringent and detailed food and drug



labeling requirements. Rather, any such promotional information should be regarded, at best, as advertising, and thus subject in certain circumstances to review by the Federal Trade Commission (FTC) under its "false and misleading" advertising standard. The FTC standard is more consistent with First Amendment protections of commercial speech than FDA labeling requirements. WLF's filing was prompted by an alarming FDA Warning Letter sent to Ocean Spray Cranberries, Inc. on January 19, 2001, the final day of the Clinton Administration. FDA claimed that Ocean Spray's cranberry and grapefruit juices were "misbranded" and subject to seizure simply because of certain health claims and other information that appeared on the company's website and related links. In its response to WLF's petition, FDA indicated that it would not be issuing an across-the-board regulation at this time, but that it would not generally regard a company's website content as labeling if the company does not sell products online.

**Petition Regarding Disclosure of Clinical Trial Results.** On December 28, 1995, WLF filed a joint petition for rulemaking with FDA and the Securities and Exchange Commission (SEC), urging FDA to exempt from FDA regulation the public disclosure of clinical test results of Investigational New Drugs (INDs). Such information is required by SEC rules to be disclosed to the investment community. Current FDA rules and policies prohibit drug companies from "promoting" or "commercializing" an IND until the drug obtains final approval. Yet the SEC requires that drug companies file reports with that agency and inform the investment community of major product developments. FDA has interpreted its rule against "promoting" an IND to include press releases and other communications made by companies regarding the results of clinical tests of INDs. FDA has not taken any decisive action on this issue, and WLF continues to press for relaxation of speech restrictions in this area. WLF argues that investors need to receive truthful information about drugs in "the pipeline" if they are to measure accurately the value of a pharmaceutical company's stock.

*Citizen Petition on Pharmacy Compounding.* On March 6, 1992, WLF filed a Citizen Petition with FDA, alleging that the agency's efforts to control advertising by pharmacies regarding their drug compounding capabilities violated the First Amendment, and urging the agency to utilize notice-and-comment rulemaking before adopting new regulations on that subject. FDA failed to heed WLF's warnings, resulting in the U.S. Supreme Court's 2002 decision in *Thompson v. Western States*, which found that FDA's efforts to regulate advertising regarding pharmacy compounding of drugs violated the First Amendment.

**FDA Draft Guidance on Medical Product Promotion.** On April 6, 1998, WLF filed comments expressing its deep reservations regarding FDA's Draft Guidance regarding "medical product promotion by health care organizations or pharmacy benefits management companies." WLF argued that FDA failed to demonstrate any need for the guidance and that it would have an adverse impact on health care. WLF also argued that FDA lacked statutory authority to issue the guidance and that it infringed the First Amendment rights of drug companies, doctors, and consumers. WLF requested that FDA withdraw the Draft Guidance and not issue it in final form. In light of intense opposition, FDA placed the proposal on hold in July 1998 and has taken no further action.

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**Opposing Proposed Controls on Tobacco Advertising.** On September 24, 2003, WLF submitted to U.S. Senator Jeff Sessions its analysis of proposed legislation that would impose severe federal controls on tobacco advertising and marketing. WLF completed the analysis at Senator Sessions's request. WLF concluded that the bill violates the First Amendment because it would prohibit vast amounts of truthful advertising, yet it is not narrowly tailored to achieve its stated goals – reduction of tobacco use by youth and adults. The bill would write into law 1995 FDA tobacco restrictions that were never enforced because the courts determined that FDA was not authorized to issue them. WLF noted that a 2001 Supreme Court decision that struck down Massachusetts tobacco advertising restrictions on First Amendment grounds made clear that many provisions in the 1995 FDA regulations – provisions that are incorporated into the pending legislation – are unconstitutional. WLF was particularly critical of provisions in the proposed legislation that would greatly restrict any comparative health claims by tobacco manufacturers. WLF argued that the First Amendment bars restrictions on such claims as long as manufacturers can demonstrate that the claims are truthful.

**Opposing Restrictions on Alcohol Advertisements.** WLF filed a petition with the FCC in October 1996, urging it not to take any action limiting the advertising of distilled spirits on television. WLF argued that the Supreme Court's recent decisions in this area made it absolutely clear that restrictions on truthful commercial speech are rarely, if ever, an effective or appropriate way for the government to achieve a public policy goal. WLF argued that this strict standard cannot be met with respect to liquor ads. There is little or no evidence that prohibiting television advertising of liquor will have a significant effect on underage drinking. Moreover, any restriction on the advertising of distilled liquor would primarily affect adults and would be far broader than necessary to reduce underage drinking. WLF made clear that the legitimate problem of underage drinking should be attacked through greater enforcement of existing laws, not through restrictions on the free speech rights of adults. Although FCC Chairman Reed Hundt had been advocating new limitations on television advertising, the FCC dropped the matter in June 1997 by voting not to issue a Notice of Inquiry regarding alcohol advertising.

**Relaxing Restrictions on Speech about Securities.** On December 20, 1995, WLF filed a petition for rulemaking with the Securities and Exchange Commission (SEC), asking the agency to revise its rules on the contents of securities prospectuses and advertisements to allow any truthful and nonmisleading information to be included. The permissible contents of an advertisement or prospectus within the SEC's jurisdiction are limited to certain information enumerated by statute and regulation. WLF argued that present regulations are inordinately restrictive and violate the First Amendment. WLF argued that although the SEC can compel disclosures in advertising and prospectuses to protect the public from fraud and abuse, it should not impose limitations on advertising content and on the content of prospectuses except to require that all information be truthful and nondeceptive.

# **B.** Product Labeling

Some bureaucrats argue that consumer decisions (particularly decisions related to food



consumption and health care) should be dictated by government officials because, they claim, most consumers cannot begin to understand the issues involved. Such paternalism is particularly prevalent with respect to the information that manufacturers are permitted to place on their product labels; bureaucrats regularly adopt rules that tightly restrict the information that may be included on a label, without regard to its truthfulness. WLF takes the opposite approach; it believes that providing consumers with access to accurate information vastly improves the quality of their choices, and including that information on a product label is often the best way to ensure that consumers have access to it. Accordingly, WLF has worked tirelessly over the past decade – both in the courts and before administrative agencies – to eliminate overly strict rules governing product labeling.

**Rubin v. Coors Brewing Co.** On April 19, 1995, WLF scored a decisive free-speech victory in the U.S. Supreme Court when the Court struck down a federal law that prohibited beer manufacturers from including the alcoholic content of their products on their labels. WLF's brief challenging the law was written with the assistance of former U.S. Solicitor General Charles Fried. The Court agreed with WLF that the First Amendment does not permit the government to bar inclusion of truthful information on product labels merely because it believes that some consumers might abuse that information. The Court held that denying consumers truthful information about a product whose sale is wholly lawful serves no legitimate government interest.

Legal Advice Regarding National Uniformity for Food Act. On November 29, 2005, at the request of U.S. Representative Edolphus Towns, WLF attorneys provided him with legal counsel regarding the propriety of the proposed National Uniformity for Food Act of 2005 ("NUFA"), which would require national uniformity in food safety and warning requirements. The bill would achieve uniformity by preventing States from imposing their own food labeling requirements once the federal government has established labeling requirements for a particular type of product. WLF's legal memorandum concluded that Congress would be acting appropriately were it to adopt the legislation. WLF concluded that NUFA is consistent with the federal government's traditional role in the regulation of interstate commerce and an appropriate response to the disruptions in interstate commerce caused by California's Proposition 65. WLF praised NUFA as "a carefully designed effort to balance the respective roles of the federal and State governments in food safety issues." WLF said that NUFA would have a significant impact only in those few States – such as California – in which excessive imposition of food warning requirements is having a negative effect on interstate commerce.

Alcohol Labeling Restrictions. On September 26, 2005, WLF filed formal comments with the Alcohol and Tobacco Tax and Trade Bureau (TTB) requesting that TTB revoke its ban on truthful alcohol labeling that would disclose basic "Serving Facts" information to consumers. WLF argued that consumers benefit when alcoholic beverage labeling lists the serving size, the number of servings per container, and the amount of alcohol per serving. WLF argued that such labeling is in the public interest, is truthful and not misleading, and is protected against unwarranted government regulations by the First Amendment. WLF argued that TTB is acting illogically by permitting manufacturers to convey this type of information in their advertisements but preventing the same information from being displayed on containers of beer, wine, or distilled spirits.

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Association of National Advertisers v. Lungren. Manufacturers often seek to include on product labels information indicating that their products do not cause environmental harm. Some state and local governments have sought to restrict (or even ban) such labeling without regard to truthfulness. WLF has regularly gone to court to oppose such restrictions on First Amendment grounds. For example, California has a law that prohibits a manufacturer from labeling its product "recyclable" in most instances, regardless whether the product is, in fact, recyclable. After WLF's challenge to the law proved unsuccessful in the lower courts, WLF asked the U.S. Supreme Court to hear the case. WLF argued that the restrictions on truthful labeling regarding environmental issues violated the First Amendment. On October 2, 1995, the Supreme Court declined to hear the case.

*"Lean" Labeling.* On February 8, 2006, WLF filed comments with FDA supporting the agency's proposal to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word "lean." WLF argued that the proposed change would assist consumers by providing them with accurate and relevant information and would also expand the market for lean foods.

**Opposing Warning Labels on Soft Drinks.** On December 16, 2005, WLF submitted comments to FDA, urging FDA to reject a petition filed by the Center for Science in the Public Interest (CSPI), a Washington-based consumer activist group. The petition would require labels on non-diet soft drinks to bear a warning that "drinking too much soft drinks may contribute to weight gain." WLF argued that such warning labels are unwarranted because labels on all beverages currently provide caloric content, sugar content, and other nutritional information to help consumers make informed choices. WLF argued that it is well known to all consumers that maintaining a healthy diet requires avoiding over-consumption of food containing sugar and fat; WLF argued that the First Amendment protects manufacturers from being forced to display warning statements under such circumstances. WLF also cited studies indicating that lack of exercise plays a far greater role in juvenile obesity than does overconsumption of sugar and fat.

**Proposed Labeling for Flavored Malt Beverages.** On October 21, 2003, WLF filed comments with the Alcohol and Tobacco Tax and Trade Bureau (a branch of the U.S. Treasury Department), opposing proposed regulations that would impose excessive and unjustified restrictions on truthful labeling and advertising by brewers of flavored malt beverages. The proposed regulations would ban a range of legitimate, non-misleading statements that brewers might wish to make about their products' taste, aroma, production process, flavoring, and the like. For example, it would prohibit brewers from truthfully informing consumers that a particular beer was aged in bourbon barrels. Citing the *Coors* decision (see above), WLF noted that the Supreme Court has specifically held that information on beer labels is commercial speech protected by the First Amendment and that the government must look to less restrictive alternatives before banning truthful statements.

**Proposal Regarding Trans Fatty Acid Nutrition Labeling.** On March 27, 2003, WLF filed comments with FDA, objecting to FDA's proposal to require all food containing trans fatty acids (trans fat) to include on its label the following statement: "Intake of trans fat should be as low as



possible." WLF argued that requiring that statement would violate the First Amendment protection against compelled speech. WLF argued that while the First Amendment permits the government to compel commercial speech when necessary to prevent consumers from being confused or deceived, there is no serious argument that the proposed statement is necessary to prevent food labels from being confusing or deceptive. WLF stated that FDA may do no more than mandate disclosure of the quantity of trans fat contained in each serving of the food being sold. While the proposed statement might contain sound health information, it might also unnecessarily alarm consumers; and WLF argued that it is not the role of the government to commandeer the property of others for the purpose of spreading information that may promote public health. In a victory for WLF, FDA announced on July 11, 2003 that it would not require food labels to include the controversial statement.

**FDA Proposals to Regulate Food Labeling.** WLF has long been at the forefront of efforts to ease FDA regulation of food labeling. For example, in a series of submissions to FDA in the early 1990s, WLF urged FDA to lift the ban on health-related information and certain types of pictures on food labels. The ban on health-related information eventually was lifted by Congress, and WLF has continuously worked to ensure that the new legislation is being fairly administered.

**Draft Compliance Policy Guide on Labeling**. On July 23, 1999, WLF filed comments with FDA, opposing its efforts to expand the definition of "labeling" under federal food and drug law. Under FDA's proposed definition, "labeling" of a drug would have included books and other publications that merely discuss a particular drug, even though that material does not "accompany" the drug as that term is commonly understood and as Congress intended. FDA ultimately abandoned its effort to expand the definition of what constitutes "labeling" of a drug or medical device.

Labeling of Genetically Engineered Products. On March 19, 2001, WLF filed comments with FDA, generally supporting the agency's proposed guidelines for the labeling of food with respect to whether it has been developed using biotechnology. WLF strongly supported FDA's tentative decision to continue its policy against mandatory labeling on the subject; WLF noted that such labeling does not provide any nutritionally meaningful information. WLF asserted, however, that industry should be afforded broad leeway when it comes to voluntary labeling with regard to bioengineering, because any effort to significantly restrict industry choice would raise major First Amendment issues. WLF asserted that the one area in which FDA restrictions are warranted is the area of health claims; WLF argued that labeling should not be permitted if it suggests that the labeled food is safer based on the presence or absence of genetically engineered ingredients — because there is no sound scientific basis for such claims. FDA ultimately adopted guidelines that closely tracked WLF's suggestions.

*Comments on Labeling of "Alcopops."* On July 23, 2001, WLF filed comments with the Bureau of Alcohol, Tobacco, and Firearms, expressing strong opposition to a request from the Center for Science in the Public Interest (CSPI) that BATF revoke existing labels for sweet-tasting malt-based alcoholic beverages (referred to by CSPI as "alcopops"). WLF argued that CSPI failed to identify any portion of such labeling that is in any way misleading to consumers or is otherwise in violation of BATF regulations. WLF also argued that any effort to prohibit "alcopop" manufacturers





from disseminating non-misleading product labeling would violate their First Amendment rights to engage in truthful commercial speech.

# C. Outdoor Advertising

State and local governments continue to impose unwarranted restrictions on billboards and other types of outdoor advertising. Sometimes these restrictions are based on an antipathy to all types of outdoor signs; WLF believes that while governments should be permitted to impose reasonable zoning restrictions on signage, many of these restrictions go much too far and significantly interfere with individuals' ability to exercise their First Amendment rights on their own property. On other occasions, the restrictions prohibit only certain types of signs, based on their content. WLF has repeatedly gone to court to oppose such content-based speech restrictions. The Supreme Court's *Lorillard* decision, in which WLF won a resounding First Amendment victory, may have put such content-based restrictions to rest for the immediate future.

Lorillard Tobacco Co. v. Reilly. On June 28, 2001, the U.S. Supreme Court overturned Massachusetts regulations that banned outdoor advertising of tobacco products while imposing virtually no restrictions on other products' advertising. The decision was a victory for WLF, which had filed a brief arguing that the regulations were unconstitutional. The Supreme Court agreed with WLF that the regulations could not be upheld in the face of a First Amendment challenge, as a measure reasonably designed to reduce underage smoking. The Court held that states could achieve that same objective by stepping up enforcement against merchants who violate the ban on sales to minors without interfering with speech. The Court also agreed with WLF that the Massachusetts regulations were preempted by a federal statute that severely limits states' power to regulate cigarette advertising.

*Federation of Advertising Industry Representatives v. Chicago.* On October 6, 2003, the U.S. Supreme Court without comment denied WLF's petition for review in this commercial speech case. WLF's July 2003 petition had urged the Court to reinstate a challenge to commercial speech restrictions imposed by the City of Chicago. WLF represented a group of advertisers that had been fighting in federal court since 1997 against a Chicago ordinance that prohibited outdoor advertising of alcoholic beverages. In April 2003, a federal appeals court dismissed the case as moot simply because Chicago repealed the ordinance after it became apparent that WLF would win the case. In its petition asking the Supreme Court to review that decision, WLF argued that a suit is never rendered moot simply because a defendant voluntarily ceases its objectionable conduct, except in very rare cases when it is absolutely clear that the conduct will not recur. WLF argued that to dismiss a suit as moot under these circumstances would leave a government free to re-impose its speech restrictions at any time.

*City of Ladue v. Gilleo.* On June 13, 1994, the U.S. Supreme Court unanimously struck down a city ordinance that prohibited homeowners from placing virtually all types of signs on their property. The Court's decision was a victory for WLF, which filed a brief arguing that the First Amendment protects the right of homeowners to express themselves by posting signs. WLF argued



that the First Amendment prohibits a municipality from deciding which signs are acceptable and which are not, based solely on their content.

Lindsey v. Tacoma-Pierce County Health Department. On November 19, 1999, the U.S. Court of Appeals for the Ninth Circuit handed WLF a major victory in this important commercial speech rights case. The appeals court struck down a Tacoma, Washington ordinance that banned outdoor advertising of tobacco products while imposing virtually no restrictions on other products' advertising. The court agreed with WLF's argument that when Congress adopted the Federal Cigarette Labeling and Advertising Act, it intended to prohibit any attempts by state and local governments to regulate cigarette advertising. WLF had also argued that the First Amendment prohibits government from deciding what advertising is acceptable based solely on the message conveyed by the advertisement. WLF argued that Tacoma's ostensible purpose in adopting the ordinance — to reduce underage smoking — could be achieved without infringing on speech rights if Tacoma intensified efforts to enforce the ban on sales to minors.

Greater New York Metropolitan Food Council v. Giuliani. On April 17, 2000, the U.S. Supreme Court issued an order declining to review this critical commercial speech case. WLF had filed a brief in the Court, urging it to hear a challenge to a New York City ordinance that banned virtually all outdoor advertising of tobacco products. The U.S. Court of Appeals for the Second Circuit had upheld the ordinance, holding (contrary to WLF's arguments) that the ordinance was not preempted by the Federal Cigarette Labeling and Advertising Act (FCLAA), which bars state and local government regulation of cigarette advertising that is "based on smoking and health." While the parties awaited a Supreme Court decision on whether to review the Second Circuit's FCLAA ruling, the plaintiffs pressed ahead in the district court with an alternative argument that the advertising ban violated their First Amendment rights. Adopting arguments raised by WLF regarding the First Amendment issue, the district court in January 2000 issued a preliminary injunction against enforcement of the ordinance. New York dropped its appeal from that decision after the Supreme Court issued its decision in the *Lorillard* case (see above).

Anheuser-Busch v. Baltimore. On April 28, 1997, the U.S. Supreme Court denied WLF's request to hear this commercial speech case, bringing to an end a challenge to Baltimore's stringent restrictions on billboards advertising liquor products. The case went up and down the federal courts several times, with WLF filing briefs opposing the billboard restrictions at every level of the judiciary. WLF scored a victory in 1996, when the Supreme Court vacated an appeals court decision upholding the ban, and remanded the case to the appeals court for reconsideration. The court of appeals, however, again upheld the speech restrictions; the Supreme Court declined to review that second decision. In its four briefs filed in the case, WLF argued that the plaintiffs should have been given the opportunity to present evidence that Baltimore's ordinance had no effect on underage drinking. Baltimore was later obliged to repeal its ordinance, following the Supreme Court's *Lorillard* decision (see above).

*Penn Advertising of Baltimore, Inc. v. Baltimore.* The U.S. Supreme Court on April 28, 1997 declined WLF's invitation to hear this case, which challenged Baltimore's near-total ban on



billboards advertising tobacco products. In November 1996, the U.S. Court of Appeals for the Fourth Circuit upheld the ban. The 2-1 decision was a setback for WLF, which filed several briefs urging the Fourth Circuit to strike down the ordinance on First Amendment grounds. Baltimore was later obliged to repeal its tobacco ordinance, following the Supreme Court's *Lorillard* decision (see above).

# **D.** Government Enforcement Actions Against Commercial Speakers

When a government agency goes to court to bring an enforcement action against companies based on statements they have made (or on their failure to include the government's preferred warnings along with their statements), WLF has joined the fray in opposing sanctions against entities that have done nothing more than speak the truth.

California v. R.J. Reynolds Tobacco Co. On June 9, 2004, the California Supreme Court declined to review a lower court decision that imposed significant sanctions on a company for engaging in nonmisleading commercial speech. The decision was a setback for WLF, which filed a brief urging the Court to grant review. WLF argued that the First Amendment protects a company's right to engage in such advertising and that tobacco companies have never agreed to waive such rights. California sued R.J. Reynolds Tobacco Co. for allegedly "targeting" youth with its advertising, based on evidence that Reynolds places advertising in magazines (such as *Sports Illustrated*) with up to 25% youth readership. WLF argued that Reynolds may not be sanctioned for its advertising in the absence of evidence that it purposely intended to target youth; mere knowledge that a youth would see its ads is not sufficient to sanction non-misleading speech.

**Trans Union LLC v. Federal Trade Comm'n.** On June 10, 2002, the U.S. Supreme Court declined to review a lower-court decision that denied full First Amendment protection to truthful speech deemed by the court not to "relate to matters of public concern." In its brief urging review, WLF argued that all truthful, noncommercial speech should be entitled to full First Amendment protection, and that a court should not get into the business of determining which speech involves topics that are insufficiently weighty and thus are less worthy of protection. In this case, the lower court upheld an FTC order prohibiting companies from transmitting truthful, noncommercial lists of names and addresses of consumers, and imposing sanctions on a company that had done so. WLF argued that the decision was inconsistent with numerous Supreme Court First Amendment decisions.

*Word-of-Mouth Marketing.* On February 2, 2006, WLF filed with the FTC a response in opposition to a petition seeking an investigation of word-of-mouth, or "buzz," marketing programs. The petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert claimed in its petition that programs inviting consumers (without compensation) to tell their peers about new products are deceptive if the consumers do not also disclose that they are participating in a marketing program. WLF argued in its response that such communications are not deceptive and that there is no basis for requiring the disclosures sought by Commercial Alert.

Novartis Corp. v. Federal Trade Commission. On August 18, 2000, the U.S. Court of



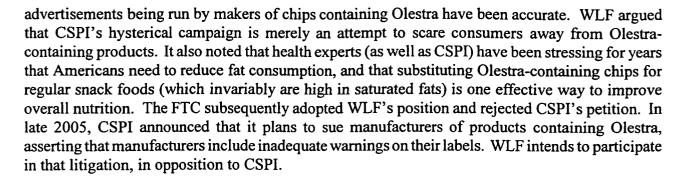
Appeals for the D.C. Circuit upheld a Federal Trade Commission (FTC) order requiring Novartis Corp., a pharmaceutical company, to include a government-dictated message in its advertising. The court ruled that the First Amendment posed no bar to the FTC's so-called corrective advertising order. The decision was a setback for WLF, which had filed a brief urging the court to set aside the FTC's order. The case involved an order from the FTC – which had determined that Novartis's advertisements for Doan's Pills had been misleading in suggesting that Doan's offers more effective relief for back pain than other pain relievers – directing Novartis to include the following statement in all Doan's advertising: *"Although Doan's is an effective pain reliever, there is no evidence that Doan's is more effective than other pain relievers for back pain."* In its brief, WLF argued that the FTC's corrective advertising order violated Novartis's right to remain silent. WLF said that the FTC order was particularly troublesome because it resulted in Novartis refraining from advertising at all rather than conveying the FTC's "corrective" message.

**Defending Corporate Speech on Food Irradiation.** On August 7, 2003, WLF filed comments with the Federal Trade Commission, objecting to efforts by activists to censure speech about food irradiation. Two activist groups, Public Citizen and the Center for Food Safety, petitioned the FTC to take enforcement action against Giant Food based on statements Giant made regarding the irradiation of its food products. Giant issued a pamphlet that, in an effort to add to consumers' understanding of irradiation, compared the irradiation process to milk pasteurization. The activist groups asserted that the law prohibits food sellers from representing irradiated food as "pasteurized." WLF countered that the comparison of irradiation and pasteurization is not misleading and assists American consumers in understanding that irradiation is a process designed to enhance food safety and cleanliness. WLF argued that the First Amendment protects Giant's right to make truthful statements regarding the irradiation process.

**PCRM Petition Regarding "Milk Mustache"** Advertisements. On March 13, 2000, WLF filed comments with the FTC, opposing a petition filed by the Physicians Committee for Responsible Medicine (PCRM), which charged that the famous "Milk Mustache" advertisements are false or misleading. The PCRM argued that the advertisements are misleading because they provide consumers with the allegedly false impression that milk consumption is good for everyone's health. WLF argued that the First Amendment protected the Milk Mustache ads from any government control. WLF argued that there is not only an overwhelming consensus in the medical community that milk consumption promotes good health among everyone except those with specific allergies, but also that the FTC and the courts have no authority to second-guess Congress's determination that milk consumption should be promoted. The FTC ultimately decided not to address the petition.

**CSPI** Petition Regarding Olestra Advertisements. On September 28, 1998, WLF filed comments with the FTC, urging the agency to reject "false advertising" claims raised by a self-appointed consumer watchdog group. The Center for Science in the Public Interest (CSPI) has been waging a quixotic campaign for years in an effort to prevent marketing of Olestra, a fat substitute used in potato chips and other snacks. The Food and Drug Administration rejected CSPI's claims that Olestra is not safe for human consumption, so CSPI then brought its campaign to the FTC arguing that advertising claims that Olestra is safe are false. In its comments, WLF argued that





Action Against Alcoholic Beverage Advertisers. On October 13, 1998, WLF filed comments with the FTC, urging it to reconsider proposed consent agreements against two companies regarding the advertising of their products. The FTC claimed that an advertisement for Beck's Beer was false and deceptive merely because it pictured actors standing on a sailboat and holding the product. The FTC claimed that such advertisements convey the false image that it is safe to drink beer while boating, and that viewers would so the same. The FTC also objected to an advertisement claiming that the Kahlua White Russian pre-mixed cocktail was "low alcohol" because beer has less alcohol. WLF argued that the advertisements were not false or misleading and that the FTC's interpretation of its authority was mistaken.

**Kraft, Inc. v. Federal Trade Comm'n.** On February 22, 1993, the U.S. Supreme Court denied review in this case involving suppression of Kraft's television and print advertisements by the FTC. The FTC contended that certain advertisements for "Kraft Singles" constituted false advertisement by implying untrue claims. The Supreme Court's decision was a setback for WLF, which filed a brief urging the Court to hear the case. WLF argued that federal agencies should not be permitted to censor an advertisement where, as in this case, every claim in the ad is literally true and the FTC has conducted no studies to substantiate its assertion that some consumers might nonetheless be misled by those truthful claims. WLF argued that the First Amendment does not permit the government to restrict advertisements without some substantial basis for asserting that the ads are misleading.

*Peel v. Attorney Registration and Disciplinary Comm'n.* On June 4, 1990, the U.S. Supreme Court ruled that the First Amendment bars states from prohibiting lawyers from publicizing their certification as "specialists" by bona fide private organizations. The decision was a victory for WLF, which filed a brief in the case in support of an Illinois lawyer who was sanctioned by state authorities for listing on his letterhead the truthful statement that he had been certified as a civil trial specialist. The Court agreed with WLF that the First Amendment protects the right of professionals to make truthful statements about their qualifications.

#### **E.** Private Tort Actions Against Commercial Speakers

It is not just government agencies that bring enforcement actions against companies based on what they say or do not say. Such actions also take the form of tort actions filed by private



parties. WLF has been particularly vigilant in opposing lawsuits by private parties who do not claim to have been hurt by the speech; they sue simply because they do not like what the company has said. For example, WLF has also gone to court in an effort to curb abuse of state statutes (*e.g.*, California's 17200 "unfair competition" statute) that allow trial lawyers and other uninjured individuals to seek court sanctions against commercial speakers by purporting to act on behalf of the state government.

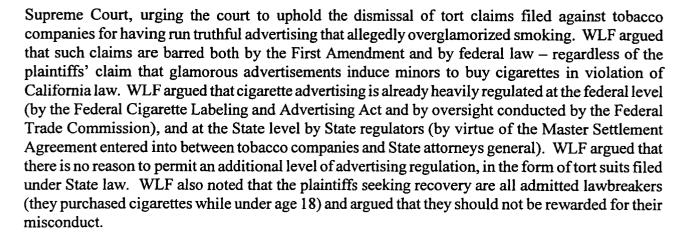
*Doe v. Wal-Mart Stores, Inc.* On May 5, 2006, WLF filed a brief in U.S. District Court in Los Angeles, urging the Court to dismiss a lawsuit brought against Wal-Mart by activists who are critical of Wal-Mart's overseas labor practices. In response to such criticisms, Wal-Mart issued statements denying that it purchases products manufactured overseas under "sweat shop" conditions. The activists responded by filing suit against Wal-Mart under California's infamous 17200 "unfair competition" law, claiming that Wal-Mart's denials are false and constitute unfair competition. WLF's brief urged dismissal on the ground that the First Amendment fully protects Wal-Mart's right to speak out on issues of public importance, such as international labor conditions. WLF also urged dismissal of the plaintiffs' claims that overseas labor practices used by Wal-Mart's suppliers violate international human rights laws because they constitute "slavery."

*Nike, Inc. v. Kasky.* On June 26, 2003, the U.S. Supreme Court declined review of a California Supreme Court decision threatening to impose severe restrictions on the right of corporations to speak freely on matters of public importance — including manufacturers seeking to respond to critics of their overseas labor practices. In January 2003, the Court agreed to review the case but five months later changed its mind and dismissed as "improvidently granted" its original order granting review. In two separate briefs filed in the case, WLF argued that the California court effectively held that *all* corporate speech — even speech on matters of great public importance — is entitled to reduced levels of First Amendment protection. WLF argued that the decision is contrary to a long line of Supreme Court decisions and threatens to chill significant amounts of speech by corporations.

*Baxter International Inc. v. Asher.* On March 21, 2005, the U.S. Supreme Court issued an order declining to review (and ultimately overturn) an appeals court decision that eviscerates a 1996 federal law intended to limit the liability of corporations that make projections ("forward-looking statements") regarding future sales and earnings. The decision was a setback for WLF, which had filed a brief urging the court to review (and ultimately overturn) the appeals court decision. The 1996 law creates a "safe harbor" for forward-looking statements; provided such statements are accompanied by "meaningful" cautions, the safe harbor mandates that the statements cannot be used to hold a publicly held corporation liable to its shareholders for subsequent drops in stock prices, regardless how inaccurate the statements turn out to be. The appeals court interpreted the safe harbor so narrowly that it provides virtually no protection to corporations. WLF argued that Congress intended to provide broad protection for forward-looking statements in order to encourage companies to provide such information. WLF is looking for other cases raising the same issue, with a goal of bringing the issue to the Supreme Court's attention once again.

In re Tobacco Cases II. On September 14, 2005, WLF filed a brief in the California





Physicians Comm. for Responsible Medicine v. General Mills . On September 2, 2005, WLF filed a brief in the U.S. District Court for the Eastern District of Virginia, urging the court to dismiss a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. WLF argued that the suit threatens to undermine manufacturers' commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled as manufacturers become increasingly unwilling to comment on such issues. The suit targets a recent milk industry advertising campaign that advocates increased consumption of dairy products as a method of losing weight. The Physicians Committee for Responsible Medicine (PCRM) challenges the validity of the scientific studies that form the basis for the industry's advertising. PCRM argues that the weight-loss claim is false and violates Virginia's consumer protection and false advertising laws. Their principal request is that the court issue an injunction against any further promotion of the weight-loss claims. WLF argued that Virginia law does not permit individuals to obtain injunctions against speech. WLF also argued that such suits raise serious First Amendment issues because of their potential to chill truthful speech on issues of public importance, such as whether increases in consumption of dairy products are good for one's health.

*Philip Morris USA v. Boeken.* On March 20, 2006, the U.S. Supreme Court declined to review a California court decision that imposed a massive liability award against the manufacturer of a "light" cigarette on the ground that the public believes that "light" cigarettes pose less of a health risk than they actually do. The order, issued without comment, was a setback for WLF, which filed a brief urging the Court to review the case. WLF argued that such tort claims are preempted by federal law because cigarette manufacturers already display all the health and safety warnings mandated by the federal government. WLF argued that Congress determined, when it adopted the Federal Cigarette Labeling and Advertising Act, the health warnings that manufacturers must include in advertising and on their labeling. WLF argued that states should not be permitted to second-guess that congressional determination by allowing tort suits that would require manufacturers to impose additional warning requirements. WLF argued that Congress has passed a series of laws designed to allow companies in a wide variety of industries to advertise nationwide by imposing a uniform



advertising standard and barring States from adopting conflicting standards. WLF argued that the California court decision could have the effect of undermining all such laws.

*Metro-Goldwyn-Mayer Studios v. Grokster*. On June 27, 2005, the U.S. Supreme Court issued a decision that provided appropriate protection for copyrights without unduly interfering with commercial speech rights or otherwise interfering with computer software development. The Court held that a company whose file-sharing software allows others to illegally copy and disseminate copyrighted music and films on the Internet also itself violates the copyright law. The decision addressed several important and previously undecided copyright issues. WLF had filed a brief in November 2004, urging the Court to address those issues. Copyright laws protect owners of the copyrighted work from having their music or films downloaded without paying the owner a royalty fee. Grokster software enabled computer users to share music and film files between each other utilizing so-called "peer-to-peer services," usually violating the copyright laws. Consequently, major motion picture studios and record companies sued Grokster on the theory that it was guilty of contributory infringement. The Court ruled against Grokster, but in a manner unlikely to infringe speech rights or to inhibit development of innovative software products.

National Cable & Telecomm. Ass'n v. Brand X Internet Services. On June 27, 2005, the U.S. Supreme Court ruled that the Federal Communications Commission (FCC) could properly decide not to infringe the speech rights of cable and DSL companies by imposing burdensome regulatory requirements on the delivery of broadband Internet access. The decision was a victory for WLF, which filed a brief with the Court supporting the FCC's position. The case arose from a decision by the FCC to treat cable modem service as an "information service" rather than a "telecommunications service." The decision meant that cable modem providers (local cable television providers) would not be required to share their lines with other providers of Internet. The Supreme Court agreed with WLF that the FCC's decision was sound policy because intense competition in the broadband market – among cable companies, local telephone companies (which provide DSL service), and companies in the process of developing new technologies for broadband service – ensures that consumers will be well served without the need for exacting FCC regulation of what these companies do and say.

#### F. Discriminatory Treatment of Commercial Speakers

Often, governments discriminate against commercial speakers by treating differently two speakers who act and speak in an identical manner, based solely on that fact that one speaker is speaking in a commercial context and one is not. WLF views such discrimination as a blatant violation of the First Amendment and has regularly gone to court to ensure that commercial speakers are not treated as second-class citizens.

**Petition Regarding Restrictions on Speech About Part D Plans.** On April 4, 2006, WLF petitioned the federal Centers for Medicare and Medicaid Services (CMS) to lift restrictions on commercial speech imposed by CMS's marketing guidelines for carriers offering Medicare prescription drug benefit plans. The guidelines prohibit carriers from making truthful and non-



misleading statements comparing their plans to other plans. WLF's petition asserted that the speech restrictions are beyond the scope of CMS's authorizing regulations and violate the First Amendment rights of carriers and consumers.

Los Angeles Police Dep't v. United Reporting Publishing Corp. On December 7, 1999, the U.S. Supreme Court refused to overturn a California law that permits localities to withhold from the public at large (including commercial users) the names and addresses of those arrested, while simultaneously releasing that information to select noncommercial groups. The 7-2 decision was a setback for WLF, which had filed a brief urging that the statute be struck down. In its brief, WLF had argued that the Los Angeles Police Department was violating the First Amendment by favoring noncommercial users over commercial users. The Court said that the plaintiffs could not bring a *facial* First Amendment challenge to the law (that is, a suit asserting that the law is unconstitutional in all possible situations) because they were not being prohibited from conveying information in their possession; rather, their only complaint was that they were being denied access to government information. But the Court said that on remand the plaintiffs (commercial users of the names) could argue that the statute is unconstitutional as applied to them in particular, because it treats them less favorably than it treats other groups (such as newspapers) seeking the arrestee information.

*City of Cincinnati v. Discovery Network.* On March 24, 1993, the U.S. Supreme Court struck down a Cincinnati ordinance prohibiting the distribution of commercial publications (such as real estate listings) by means of news racks placed on city streets, while simultaneously allowing newsrack distribution of general-circulation newspapers. The decision was a victory for WLF, which filed a brief urging that the ordinance be struck down on First Amendment grounds. WLF argued that the First Amendment prohibits such government content-based discrimination against commercial speakers, particularly where (as in this case) the potential harm created by news rack distribution of commercial circulars (litter on the streets) is no greater than the harm created by news rack distribution of general-circulation newspapers.

Austin v. Michigan State Chamber of Commerce. On March 27, 1990, the U.S. Supreme Court held that the First Amendment does not protect the right of corporations to make independent political expenditures in support of a candidate for public office — even though individuals *do* have a constitutional right to make such expenditures. The decision was a setback for WLF, which filed a brief urging the Court to strike down a Michigan law prohibiting such corporate expenditures. WLF argued that there is no reason to afford corporations less protection than individuals under the First Amendment. WLF argued that the danger of corruption is no greater when the independent expenditures are made by a corporation than when they are made by individuals.

#### G. Compelled Speech

The First Amendment protects not only the right to speak but also the right *not* to speak. All too often, governments attempt to compel companies to speak against their will, either by forcing them to say things they do not wish to say or by forcing them to provide financial support for speech with which they disagree. WLF repeatedly has litigated in support of companies and individuals



whose First Amendment right not to speak is being infringed upon.

Johanns v. Livestock Marketing Ass'n. On May 23, 2005, the U.S. Supreme Court ruled that the federal government may force beef producers to provide financial support for advertising with which they disagree, because the government at least nominally supervises the advertising. The 6-3 decision was a setback for WLF, which filed a brief urging the Court to strike down the advertising program. WLF argued that the First Amendment protects not only the right to speak but also the right not to speak, and that forcing someone to provide financial support for private speech with which he disagrees violates his First Amendment rights. The Court held that so long as the speech in question originates with the government, the First Amendment does not prohibit the government from forcing small groups of people to fund the speech against their will. The Court left open the possibility that the plaintiffs could still establish, in later proceedings, that the government was not exercising any control over the speech – in which case they could prevail on their First Amendment claims.

**R.J. Reynolds Tobacco Co. v. Shewry.** On February 21, 2006, the U.S. Supreme Court declined to review an appeals court decision that rejected a First Amendment challenge to an advertising campaign conducted by the State of California. The Court's action, made without comment, was a setback for WLF, which filed a brief urging the Court to review the appeals court ruling. WLF argued that the First Amendment prohibits a State from forcing a company to pay for advertisements that vilify the company. California imposes a special fee on the tobacco industry and then uses it to finance a \$25 million per-year ad campaign that repeatedly portrays tobacco companies as liars and "public enemies." WLF argued that the First Amendment protection against compelled financial support of speech to which one objects has been recognized repeatedly by the courts and applies just as strongly when the speaker is the government as it does when the speaker is a private party. WLF argued that the vilification campaign is unconstitutional because the government may not use funds obtained from a small group of citizens to finance ideological speech to which those citizens object. WLF also filed briefs in the case when it was before the appeals court.

Gerawan Farming, Inc. v. Kawamura. On June 3, 2004, the California Supreme Court issued a decision that sets strict free-speech standards for reviewing a California law that compels farmers to pay for advertisements generically promoting plums. The court did not strike down the law; rather, it remanded the case for a trial, during which the California Supreme Court's new standards were to be applied. The decision was a partial victory for WLF, which filed a brief arguing that forcing individuals to fund advertising with which they disagree violates their free-speech rights. WLF had asked the court to strike down the law without ordering a trial. The advertising in question conveys the message that all California plums are of uniformly good quality. Gerawan objects to being forced to pay for those ads, because it has invested heavily in developing a distinctive, high-quality plum.

United States v. United Foods, Inc. On June 25, 2001, the U.S. Supreme Court handed WLF a victory by striking down a federal program forcing farmers to contribute to generic advertising with



which they disagree. The Court agreed with WLF that compelled *commercial* speech deserves no less constitutional protection than other forms of compelled speech. This case arose from a constitutional challenge brought to overturn certain provisions of a federal law that requires mushroom growers to fund generic advertising. In its brief filed with the Supreme Court, WLF had urged the Court to adopt the most searching standard of judicial review – strict scrutiny – in cases where a governmentally mandated subsidy program is challenged on free speech grounds. WLF concluded that the mandatory subsidy in this case cannot survive the strict scrutiny test.

**Board of Regents of the Univ. of Wisconsin v. Southworth.** On March 20, 2000, the U.S. Supreme Court overturned a court of appeals ruling and held that compelling objecting students to pay "student fees" to subsidize the political activities of activist campus groups does not violate the students' First Amendment rights because the funding scheme was viewpoint neutral. The University of Wisconsin at Madison distributes approximately \$1 million a year in student fees to private organizations on campus, including Ralph Nader's Public Interest Research Group (PIRG); the Internationalist Socialist Organization; and the Militant Student Union. Other universities across the United States have similar funding schemes, although some of them allow objecting students to opt out of the system. WLF argued that compelling college students to subsidize the political speech and lobbying activities of activist groups violates the objecting students' fundamental First Amendment rights not to be forced to subsidize the speech of others.

Glickman v. Wileman Bros. & Elliott, Inc. On June 25, 1997, the U.S. Supreme Court upheld a federal program that requires California fruit growers and distributors to fund generic fruit advertising even though they disagree with the message being conveyed by the advertisements. The 5-4 decision was a setback for WLF, which had filed a brief arguing that the program violated First Amendment protections against compelled speech. WLF's brief argued that the First Amendment protects not only the right to speak but also the right not to speak, and that the latter includes the right not to be forced to provide financial support for others' speech. WLF also argued that the protection against compelled speech is not lessened simply because the speech one is forced to support is commercial in nature.

Hollingsworth v. Lane Community College. On March 24, 1999, the U.S. Court of Appeals for the Ninth Circuit upheld a lower court decision that rejected a challenge by a group of students who were forced to fund Oregon Student Public Interest Research Group (OSPIRG) at Lane Community College. The decision was a setback for WLF, which filed a brief urging the appeals court to overturn a lower court decision dismissing a challenge to the funding scheme. WLF argued that compelling the students to subsidize a political and ideological group with which they disagreed violated their First Amendment rights. OSPIRG is just one of many Naderite PIRG groups that operate on campuses across the country and lobby state legislatures on behalf of liberal causes. All students at these schools are forced to pay a portion of their student fees to these campus PIRG groups, although a few universities refund students the portion of fees earmarked for PIRG if they so request through a cumbersome procedure.

Smith v. Regents of University of California. In February 1993, WLF scored a victory when



the California Supreme Court ruled that state universities are prohibited by the state constitution as well as the First Amendment from using a student's mandatory fees to fund campus organizations whose political activities the student finds objectionable. The court agreed with WLF that requiring students to financially support political and ideological organizations through mandatory student fees violates the students' rights to freedom of speech and association. The case arose at the University of California at Berkeley, where student fees were used to subsidize a number of environmental, antibusiness, and radical organizations.

*Keller v. State Bar of California.* On June 4, 1990, the U.S. Supreme Court unanimously held that attorneys cannot be compelled to support the political and ideological campaigns of state bar associations as a condition of practicing law. The decision was a victory for WLF, which filed a brief in support of the objecting attorneys. WLF argued that because California requires individuals wishing to practice law to join the state bar, the use of mandatory bar dues to support political and ideological causes violates the First Amendment rights of attorneys not to be forced to fund speech with which they disagree.

## **II. CIVIC COMMUNICATIONS PROGRAM**

WLF recognizes that its litigation and administrative agency advocacy is not enough to bring about a long-term effect in opposing the efforts of activists and policy makers hostile to commercial speech. WLF has also sought to influence public debate and provide information through its Civic Communications Program. This targeted and broad-based program features WLF's sponsorship of frequent, well-attended media briefings featuring experts on a range of commercial speech-related topics, the publication of advocacy advertisements in national journals and newspapers, and participation in countless advertising and commercial speech symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media — from reporters for general-circulation newspapers to writers for specialized legal journals.

#### **A. Media Briefings**

The centerpiece of WLF's Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on health-related topics. Recent media briefings on commercial speech-related issues have included the following:

#### Scrutiny of Medical Education Grants: A Chilling Wind for Doctors and Patients?,

•Jeffrey N. Gibbs, Hyman, Phelps & McNamara, P.C. •Steven E. Irizarry, ML Strategies •Laura Frick Laemmle, Patton Boggs LLP



Regulating Drug Promotion: Assessing a Tumultuous 2005 and Prospects for the New Year •David Bloch, Reed Smith

•Adonis Hoffman, American Association of Advertising Agencies •Richard A. Samp, Washington Legal Foundation

# Veneman v. Livestock Marketing: Compelled Commercial Speech Pays Another Visit to the Supreme Court

Philip C. Olsson, Olsson, Frank and Weeda, P.C.
Gregory G. Garre, Hogan & Hartson L.L.P.
Thomas C. Goldstein, Goldstein & Howe, P.C.

Alcohol Use and Promotion: The Next Target for "Regulation by Litigation"?
•John A. Calfee, American Enterprise Institute
•Jonathan Turley, George Washington University
•John J. Walsh, Carter, Ledyard & Milburn LLP

"Off Label" Communications At Risk: Promoting Prescription Drugs in an Uncertain Legal Environment

•John F. Kamp, Wiley, Rein & Fielding •Stephen Paul Mahinka, Morgan Lewis LLP •Richard A. Samp, Washington Legal Foundation

- Free Speech & Public Health: FDA, Congress, and the Future of Food and Drug Promotion •John E. Calfee, American Enterprise Institute •Richard L. Frank, Olsson, Frank & Weeda •Sandra J. P. Dennis, Morgan Lewis LLP
- Washington Legal Foundation v. Henney: The Appeals Court's Ruling and FDA's Curious Response on Off-label Promotion

Bert W. Rein, Wiley, Rein & Fielding
Robert A. Dormer, Hyman, Phelps & McNamara
Richard A. Samp, Washington Legal Foundation

- Does FCC's "Public Interest Mandate" Inhibit Our Freedom to Communicate? •The Honorable Harold Furchtgott-Roth, Federal Communications Commission •Richard E. Wiley, Wiley, Rein & Fielding •Robert L. Corn-Revere, Hogan & Hartson LLP •Randolph J. May, The Progress and Freedom Foundation
- Tobacco Legislation: A Constitutional Tragedy in the Making? •Solange E. Bitol, American Civil Liberties Union •Robert A. Levy, The Cato Institute
- FCC and the First Amendment: An 'Elastic' Public Interest Mandate? •The Honorable James H. Quello, former Commissioner of the Federal Communications Commission



#### **B.** Web Seminars

WLF Web Seminars, initiated in March 2005, present viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF's website. The speakers for the programs, who provide their insights on a *pro bono* basis, are leading experts in the field of law to be discussed. Recent web seminars on commercial speech-related issues have included the following:

An Unattractive Legal Theory: Lessons from the Successful Defense of Anti-Alcohol Advertising Class Actions

•J. Russell Jackson, Skadden, Arps, Slate, Meagher & Flom LLP

Serono and DOJ's False Claims Settlement: Implications for Medical Product Marketing •Laura Frick Laemmle, Patton Boggs LLP •Richard A. Samp, Washington Legal Foundation

Got Lawyers?: Why Court Should Dismiss Activists' Anti-Milk "Consumer Protection" Suit •Richard A. Samp, Washington Legal Foundation

## C. Advocacy Ads

Since 1998, the Washington Legal Foundation has published a series of opinion editorials titled "In All Fairness" on the op-ed page of the national edition of *The New York Times*. The op-ed series has appeared over 100 times, reaching over five million readers in 70 major markets as well as 90 percent of major newspaper editors. Excessive government regulation of commercial speech has been the focus of many "In All Fairness" columns:

#### Exploiting Beer, Liquor & Food

(Activists' attacks on advertising of disfavored products in the name of protecting children and health are actually a tactic to promote their special interest agenda)

#### Will Ronald McDonald Survive the Millennium?

(Consumer and regulatory activism against disfavored products poses threat to consumer choice)

#### A Constitutional Tragedy in the Making

(Legislation regulating tobacco advertising raises serious First Amendment concerns for all businesses)

#### Gagging Free Enterprise

(Courts and regulators should demonstrate more sensitivity to the constitutional implications of restricting businesses' speech)



#### Eating Away at Our Freedoms

(Attacks by consumer activists against certain food products harm consumer choice and result in costly regulations and taxes)

#### A New FDA?

(FDA should expedite its drug approval procedures to improve public health and stop micromanaging drug advertising)

#### Bring Accountability to FDA

(Excessive FDA enforcement and misguided regulatory policies harm the health of Americans)

#### The World According to FDA

(FDA's policy to regulate the dissemination of publications describing off-label use of FDAapproved drugs harms the health of Americans and violates the First Amendment)

These and other "In All Fairness" columns are available at WLF's web site, www.wlf.org.

### **D.** Public Appearances

WLF attorneys regularly address policymakers and thought leaders on commercial speech issues. WLF attorneys have appeared as featured panelists and speakers on commercial speech issues before such institutions as the Federal Trade Commission, the Food and Drug Law Institute, the American Medical Association, the Federalist Society, the Heritage Foundation, the American Bar Association, the Pharmaceutical Research and Manufacturers of America, and MedicalAlley. What follows are highlights of the numerous public appearances that WLF attorneys have made in the past decade to address commercial speech issues:

March 30, 2006, WLF Chief Counsel Richard Samp was a featured panelist at the Medical Device Regulatory and Compliance Congress, held at Harvard University; Samp discussed manufacturers' First Amendment rights to speak truthfully about FDA-approved medical products.

December 14, 2005, Samp was the keynote speaker at a breakfast symposium in Minneapolis sponsored by MedicalAlley and MNBIO. Samp's speech focused on recent federal government enforcement actions – directed against advertising and promotional activities of the pharmaceutical and medical device industries – under the False Claims Act and the anti-kickback statute.

May 11, 2005, Samp was a featured speaker at a seminar in New York City sponsored by Harvard Business School Publishing. Samp spoke on the corporate community's First Amendment rights to speak out on issues of public importance.

January 27, 2005, Samp was a featured speaker at a conference organized by the Food & Drug Law Institute in Washington, D.C. entitled, "Product Liability for FDA Regulated Products: In What Kind of World Are We Living?" Samp addressed tort liability faced by drug manufacturers for speaking truthfully about their products.





January 23, 2004, Samp was a featured speaker at the annual meeting in Atlanta of NAAMECC (a trade group for companies that produce continuing medical education symposia), warning against government restrictions on the First Amendment right to speak truthfully regarding medical issues.

November 20, 2003, Samp addressed the American Bar Association's annual pharmaceutical conference in Philadelphia, arguing that expanded use of the False Claims Act as a vehicle for suing drug companies is jeopardizing free speech rights and the ability of drug company's to continue to develop new, life-saving therapies.

November 8, 2003, Samp addressed the annual meeting of the Society for Academic Continuing Medical Education in Washington, arguing that proposed restrictions on who may speak at Continuing Medical Education events are far too restrictive.

September 9, 2003, Samp addressed the American Medical Association's National Task Force on Continuing Medical Education (CME) in Chicago; Samp argued that proposed restrictions on who can speak at CME gatherings violate First Amendment norms.

April 23 and again June 26, 2003, Samp appeared on CNBC to discuss *Nike v. Kasky*, the Supreme Court case that addressed the First Amendment right of corporations to freely discuss matters of public interest.

October 25, 2002, Samp was a featured panelist at a symposium organized by the Federalist Society, entitled, "FDA and the First Amendment."

October 7, 2002, Samp was a panelist at the annual conference of the Regulatory Affairs Professional Society in Washington, D.C., speaking on "The First Amendment and FDA Regulation."

September 11, 2002, Samp spoke at the Food and Drug Law Institute's ("FDLI") annual conference in Washington, regarding First Amendment constraints on FDA regulation of speech by pharmaceutical companies.

August 1, 2002, Samp was a featured panelist in an audio conference sponsored by FDLI on "First Amendment Issues Facing the Food and Drug Administration."

May 22, 2002, WLF Chairman Daniel Popeo was the featured speaker at the Annual Meeting of the Medical Device Manufacturers Association (MDMA). At the MDMA Chairman's Luncheon, Popeo discussed the crucial work of WLF in promoting open markets, free enterprise, and competition, and WLF's legal activities challenging excessive regulation by FDA.

May 18, 2001, Samp spoke at a luncheon of the Philadelphia chapter of the Federalist Society, regarding FDA regulation of manufacturer speech.

April 20, 2000, Samp was a featured panelist at a New York City symposium sponsored by the Federalist Society, entitled, "The Future of Commercial Speech."

April 6, 2000, Samp addressed a symposium in Washington, D.C. sponsored by the Drug Information Association, regarding "Promoting, Prescribing, and Paying for Off-Label Indications."



September 13, 1999, Samp was a panelist at the FDLI's annual conference, discussing First Amendment restrictions on FDA regulation.

August 25, 1999, Samp was the keynote speaker at the annual meeting of the Indiana Medical Device Manufacturers Association in Indianapolis, where he discussed WLF's successful challenge to FDA speech restrictions.

June 29, 1999, Samp addressed an FDLI conference regarding manufacturer dissemination of peerreviewed journal articles that discuss off-label uses of FDA-approved products.

May 20, 1999, Samp addressed an FDLI conference regarding WLF's First Amendment victory over the FDA in WLF v. Henney.

January 28, 1999, Samp addressed the Food, Drug, and Cosmetics law section of the New York Bar Association on WLF's victory in *WLF v. Henney*.

January 13, 1999, WLF Legal Studies Division Chief Glenn Lammi provided educational commentary on the *WLF v. Henney* case to a group of pharmaceutical marketers at a Center for Business Intelligence seminar.

October 26, 1998, Samp was the keynote luncheon speaker at the annual meeting of the Outdoor Advertising Association of America; Samp spoke about First Amendment limitations on the power of government to prohibit billboards.

September 10, 1998, Samp addressed a FDLI symposium, to discuss WLF's court victories over FDA on First Amendment issues.

June 13, 1997, WLF Senior Executive Counsel Paul Kamenar was a featured speaker at the 6th Annual Conference on Biologics and Pharmaceuticals sponsored by International Business Communications, discussing WLF's First Amendment lawsuit against FDA.

April 9, 1997, Samp addressed a conference sponsored by the Drug Information Association in New Orleans, regarding efforts by FDA to suppress speech regarding off-label uses of approved drugs and medical devices.

March 20, 1996, Popeo was a keynote speaker at a conference of the Healthcare Marketing & Communications Council in New York City discussing reform of FDA, WLF's litigation against FDA, and other related programs promoting commercial free speech.

December 7, 1995, Samp spoke to a group of pharmaceutical executives at a Rockville, Maryland forum sponsored by International Business Conferences, regarding WLF's continuing efforts to prevent FDA abuse of First Amendment rights.

December 7, 1995, Samp was a featured speaker (along with Rep. Joe Barton) at a forum sponsored by the Heritage Foundation entitled, "Is the FDA Killing America?"



October 20, 1995, Samp addressed (along with U.S. Senator Bill Frist of Tennessee) a gathering of orthopedic surgeons at a symposium of the North American Spine Society on the need to streamline FDA.

October 18, 1995, Samp testified before an FDA panel, urging FDA to lift restrictions on direct-toconsumer advertising of prescription drugs.

September 20, 1995, Lammi spoke at a meeting of the Ad Hoc In-House Counsels Working Group, a group of attorneys for pharmaceutical companies, on FDA's restrictions on advertising and promotion.

September 19, 1995, Popeo served on the faculty at the American Medical Association's Sixth National Conference on Continuing Medical Education. Popeo discussed WLF's lawsuit against FDA regarding the suppression of medical literature discussing off-label uses of FDA-approved drugs and devices.

June 27, 1995, Kamenar was a featured speaker at an FDLI conference in Washington, D.C. He discussed WLF's FDA-reform project and its lawsuit against FDA for prohibiting the dissemination of information about off-label uses of approved drugs and devices.

June 16, 1995, Lammi appeared on National Empowerment Television to discuss FDA reform.

May 22, 1995, Kamenar debated U.S. Representative Don Wyden (D-Ore.) and Bruce Silverglade of the Center for Science in the Public Interest on "America's Talking" cable television network, regarding FDA reform.

March 13, 1995, Samp addressed the annual meeting of the Pharmaceutical Research and Manufacturers of America (PhRMA) on the need for reform of FDA.

January 31, 1995, Samp was a featured guest on the Diane Rehm Show (syndicated by WAMU-Radio in Washington, D.C.), debating the need for reform of FDA with Dr. Sidney Wolfe of the Public Citizen Health Research Group.

## **III. PUBLICATIONS**

WLF's Legal Studies Division is the preeminent publisher of persuasive, expertly researched, and highly respected legal policy papers. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDERS covering current developments affecting the American legal system, to comprehensive Monographs providing law-review-length inquiries into significant legal issues.

Since its inception fifteen years ago, WLF's Legal Studies Division has produced a voluminous library of publications regarding commercial speech rights. The areas on which these papers have focused range from substantive explanations of key court decisions to analyses of federal and state regulations and legislation for their impact on commercial speech rights. Authoring these





papers *pro bono* for WLF are America's leading commercial speech experts from business, government, the judiciary, private law firms, and academia. Notable authors include: New York University law professor **Burt Neuborne**; University of San Diego Distinguished Professor of Law **Bernard Siegan**; U.S. Court of Appeals for the Ninth Circuit Judge Alex Kozinski; then-FDA Chief Counsel **Daniel Troy**; and former Federal Appeals Court Judge Robert Bork.

WLF commercial speech publications have been cited in influential court rulings, law review articles, legal briefs, and congressional debates; have provided intellectual firepower to those who are fighting against advertising restrictions at the federal and state levels; are relied upon by constitutional and advertising issue reporters; and are frequently reprinted in widely read trade journals and newsletters.

Judicial Chorus Against "Attractive Advertising" Suits Grows Louder With Ruling By J. Russell Jackson, a partner at Skadden, Arps, Slate, Meagher, & Flom LLP and an adjunct professor of law at Brooklyn Law School. LEGAL OPINION LETTER, June 16, 2006, 2 pages

#### D.C. Court Dismisses "Attractive Advertising" Class Action Lawsuit

By **J. Russell Jackson**, a partner in the Complex Mass Torts Group of New York's Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School. COUNSEL'S ADVISORY, May 5, 2006, 1 page

#### Health And Speech Rights At Risk from Attacks On Medical Education

By Jeffrey N. Gibbs, a principal with the law firm Hyman, Phelps & McNamara, P.C. in its Washington, D.C. office. LEGAL BACKGROUNDER, April 7, 2006, 4 pages

#### Advertising And Preemption Under FDA's New Drug Labeling Rule

By Tish E. Pahl, a principal with Olsson, Frank and Weeda, P.C. LEGAL OPINION LETTER, March 24, 2006, 2 pages

#### Federal And State Courts Reject "Attractive Advertising" Claims

By **J. Russell Jackson**, a partner in the Complex Mass Torts Group of New York's Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School. LEGAL BACKGROUNDER, March 10, 2006, 4 pages

#### **Court Properly Dismisses Anti-Alcohol Class Action Suit**

By Cari K. Dawson, a partner, and Tiffany L. Powers, an associate, with the law firm of Alston & Bird LLP.

COUNSEL'S ADVISORY, December 16, 2005, 1 page

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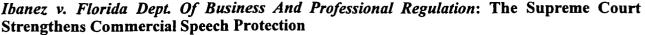
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# **ACTIVITIES REPORT**

to the

# WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

# SUPPORTING NATIONAL AND HOMELAND SECURITY

July 21, 2006

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### JULY 21, 2006

## ACTIVITIES REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

## SUPPORTING NATIONAL AND HOMELAND SECURITY

The ideals upon which America was founded – individual freedom, limited government, a free market economy, and a strong national security and defense – are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. WLF's overriding mission is to defend and promote the principles of freedom and justice.

Over the last 29 years, WLF has been the only public interest law and policy center on the forefront of legal battles to defend our national security and oppose terrorism, including filing legal briefs opposing the terrorists who bombed the World Trade Center in 1993. Since the attacks on America on September 11, 2001, WLF has redoubled its efforts in the courts, agencies, and public arena to promote its belief that the clearest path to peace and prosperity is through military strength and zero tolerance for those who seek to do us harm. This report highlights some of the more significant WLF national security/anti-terrorism activities over the past five years:

## I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF's public interest programs. WLF litigates across the country before courts and administrative agencies in support of maintaining national security, both by providing our armed forces and law enforcement personnel with the tools to carry out their missions and by securing our nation's borders.

#### A. Detaining and Prosecuting Enemy Combatants

Before 9/11, the United States generally responded to terrorism by bringing traditional criminal prosecutions. One of the lessons of 9/11 was that the war on terrorism cannot be fought effectively if we continue to provide every terrorist with a full-blown criminal trial rather than doing as we have done in past wars: locking up enemy combatants without trial for the duration of hostilities. WLF has repeatedly gone to court to support the federal government when it is challenged by anti-war groups whose actions, if successful, would cripple our ability to prevent another major attack within this country. In many cases, *hundreds* of groups have lined up against the Bush Administration, while WLF is the Administration's only courtroom supporter.



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Hamdi v. Rumsfeld. On June 28, 2004, the U.S. Supreme Court upheld the federal government's right to detain Yaser Hamdi, a Saudi-American accused of serving as a Taliban soldier in Afghanistan, without initiating criminal proceedings. The decision was a partial victory for WLF, which filed a brief in the case in support of the military. The Court agreed with WLF that the government's right to detain Hamdi as an enemy combatant is not diminished simply because of his claim to citizenship – he was born in Louisiana to Saudi parents and moved with his family to Saudi Arabia as an infant. The Court also agreed with WLF that the courts should deferentially treat the military's factual determination that Hamdi was in Afghanistan to fight for the Taliban, not (as Hamdi claims) to undertake humanitarian work. The Court remanded the case to the lower courts, however, finding that Hamdi should have been given a greater opportunity to prove his innocence than he was initially afforded by the federal appeals court. Hamdi was later released from custody after he agreed to abandon his U.S. citizenship and the military determined that he no longer posed a threat to national security.

Padilla v. Hanft. On April 3, 2006, the U.S. Supreme Court declined to review a lower court decision upholding the federal government's detention of Jose Padilla, the "dirty bomber" accused of being an al Qaeda operative. The decision was a victory for WLF, which filed a brief urging the Court not to hear the case. The Supreme Court neither declared the case moot nor vacated the lower court decision on mootness grounds, even though Padilla, a U.S. citizen, is no longer being held as an "enemy combatant" - Padilla was recently released from military custody and turned over to civilian authorities to face trial in connection with largely unrelated charges that he conspired to aid overseas terrorist organizations. As a result of the Supreme Court not taking any action to declare the case moot, the September 2005 appeals court decision in the government's favor remains standing and can serve as a precedent in future enemy combatant cases. WLF filed a total of four briefs in support of the government as Padilla's case wended its way through the federal courts over the past four vears. On September 9, 2005, the U.S. Court of Appeals for the Fourth Circuit in Richmond upheld the federal government's detention of Padilla. As a result of decisions in this case, the courts have now clearly established that the government is entitled to detain without trial American citizens discovered fighting for enemy forces, just as it is entitled to detain any enemy soldier captured in time of war. The courts also agreed with WLF that the right to detain Padilla was not diminished simply because he was captured in Chicago rather than on some overseas battlefield. The government alleges that Padilla fought with al Qaeda/Taliban forces in Afghanistan against the United States. Padilla is currently imprisoned in Miami, awaiting trial on criminal charges alleging conspiracy to promote terrorism.

Hamdan v. Rumsfeld. On June 29, 2006, the U.S. Supreme Court struck down the Bush Administration's plan to convene military commissions to conduct trials of al Qaeda leaders accused of war crimes. The 5-3 decision was a setback for WLF, which filed a brief in the case urging that the plan be upheld. The Court held that while the President has the authority to convene military commissions, the commissions that he established were improper because they did not provide defendants with all of the procedural rights required under the



Uniform Code of Military Justice (UCMJ). The Court said that if the Administration wishes to employ its proposed procedures, it will have to go to Congress and ask it to amend the UCMJ. Alternatively, the Court ruled, the Administration could conduct trials before military commissions but must use the same procedural rules commonly employed in courts martial. WLF's brief argued that Congress has explicitly endorsed the creation of such commissions, which have been used throughout American history. WLF also filed briefs in the case when it was before the district court and the court of appeals. Despite the Court's ruling, the petitioner – who served as Osama bin Laden's personal driver and is accused of conspiring to murder Americans – remains in custody at Guantanamo Bay, Cuba; the ruling affects only the government's right to proceed with a trial, not its right to detain Hamdan.

Al Odah v. United States On March 22, 2006, the U.S. Court of Appeals for the District of Columbia Circuit held a second set of oral arguments in this case, which challenges detention of suspected terrorists at Guantanamo Bay, Cuba. The latest hearing was necessitated by Congress's adoption in December 2005 of the Detainee Treatment Act (DTA), which withdraws from the federal courts all jurisdiction to hear cases filed by Guantanamo detainees. WLF filed a brief on January 8, 2006, urging the court to rule both that the DTA is applicable to cases (such as this one) that were pending when the DTA was adopted, and that Congress acted constitutionally in withdrawing jurisdiction. WLF also filed a brief in April 2005, contesting the merits of the detainees' claims. WLF argued that the U.S. Constitution does not extend protections to aliens not living in the United States. WLF argued that the protections of the Constitution are reserved for U.S. citizens and others, such as resident aliens, who have contributed to American society and thus have a legitimate basis for invoking constitutional protections. WLF also argued that even if detainees were entitled to Due Process Clause protections, they have already received all the process that could possibly be due them under the Constitution. WLF noted that the American military has established the Combatant Status Review Tribunal (CSRT) system for adjudicating detainees' claims that they never fought for either the Taliban or al Qaeda. All of those still being detained at Guantanamo Bay have been determined by a CSRT to be enemy combatants who took up arms against the United States or its allies. It is uncontested that the military is authorized to detain enemy combatants until hostilities cease. WLF argued that the CSRT system satisfies the detainees' due process concerns, because it ensures that all detainees have a fair opportunity to contest their detention. This case is a follow-on to Rasul v. Bush (see below), in which the Supreme Court held that federal courts have jurisdiction to hear claims of nonresident aliens who are challenging their detention.

**Rasul v. Bush.** On June 28, 2004, the U.S. Supreme Court held that the federal courts have jurisdiction to hear a challenge to the U.S. military's decision to detain captured Taliban and al Qaeda fighters at the Naval Base in Guantanamo Bay, Cuba. The decision was a setback for WLF, which filed a brief urging a finding of no jurisdiction. The detained fighters filed petitions for writs of habeas corpus, alleging that their detention without trial violates their rights under the Fifth Amendment's Due Process Clause as well as their rights under international law. Ignoring a 1950 precedent to the contrary, the Court ruled 6-3 that the



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habeas corpus statute adopted by Congress grants federal courts jurisdiction to hear claims filed by nonresident aliens who are challenging their detention. The Court did not address the merits of the detainees' claims, nor did it indicate how such claims are to proceed (e.g., whether detainees should have access to counsel). In urging the Court to deny jurisdiction, WLF had argued that allowing America's enemies to use our courts to challenge military detention is one of the surest ways to hamper our military effectiveness.

**Coalition of Clergy, Lawyers, and Professors v. Bush.** On November 18, 2002, the U.S. Court of Appeals for the Ninth Circuit dismissed a habeas corpus petition filed by a group of activists on behalf of the detainees at Guantanamo Bay, Cuba. The court agreed with WLF that the plaintiffs lacked standing to bring the case. The activists had filed a petition for a writ of habeas corpus in federal district court in California, seeking judicial review of the conditions of confinement of the detainees, who include Taliban and al Qaeda fighters captured by U.S. forces in Afghanistan. The so-called "Coalition of Clergy, Lawyers, and Professors" included such activists as Ramsey Clark, a former Attorney General who has represented radicals and terrorists (including the PLO and one person who was convicted in the 1993 World Trade Center bombing), and activist law professor Erwin Chemerinsky.

**Opposing ABA's Resolution on Torture.** On August 9, 2004, the American Bar Association's (ABA) governing body, the House of Delegates, adopted a resolution at the ABA's annual meeting in Atlanta, Georgia, that condemned "degrading" or "cruel" treatment of any terrorist suspect who is in the physical control of the U.S. government – but it failed to define those terms. Because the ABA resolution could easily be read to prohibit the military from using effective and well-recognized interrogation techniques, WLF actively opposed the resolution. WLF argued before the House of Delegates that the ABA's extreme position was wrong both as a matter of law and on public policy grounds. WLF's views were presented by David B. Rivkin, Jr., a partner in the Washington, D.C. office of Baker & Hostetler, who represented WLF *pro bono* at the ABA meeting.

Opposing ABA's Resolution Condemning Designation of Enemy Combatants. On February 10, 2003, WLF presented testimony before the ABA's winter meeting in Seattle, Washington, opposing a Board of Governor's Resolution that condemned the Bush Administration's designation of certain terrorists and their supporters as "enemy combatants." WLF argued that the President has the constitutional authority to make such designations, regardless whether the terrorist is a United States citizen. Although the resolution was passed with modifications, WLF's legal arguments were ultimately vindicated in lawsuits involving U.S. citizens, and enemy combatants, Yaser Hamdi and Jose Padilla.

Jurisdiction of Military Tribunals over Terrorists. On March 7, 2003, WLF filed comments with the Department of Defense urging it to expand the categories of offenses committed by terrorists that could be subject to trial before military tribunals. WLF's comments related to crimes involving the use of poisonous gases, the improper use of a flag of truce, and aiding the enemy. WLF also recommended expanding acts of terrorism to include



solicitation, conspiracy, and attempted offenses. The Defense Department agreed, and ultimately revised its rules to expand the jurisdiction of military tribunals.

**Revisions to Sentencing Guidelines for Terrorism.** On March 19, 2002, WLF submitted comments to the U.S. Sentencing Commission supporting certain proposed revisions to its guidelines, policy statements, and commentary in response to adoption of the USA PATRIOT Act of 2001. WLF urged the Commission to adopt changes to its guidelines that would allow federal courts to impose the maximum punishment permitted by law for those who commit terrorist acts and for those who aid and conspire with them. The Sentencing Commission ultimately adopted the revisions.

Regulation Providing for Monitoring of Detainee-Lawyer Communications. On December 28, 2001, WLF filed comments with the U.S. Department of Justice (DOJ) supporting its interim regulations that allow DOJ to monitor conversations between certain suspected terrorists who are being detained and their attorneys. WLF argued that the regulations are clearly constitutional inasmuch as the attorney-client privilege does not extend to communications to an attorney that involve the commission of further crimes. WLF also noted that the DOJ regulations include constitutional safeguards, such as notification to both the detainee and the attorney that their conversations may be monitored and use of a special "taint team" that ensures that information obtained from monitoring is not given to prosecutors for use in any criminal trial. DOJ ultimately adopted the regulations on a permanent basis.

#### **B.** Detaining Alien Felons Pending Deportation

Federal law requires the deportation of all aliens convicted of supporting terrorism or of other felonies. However, effecting those deportations often takes years. WLF has repeatedly gone to court to ensure that convicted felons remain in detention while they are fighting deportation. Even after a deportation order has been entered, deportation can be delayed for years while immigration authorities seek a country willing to accept the convicted felon; many countries are slow in taking back their own citizens, while others (*e.g.*, Cuba) will not take anyone back. WLF also litigates in support of detention of convicted felons who are subject to final deportation orders; WLF argues that indefinite detention is appropriate, even when an alien felon subject to a final deportation order has no realistic short-term prospect of finding a country willing to accept him, if the convicted felon is deemed to pose a serious public safety risk.

*Clark v. Martinez.* On January 12, 2005, the U.S. Supreme Court held that the federal government may not indefinitely detain excludable aliens while they await deportation to their native countries, even if the aliens are dangerous felons. The decision was a setback for WLF, which filed a brief urging the Court to permit such detentions. The decision has resulted in the release from detention of more than 1,100 illegal aliens convicted of violent crimes. WLF had





argued that society's interest in being protected from violent criminals and terrorists far outweighs any interest that illegal aliens may have in being free from detention during the time it takes to arrange their deportation. The two cases before the Court involved Cubans who came to this country illegally in 1980 as part of the Mariel boatlift. Although at least one of them had been convicted of armed robbery in Cuba, they were released "temporarily" into U.S. society until Cuba could be persuaded to take them back. In the ensuing years, both Cubans were repeatedly convicted of violent crimes. WLF argued that the U.S. government need not give them yet another chance at freedom while they await deportation. The Court disagreed, holding that a 1996 federal statute bars indefinite detention of aliens with no prospect of being returned to their native countries. The Court made clear, however, that Congress was free to amend the law to provide for such detentions.

Snyder v. Rosales-Garcia. On June 23, 2003, the U.S. Supreme Court declined to review a lower-court decision that raised the same issue (detention of excludable aliens pending deportation to Cuba) that was later decided in *Clark v. Martinez* (see above). The decision was a setback for WLF, which on May 23, 2003 filed a brief urging that review be granted. The case involved two Cubans who sought to sneak into the country illegally in 1980 and were later convicted of numerous violent felonies. When their prison terms were completed, the INS sought to detain them indefinitely until their deportation could be arranged. The U.S. Court of Appeals for the Sixth Circuit (in conflict with other appeals courts) ruled that indefinite detention violated the alien felons' rights to liberty.

Al Najjar v. Ashcroft. On August 30, 2002, the Immigration and Naturalization Service (INS) deported Mazen Al Najjar, a suspected fundraiser for Palestinian terrorists, to Lebanon. Despite efforts by the ACLU and other civil libertarian groups, the INS was allowed to continue to detain Al Najjar up until the date of his departure. The continued detention of the suspected terrorist was a victory for WLF, which on two occasions filed briefs in the U.S. Court of Appeals for the Eleventh Circuit in Atlanta in support of Al Najjar's detention. His deportation brought to an end Al Najjar's final court challenge to his detention; the appeals court several weeks later dismissed the challenge as moot. In its most recent brief supporting Al Najjar's detention, filed on May 28, 2002, WLF argued that the INS does not violate the First Amendment rights of illegal aliens by detaining those it believes have engaged in fundraising for terrorist groups. WLF argued that such detention does not interfere with rights of political association, because fundraising goes beyond mere association and is not protected by the First Amendment.

*Kiareldeen v. Ashcroft.* On December 5, 2001, the U.S. Court of Appeals for the Third Circuit in Philadelphia reversed a district court decision finding that the INS was not even "substantially justified" in detaining a suspected alien terrorist pending deportation. Based on that finding, the lower court had ordered taxpayers to pay the suspected terrorist, Hany Kiareldeen, \$110,000 to cover his attorney fees. In reversing, the Third Circuit held that the district court's decision was "an abuse of discretion." The decision was a victory for WLF, which on October 25, 2001 had filed a brief in the case, arguing that the government is



always justified in detaining an illegal alien when it has reason to suspect that the illegal alien is a terrorist. The appeals court agreed with WLF that the government was justified in relying on classified evidence (i.e., evidence shown to the defendant in summary form only) in deciding to detain him.

**Demore v. Kim.** On April 29, 2003, the U.S. Supreme Court upheld the authority of the federal government to detain, pending completion of deportation proceedings, all aliens (including permanent resident aliens) subject to deportation because they have been convicted of aggravated felonies. The decision was a victory for WLF, which had filed a brief with the Court arguing that alien felons have no constitutional right to be free from detention during the time it takes to complete deportation proceedings. A federal law mandates detention of all such felons; the U.S. Court of Appeals for the Ninth Circuit struck down the law as a violation of felons' due process rights. The Court agreed with WLF that the statute is based on the reasonable assumption that *any* felon facing deportation will flee if released from detention after he has completed his criminal sentence. WLF also argued that Congress has explicitly prohibited courts from second-guessing such detention decisions.

*Riley v. Radoncic.* On May 5, 2003, the U.S. Supreme Court overturned a decision that challenged the authority of the federal government to detain, pending completion of deportation proceedings, those *illegal* aliens subject to deportation because they have been convicted of aggravated felonies. The decision was a victory for WLF, which had filed a brief urging the Court to uphold the authority of the federal government to detain such aliens. WLF argued that alien felons who admittedly are in this country illegally have no constitutional right to be free from detention during the time it takes to complete deportation proceedings. A federal law mandates detention in all such cases; the U.S. Court of Appeals for the Third Circuit struck down the law as a violation of illegal aliens' due process rights. In successfully urging the Supreme Court to overturn that decision, WLF argued that illegal aliens should be afforded extremely limited due process rights and that the federal statute mandating detention is based on the reasonable assumption that illegal alien felons will flee if released from detention after they have completed their criminal sentences. The case involved Sabrija Radoncic, a citizen of Yugoslavia who sneaked into the U.S. in 1991 and thereafter earned his livelihood smuggling other illegal aliens into the country.

Rule Denying Permanent Residency to Refugees Who Commit Major Crimes. On September 9, 2002, WLF filed comments with the Immigration and Naturalization Service (INS), supporting an INS proposal (ultimately adopted) that tightened immigration rules for refugees who commit major crimes and urging the INS to adopt rules that would absolutely prohibit granting permanent resident alien status to refugees who commit major crimes after arriving in this country. WLF argued that Congress has made clear that even permanent resident aliens who commit felonies should be deported as soon as possible, so there can be no justification for granting more leniency to refugees (who have a lower immigration status than do resident aliens) who engage in criminal activity. The INS's rule provided that refugees who commit violent crimes should be granted permanent resident alien status only in the most



extraordinary circumstances. While applauding that proposal as a step in the right direction, WLF argued that the rule should be amended to eliminate *all* exceptions.

**Proposed Rule Regarding Detention of Aliens Subject to Final Deportation.** On January 15, 2002, WLF filed comments with INS, strongly supporting the INS's proposed changes (ultimately adopted) to its custody review process governing the detention of aliens who are subject to a final order of removal. A June 2001 Supreme Court decision barred the INS in most cases from holding such aliens in custody *indefinitely* if the INS cannot locate a country willing to accept them. WLF applauded INS for coming up with new rules that comply with the Supreme Court's mandate without unnecessarily endangering public safety. WLF urged INS to change its policy in one significant respect: WLF urged that *all* aliens who have been convicted of an aggravated felony and are subject to a final order of removal be detained, *regardless* whether the INS can prove that they pose a threat to public safety.

Proposal for Procedural Reforms for Case Management of Board of Immigration Appeals. On March 21, 2002, WLF submitted comments in support of DOJ's proposed procedural reforms to improve case management at the Board of Immigration Appeals (BIA). The proposed rule (ultimately adopted) revised the structure and procedures of the BIA, provided for an enhanced case management procedure, and expanded the number of cases referred to a single BIA member for disposition. These changes have been a major factor in BIA's ability in subsequent years to significantly reduce its notoriously long backlog of cases.

**Proposed Interim Rule Regarding Temporary Detention of Aliens.** On November 19, 2001, WLF submitted comments in support of the interim rule amending the INS's rules on "Custody Procedures." The interim rule was a modest but needed measure that allowed the INS up to 48 hours, rather than the previous 24-hour period, within which to make a determination whether an arrested alien will continue to be held in custody or released on bond or recognizance. Adoption of this measure on a permanent basis has decreased the danger that suspected terrorists will be released before their identity can be uncovered.

Stays Pending Appeal in Immigration Detention Cases. On December 28, 2001, WLF filed comments with the Department of Justice supporting DOJ's proposal to provide an automatic stay pending appeal in any case in which an Immigration Judge orders the release of an alien previously ordered detained by the INS. WLF argued that in light of the enhanced risk of terrorist attacks, it is crucial that the INS take all steps to ensure that aliens who it believes pose a threat to public safety not be released while the issue of whether they pose a threat is still being litigated. WLF argued that aliens objecting to being detained while they fight deportation will still be entitled to rapid adjudication of their objections, because the DOJ proposal requires that any appeals from an Immigration Judge to the Board of Immigration Appeals must be handled expeditiously.

### C. Protecting Victims of Terror

When Americans are killed or injured by terrorists, WLF supports their right to obtain compensation from the perpetrators. Most American terrorism victims do not bother to sue, because the potential defendants either lack financial resources or are not amenable to suit in American courts. But when a foreign government is shown to have assisted the terrorists, WLF regularly goes into court to assist Americans seeking compensation from those foreign governments – which often have substantial assets that plaintiffs can seize to satisfy judgments.

Acree v. Iraq. On April 25, 2005, the Supreme Court declined to review this important case seeking damages against Iraq and Saddam Hussein for torturing American Prisoners of War (POWs) during the 1991 Gulf War. The decision was a setback for WLF, which had filed a brief urging Supreme Court review. WLF also filed a brief in support of the former POWs when the case was before a federal appeals court; that court dismissed the case in 2004. It ruled that while the district court had jurisdiction in the case, federal law does not provide a cause of action for the POWs. The plaintiffs, Colonel Clifford Acree and 16 other American servicemen, filed suit against the Republic of Iraq in early 2002, seeking damages for injuries they suffered when they were physically and psychologically tortured after being captured by Iraqi forces during the 1991 Gulf War. The district court entered a large judgment in their favor, but the appeals court reversed. WLF filed its briefs on behalf of a bipartisan congressional group that included U.S. Senators George Allen, Tom Harkin, Patty Murray, and Harry Reid, and 17 Members of the U.S. House of Representatives.

Ungar v. Palestine Liberation Organization. On March 31, 2005, the U.S. Court of Appeals for the First Circuit in Boston required the Palestine Liberation Organization (PLO) and the Palestinian Authority (PA) to be answerable in court to claims that they are complicit in the deaths of Americans killed by Middle East terrorists. Because the PLO and PA refused to raise a merits-based defense in the trial court but instead chose to rely solely on their alleged sovereign immunity, that court entered a \$116 million default judgment against them in 2004. The First Circuit's decision upheld that massive judgment. The decision was a victory for WLF, which filed a brief in the case in support of the plaintiffs. The appeals court agreed with WLF that because there is not now a sovereign state of Palestine, neither the PLO nor the PA should be granted sovereign immunity from suit in U.S. courts, a privilege normally granted by the U.S. to other nations. The case arose in the aftermath of the murders of Yaron Ungar (an American citizen) and his wife Efrat at the hands of Hamas terrorists. Their survivors filed suit under the Antiterrorism Act against (among others) the PLO and the PA, claiming that those groups aided and abetted the murders. WLF's victory in the case became complete on November 28, 2005 when the Supreme Court declined to review the First Circuit's decision.

Jacobsen v. Oliver. On July 29, 2003, WLF filed a brief in the U.S. District Court for the District of Columbia, urging the court to hold that victims of Middle East terrorism are



permitted to seek punitive damages against MOIS (the Iranian foreign intelligence agency) based on MOIS's active involvement in the terrorist activity. WLF argued that allowing punitive damage awards against government sponsors of terrorism will make it less likely that governments will be willing to provide such support in the future. WLF argued that 1996 amendments to the Foreign Sovereign Immunities Act made clear that Congress did not intend to grant immunity to groups such as MOIS. On March 30, 2006, the court issued an order granting partial summary judgment to the defendants and dismissing a portion of the plaintiff's claims. Although the order said that a written decision would be forthcoming soon explaining the court's action, no decision had been issued by July 2006.

### **D.** Protecting National Security Information

In this information age, the federal government needs to be careful not to make sensitive government information too readily accessible to potential terrorists. WLF regularly takes steps to ensure that government agencies are not inadvertently disclosing sensitive information and has gone into court to oppose activists' efforts to require disclosure of information that could endanger national security.

Center for National Security Studies v. Dep't of Justice. On June 17, 2003, WLF scored a major victory when the United States Court of Appeals for the District of Columbia Circuit upheld the decision by the Department of Justice (DOJ) to withhold the public release of the names and certain other information about those aliens detained in the United States following the September 11, 2001 terrorist attacks on America. The court agreed with WLF that releasing the information could interfere with law enforcement efforts, and that the government was not required by law to disclose the information. WLF filed briefs in the case in both the district court and court of appeals. The suit against the government was filed under the Freedom of Information Act (FOIA) by a group of activists, led by the ACLU. The suit sought the names of all aliens who were arrested or detained in connection with DOJ's investigation of the 9/11 terrorist attacks, as well as the names of any of their attorneys. The Supreme Court later denied the ACLU's request to review the case.

Interim Rule to Keep Detainee Information Confidential. On June 26, 2002, WLF filed formal comments with the INS supporting an interim rule (ultimately made permanent) that prohibited state and local governments from releasing any identifying information about alien detainees that are held in non-federal facilities under contract with the INS. Due to limited space availability in federal detention facilities, many of the aliens detained following the 9/11 terrorist attacks were held in state and local facilities. The effect of this rule was to pre-empt state and local disclosure laws that would otherwise have allowed the information to be released. The interim rule was issued in response to a ruling in a lawsuit brought by the American Civil Liberties Union of New Jersey, seeking the release of the names of alien detainees held in New Jersey's county jails under New Jersey's Right-to-Know law. WLF argued that releasing the names of all detainees would endanger national security.



Closing Public Reading Rooms Containing Sensitive Information About Dangerous Chemicals. Citing the risk of foreign and domestic acts of terrorism, WLF petitioned the EPA on December 8, 2001, to close all of its public reading rooms where sensitive information and data on the chemical industry can be easily obtained. WLF also petitioned the EPA to refrain from posting sensitive information on its website. Following the terrorist attacks on America on September 11, 2001, the EPA only "temporarily" shut down that part of its website which provided information to the public about the Risk Management Plans (RMP) submitted by companies regarding the specific location, use, storage, and production of dangerous chemicals. EPA nonetheless continued to make this sensitive information readily available for inspection by anyone who visited EPA reading rooms across the country. In response to WLF's petition, EPA revised its policies by imposing additional restrictions on access to sensitive information.

Deleting Sensitive Materials from Government Websites. On December 31, 2001, WLF filed petitions with three separate government agencies, urging them to review their policies regarding posting sensitive information on their Internet sites. The three agencies were the National Nuclear Security Administration (NNSA), the Department of Transportation's Office of Pipeline Safety (OPS), and the Nuclear Regulatory Commission (NRC). The NNSA's responsibilities include the manufacture and maintenance of nuclear weapons materials for the Department of Defense. The OPS's activities include the National Pipeline Mapping System, which provides detailed mapping information about utility pipelines located in the U.S., including data on "sensitive" areas through which pipelines pass (e.g., areas that are sources of drinking water or are otherwise ecologically sensitive). The NRC's responsibilities include the regulation of all nuclear power plants in this country. WLF argued that NNSA, OPS, and NRC had all failed to remove sensitive information from their websites that might prove useful to terrorists. In response to WLF's petitions, each of the three agencies revised its Internet posting policies to take greater account of national security concerns. A similar petition filed with the Federal Energy Regulatory Commission (FERC) on March 25, 2005 led to similar changes in FERC policies regarding public access to documents.

### E. Protecting Our Nation's Borders

Preventing terrorist attacks within the United States requires the federal government to increase efforts to protect the nation's border, in order to prevent terrorists and weapons from being smuggled into the country. WLF has regularly litigated in support of allowing increased law enforcement activity along the border, making it more difficult for terrorists and criminals to obtain false identification documents (such as driver licenses) and public benefits, and deporting aliens engaged in terrorism or other criminal behavior as quickly as possible. WLF also works to reduce the incentives for illegal aliens to sneak into this country; such efforts include reducing awards available to illegal aliens in lawsuits and reducing their ability to obtain public benefits.

### CONFIDENTIAL



Day v. Bond. On October 25, 2005, WLF filed a brief in the U.S. Court of Appeals for the Tenth Circuit in Denver, urging the court to reinstate a challenge to a Kansas statute that, WLF charges, violates the civil rights of U.S. citizens who live outside the State. The statute grants illegal aliens the right to attend Kansas universities at in-state rates but denies that same right to U.S. citizens who live outside of Kansas. WLF argued that the Kansas law violates a 1996 federal statute that prohibits States from granting more favorable tuition rates to illegal aliens than they grant to citizens. A federal district court dismissed the suit in 2005 on procedural grounds; WLF urged the appeals court to overturn that dismissal. WLF filed its brief on behalf of Brigette Brennan, who attended and graduated from a Kansas high school and has been living for the past four years in Kansas while attending the University of Kansas. But Kansas has refused to offer her in-state tuition rates because she lived in Kansas City, Missouri while attending high school. The result is that she is paying considerably higher tuition than do illegal aliens who lived in Kansas illegally while attending high school and whose presence in this country continues to be illegal.

Balbuena v. IDR Realty LLC. On February 21, 2006, the New York Court of Appeals declined to bar illegal aliens who are plaintiffs in personal injury lawsuits from recovering wages lost as a result of their injuries. The decision was a setback for WLF, which filed a brief in the case, urging that such damages be barred. WLF argued that awarding illegal aliens the "lost" wages they would have earned if they had not been injured would be inequitable because it would have been illegal for them actually to have earned those wages by taking a job in this country. WLF argued that such awards are preempted by federal law because they undermine federal immigration policy by encouraging more illegal aliens to enter the country and to seek employment. The Court of Appeals rejected WLF's position, contending that to deny damages for lost wages would encourage employers to reap the economic benefits of hiring illegal aliens. This personal injury tort suit was filed by Gorgonio Balbuena, an illegal alien who was severely injured while performing construction work. Balbuena alleges that his injuries were caused by his employer's negligence. Balbuena's right to recover for his injuries and medical expenses was not challenged; but WLF challenged Balbuena's claim that he is entitled to recover the wages he could have earned in this country had he not been injured.

**Paramount Citrus v. Superior Court.** On January 5, 2006, the California Supreme Court declined to review a trial court decision that allows illegal aliens who file tort actions to seek recovery for damages not yet incurred and to base those damage claims on an assumption that they will remain in the United States for the remainder of their lives. The decision was a setback for WLF, which filed a brief urging the court to grant review. WLF argued that, because illegal aliens have no right to remain in this country, such damage claims should be limited to the amount of damages that would be incurred if the illegal alien returned to his native country. The case involves an illegal alien who was permanently disabled in a car accident. He seeks recovery of the cost of providing him "life care" for the next 50 years. The present value of such care is \$5.3 million if he remains in the United States, but only \$1.8 million if he returns to his native Mexico. WLF argued that because the plaintiff has no right



to remain in this country, he has no right to recover damages computed based on an assumption that he will remain here. WLF also argued that granting the plaintiffs' damage claims would undermine federal immigration policy.

Ambros-Marcial v. U.S. On July 13, 2005, a federal district court in Arizona held that immigrants rights groups should not be permitted to undermine border security measures by suing the federal government for failing to establish water stations in the Arizona desert. The decision was a victory for WLF, which filed a brief in the case arguing that although 100 or more aliens die in the Arizona desert from dehydration every year while attempting to cross the border illegally, making such crossing easier by establishing water stations would serve only to encourage more illegal immigration. The issue arose in connection with a lawsuit for damages filed by relatives of Mexicans who died in the desert. The district court agreed with WLF that the Federal Tort Claims Act does not grant the federal courts jurisdiction over tort claims based on "discretionary functions" of the federal government – such as a decision whether to install water stations.

*Cubas v. Martinez.* On October 11, 2005, WLF filed a brief in the Appellate Division of the New York Supreme Court, urging it to uphold new regulations adopted by the State of New York that make it extremely difficult for illegal aliens to obtain driver licenses. WLF argued that the restrictions are needed to ensure that terrorists and criminals do not obtain fake identification documents that can facilitate their activities. WLF urged the court to overturn a trial court's preliminary injunction against the new regulations adopted by New York's Department of Motor Vehicles (DMV). The regulations are intended to implement a statutory mandate that DMV issue licenses only to those who can adequately establish their "identity." In the past, criminals and terrorists have been able to obtain driver licenses under false names using forged identity documents. WLF argued that DMV's authority to demand proof of "identity" includes the right to adopt new rules designed to ensure that the driver license applicant is who he says he is. The regulations are not rendered invalid simply because they have the effect of preventing illegal aliens from obtaining licenses, WLF argued.

*Foreign Cooperation with U.S. Deportation of Aliens.* On March 25, 2005, WLF petitioned Secretary of State Condoleezza Rice, asking that the State Department take significant steps – including, where necessary, the imposition of economic sanctions – with regard to foreign governments that refuse to cooperate with U.S. deportations of their nationals. WLF noted that the absence of cooperation has rendered the U.S. incapable of removing thousands of aliens ordered deported because they have been convicted of violent crimes. WLF urged the Department to make explicit demands upon the governments involved. Where that does not bring cooperation, WLF urged the Department to impose sanctions, including sanctions under the power granted by the Immigration and Nationality Act to discontinue granting visas to countries that refuse to cooperate in the issuance of travel documents for purposes of repatriation of excluded aliens; and under the Immigration Act of 1990, which authorizes the Secretary of State to exclude aliens from designated countries for policy purposes.





Friendly House v. Napolitano. On August 9, 2005, the U.S. Court of Appeals for the Ninth Circuit upheld Proposition 200, an initiative adopted in November 2004 by Arizona voters and designed to deter illegal aliens from collecting welfare benefits. The decision was a victory for WLF, which represented PAN, the group that sponsored Proposition 200; that group intervened in the case as a defendant, to ensure that a vigorous defense was mounted. The group intervened because the Arizona Attorney General (along with virtually every other senior Arizona official) opposed Proposition 200, so there was some reason to suspect that he might mount a less-than-vigorous defense of the new law. The appeals court threw out the plaintiffs' challenge entirely; it agreed with WLF that the plaintiffs (mostly illegal aliens seeking welfare benefits) lacked "standing" to challenge the law. WLF's brief also argued that Arizona voters were well within their rights in adopting such measures. WLF argued that because federal law prohibits states from providing welfare benefits to illegal aliens, there can be no objection to taking steps to ensure that the prohibition is enforced. WLF argued that Proposition 200 is neither preempted by federal immigration law nor a violation of the due process rights of state employees or welfare applicants. WLF also represented PAN in the district court. WLF won a major victory in December 2004, when the district court denied the plaintiffs' request for a preliminary injunction against Proposition 200; the appeals court affirmed that victory.

Jama v. Immigration and Naturalization Service. On January 12, 2005, the U.S. Supreme Court held that the U.S. government is permitted to deport alien felons to Somalia. The decision was a victory for WLF, which filed a brief urging the Court to reject a lower court decision that prohibited deporting *anyone* to Somalia because that country lacks a functioning central government. The Court agreed with WLF that although the U.S. usually does not deport an alien when his native country objects to taking him back, federal law does *not* prohibit deportations to countries that lack a functioning government capable of formally accepting (or rejecting) its returning citizens. The issue is of critical importance in connection with alien felons from Somalia because Somalia has not had a functioning central government since 1991. There are now more than 8,000 aliens in this country awaiting deportation to Somalia, but a federal appeals court had issued an injunction blocking all such deportations. Most of those awaiting deportation, including several thousand convicted of serious crimes, are not in detention but rather are freely roaming the streets – because courts do not permit *indefinite* detention pending deportation. The Supreme Court agreed with WLF that deportation of these alien felons should be allowed to proceed.

U.S. v. Flores-Montano. March 30, 2004, the U.S. Supreme Court held that customs officials are permitted to conduct thorough inspections of all vehicles crossing the border into the United States, regardless whether they suspect that the vehicle contains contraband. The decision was a victory for WLF, which filed a brief in the case, arguing that such searches are essential to national security. The case involved the search of a car being driven into California by a Mexican citizen. Although they lacked solid evidence that the driver was engaged in smuggling, customs officials decided to remove and inspect the gas tank (a process that took less than an hour). The search turned up 37 kilograms of marijuana. The appeals



court threw out the evidence, ruling that the search was "unreasonable" in violation of the Fourth Amendment. In reversing, the Supreme Court agreed with WLF's argument that the government should have far broader rights to conduct suspicionless searches at the border than elsewhere. WLF argued that terrorists, drug cartels, and immigrant smugglers cannot effectively be thwarted unless the government is permitted to conduct random searches of all entering vehicles.

United States v. Drayton. On June 17, 2002, the U.S. Supreme Court upheld the power of police to question and search bus passengers who voluntarily consent to be searched. The decision was a victory for WLF, which had filed a brief in the case in support of the police officers. The Court agreed with WLF that consensual questioning of citizens by police is an important law enforcement tool and should not be deemed to violate the Fourth Amendment's ban on unreasonable searches and seizures simply because some bus passengers might feel uncomfortable in refusing a police request to search baggage. WLF argued that in light of terrorism threats, it is particularly important that police have all the tools necessary to ensure that public transportation systems remain safe. The case involved a police search of bus passengers in Florida who were found to be carrying nearly a kilogram of cocaine. The lower court had held that the search could not be deemed consensual in the absence of a *Miranda*-like warning that passengers had the right to refuse to consent to the search.

In-State Tuition for Illegal Aliens. On August 9, 2005, WLF filed a formal complaint with the U.S. Department of Homeland Security (DHS) against the State of Texas, charging that Texas is violating the civil rights of U.S. citizens who live outside the State. WLF filed a similar complaint against New York State on September 7, 2005. WLF charged that Texas and New York are violating federal law by offering in-state college tuition rates to illegal aliens who live in those states, while denying those same rates to U.S. citizens who do not live in those states. WLF called on DHS to bring appropriate enforcement action against Texas and New York, including ordering them to make refunds to students who have been charged excessive tuition. The federal statute at issue, 8 U.S.C. § 1623, was adopted in 1996 and is designed to ensure that any State that offers discounted, in-state tuition rates to illegal aliens on the basis of their residence in the State must offer the same discounted rates to *all* U.S. citizens. In 2001-02, Texas and New York adopted laws that allow illegal aliens to attend public universities at in-state rates, but they have refused to extend that same opportunity to U.S. citizens living outside the states. Similar laws have since been adopted in seven other States: California, Utah, Illinois, Washington, Oklahoma, Kansas, and New Mexico.

### F. Protecting Military Activities from Environmental Restrictions

The nation's military preparedness is regularly being undermined by court decisions that expansively apply federal environmental laws in ways – never intended by Congress – that prevent the military from engaging in routine training exercises. WLF recognizes that environmental laws apply to everyone, including the government; but federal courts should not



be permitted to invoke environmental laws in a manner that second-guesses the military's considered judgments regarding military needs. WLF regularly litigates against activists who seek to use environmental laws to hamstring the military.

National Audubon Society v. Dep't of the Navy. On September 7, 2005, the U.S. Court of Appeals for the Fourth Circuit in Richmond ruled that the Navy should be permitted to go forward with planning for construction of a new North Carolina airfield, even as it prepares a new environmental impact statement (EIS) for the airfield. The decision was a victory for WLF, which had filed a brief urging the court to lift a district-court injunction against all site-preparation and planning work. The airfield, desperately needed for pilots being trained to land planes on aircraft carriers, has been blocked by questions over the adequacy of the initial EIS. The appeals court held that a new EIS was required. But it agreed with WLF that the district court erred in blocking all work on the airfield while the new EIS is being prepared. The appeals court agreed with WLF that the district judge acted improperly in second-guessing the Navy's determination that building the base is vital for national security.

Center for Biological Diversity v. England. On January 24, 2003, the U.S. Court of Appeals for the D.C. Circuit overturned a lower court decision that had blocked Navy military training exercises. The decision was a victory for WLF, which had filed a brief seeking to overturn a dangerous district court decision. The Center for Biological Diversity (CBD) sued the Department of the Navy to halt all live-fire training exercises on the small uninhabited Pacific island of Farallon de Medinilla (FDM). CBD claimed that the bombing of the island resulted in the unintentional killing of a several unendangered migratory sea birds listed under the Migratory Bird Treaty Act (MBTA). The district judge issued, in effect, a "cease-fire" order against the Navy, halting the training exercises even though the Navy had taken costly measures to mitigate any environmental harm. WLF argued in its brief that the CBD lacked legal standing to challenge the military exercises because the alleged injury to its members' bird-watching activity was too speculative. WLF also argued that if the MBTA were applied to the facts in this case, it would unconstitutionally encroach on the President's Commander in Chief power under Article II of the Constitution. While the case was on appeal, Congress enacted a law that exempted military training exercises from the MBTA, whereupon the case was dismissed as moot.

Application of Environmental Rules to Combat Training Exercises. On August 2, 2004, WLF filed comments with the U.S. Fish & Wildlife Service (F&WS) regarding a proposed rule that purports to govern any Department of Defense combat training exercises that may have an adverse effect on migratory birds. WLF supported a provision in the proposed rule that would allow DoD, rather than F&WS, to determine whether proposed military activity is likely to have a "significant adverse effect" on migratory birds. However, WLF objected to the proposed rules on suspension and withdrawal of a DoD's "take" authorization (*i.e.*, authorization to engage in activity that could harm migratory birds) because the proposed rules state that F&WS may unilaterally suspend DoD's authorization. WLF argued that Congress (in adopting the 2003 National Defense Authorization Act) mandated that



"take" authorizations not be suspended or withdrawn over DoD's objections, and also argued that such unilateral action would infringe on the President's Commander-in-Chief powers under Article II of the Constitution.

### G. Opposing Application of Foreign Law in U.S. Courts

The U.S. Constitution mandates that U.S. courts are to look for guidance to U.S. law, not foreign law. Nonetheless, activists are with increasing frequency urging courts to decide cases on the basis of foreign or international law, and some judges are agreeing to do so. WLF strongly opposes this trend as an affront to American sovereignty and a threat to national security. It regularly litigates in opposition to efforts to have cases decided on the basis of foreign/international law. Activists have sought to invoke international law in each of the "enemy combatant" cases listed above. Other cases in which WLF has opposed this trend are listed here.

Abdullahi v. Pfizer. On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging the court to dismiss claims that a pharmaceutical company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits in federal court asserting that doctors violated international law by allegedly treating patients without first obtaining the patients' informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a 1789 law that lay dormant for nearly 200 years before activists began seeking to invoke it in the past several decades. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF charged that it has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations. In this case, Pfizer sent a team of doctors to Kano, Nigeria in 1996 to provide pro bono medical care to assist in dealing with a severe outbreak of meningitis in children. The doctors treated their patients with Trovan, a Pfizer-manufactured antibiotic that had not yet been approved by FDA for treating pediatric meningitis in the United States. The children treated by the Pfizer doctors had a survival rate superior to that of other Nigerian children receiving treatment. Nonetheless, lawyers from Milberg Weiss (a well-known New York plaintiffs' law firm) filed suit against Pfizer on behalf of some of the patients and their parents, alleging that Pfizer had failed to inform them. prior to commencing treatment, that Trovan was not yet fully approved by FDA. The plaintiffs claim that Pfizer's alleged failure to obtain informed consent violated international law and is actionable in U.S. federal courts under the ATS.

*Medellin v. Dretke.* On May 23, 2005, the U.S. Supreme Court dismissed as improvidently granted a case in which a criminal defendant, properly convicted of murder and sentenced to death, was attempting to invoke international law as a basis for overturning his conviction. The decision was a victory for WLF, which filed a brief on behalf of the parents





of one of the murder victims, 14-year-old Jenny Ertman. WLF argued that Jose Medellin, a Mexican citizen convicted of raping and murdering two teenage girls in 1993, has received more than a fair review of his sentence and that it is time now to bring his appeal rights to a close. Medellin, who has lived in Houston most of his life, argued that his conviction should be overturned because Texas erred when, at the time of his arrest, it failed to advise him of his rights under international law to meet with a Mexican consular official. In its brief filed in support of Texas, WLF argued that only American law, not international law, is enforceable in U.S. courts. Following the Supreme Court's dismissal of his case, Medellin is now asking (with the support of the Bush Administration) that Texas state courts consider his international law claim. WLF has pledged to continue to support the parents' interests in bringing Medellin's appeals to a close.

Sosa v. Alvarez-Machain. On June 29, 2004, the U.S. Supreme Court unanimously overturned a lower-court ruling that allowed aliens to second-guess American law enforcement policy by filing suits for money damages under the Alien Tort Statute (ATS), alleging violations of international law. The decision was a major victory for WLF, which filed a brief in the case. The lower court had affirmed an award of damages imposed against Sosa, a former Mexican policeman, because, at the request of the U.S. government, he assisted the U.S. in apprehending a Mexican doctor indicted for torturing and murdering an American drug enforcement agent. In response to the doctor's civil suit, the appeals court ordered Sosa to pay \$25,000 in damages for a supposed violation of international law. The appeals court held that the ATS, a 1789 statute designed to deal with piracy issues, permits foreigners to sue in U.S. courts for alleged violations of international law. The Supreme Court agreed with WLF not only that Sosa's conduct did not violate international law, but also that the ATS does not authorize suits in the federal courts to enforce international law.

Doe v. Unocal Corporation. On April 22, 2003, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, seeking to overturn a lower court ruling that greatly expanded the reach of the Alien Tort Statute (ATS). The ATS provides for jurisdiction in U.S. courts by aliens for torts "committed in violation of the law of nations or a treaty of the United States." Although the law originally was intended to govern relations between nation states when enacted in 1789, human rights activists are now invoking the law to hold U.S. corporations operating abroad liable for human rights abuses allegedly suffered by citizens of the host country. In this case, the aliens claimed that injuries they suffered at the hands of the Myanmar military should be attributed to Unocal Corp. because the military was protecting an oil pipeline being built by Unocal. Following the Supreme Court's *Sosa* decision (see above), which greatly cut back on liability under the ATS, the parties settled this case before the appeals court could issue a decision.

### H. Enhancing Homeland Security

Ever since September 11, 2001, governments at all levels have been implementing new



programs to enhance homeland security by tracking and deterring potential terrorists. Unfortunately, a wide variety of activist groups have gone to court repeatedly in an effort to block virtually all such programs. WLF has responded by joining the judicial battle in support of these vital security measures.

Humanitarian Law Project v. Gonzales. On April 13, 2006, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit in San Francisco, urging the court to uphold a portion of the USA PATRIOT Act that makes it a crime to provide "material support" to any group that has been designated by the Attorney General as a "foreign terrorist organization." WLF argued that the statute is not impermissibly vague and does not violate the First Amendment rights of individuals who wish to support humanitarian work conducted by terrorist groups. WLF also argued that the First Amendment does not prevent Congress from barring actions taken to aid terrorist groups simply because the actions may have an expressive component. The law in question, 18 U.S.C. § 2339B, was adopted in 1996 and was strengthened by the USA Patriot Act in 2001 and by other legislation in 2004. WLF argued that § 2339B is not impermissibly vague (in violation of the Fifth Amendment's Due Process Clause) because it provides people of ordinary intelligence with a reasonable opportunity to understand what conduct it prohibits. WLF argued that Congress's intent was clear: to bar virtually all significant direct support of designated terrorist groups. WLF argued that the plaintiffs' real objection is that they disagree with Congress's decision, not that Congress has failed to specify what actions are prohibited.

*MacWade v. Kelly.* On April 4, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit to preserve the victory it won in the district court that upheld the right of New York City's police to search bags on subways to deter possible terrorist activity. WLF's victory occurred on December 2, 2005, when the district court rejected the New York Civil Liberties Union's (NYCLU) challenge to the constitutionality of the bag inspection program. The program, implemented shortly after the London terrorist subway bombings in the summer of 2005, is designed to detect and deter would-be terrorists who would bring explosive devices aboard the subway system. WLF filed two briefs in the case on behalf of its clients, the second one following the two-day trial that began on October 31, 2005, at the specific request of the presiding judge and over the objections of the NYCLU. The judge agreed with WLF that the inspection program does not violate the Fourth Amendment's prohibition against unreasonable searches and seizures.

ACLU v. National Security Agency; Center for Constitutional Rights v. Bush. On May 30, 2006, WLF filed a brief in the U.S. District Court for the Eastern District of Michigan, opposing a lawsuit filed by the ACLU that challenges electronic surveillance by the National Security Agency (NSA) of international communications to which one of the parties is a suspected al Qaeda agent or affiliate. On June 6, 2006, WLF filed a similar brief in New York federal court in a related case filed by the Center for Constitutional Rights (CCR). In ACLU v. NSA and CCR v. Bush, the activist groups claim that the NSA surveillance program, which is conducted without court order, violates the Foreign Intelligence Surveillance Act of





1978 (FISA). FISA requires that government surveillance be approved by a special FISA court, based on a showing that there is probable cause to believe that the targeted person is an agent of a foreign power. However, after the terrorist attacks on the United States on September 11, 2001, the President authorized the collection of international communications without court order where there is reasonable belief that one of the parties to the call is an al Qaeda agent or affiliated with al Qaeda or other terrorist organization. In its brief, WLF argued that FISA itself is unconstitutional because it violates the separation of powers by purporting to impair the President's ability to carry out his constitutional responsibilities to defend the country from further attack and to collect foreign intelligence. WLF also argued that the surveillance activities do not violate the Fourth Amendment prohibition against unreasonable searches.

### **II. CIVIC COMMUNICATIONS PROGRAM**

WLF recognizes that its litigation and regulatory activities cannot alone suffice if it is to have a significant impact in opposing the efforts of activists and in educating the public and policy makers regarding threats to national security. WLF has also sought to influence public debate and provide information through its Civic Communications Program. This targeted and broad-based program includes WLF's sponsorship of frequent, well-attended media briefings featuring experts on a wide range of national security-related topics; the publication of advocacy advertisements in national journals and newspapers; and participation in countless national security-related symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media – from reporters for generalcirculation newspapers to writers for specialized legal journals.

### A. Media Briefings

The centerpiece of WLF's Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on national security topics. Recent media briefings (dubbed media "noshes") on national security-related issues have included the following:

Terrorism Risk Insurance: Assessing Public & Private Roles as TRIA Nears its Sunset, September 15, 2005

- •Warren W. Heck, Greater New York Mutual Insurance Company
- •Travis B. Plunkett, Consumer Federation of America
- •Commissioner Lawrence H. Mirel, Dept. Of Insurance, Banking & Securities



The PATRIOT Act and Beyond: Is America's War On Terrorism Compromising Civil Liberties?, September 25, 2003

•Hon. Daniel J. Bryant, Acting Assistant Attorney General

•Stuart Taylor, Jr., National Journal

•Timothy Edgar, American Civil Liberties Union

Assault on Terror or Liberties?: Assessing the Administration's Legal Strategy, One Year Later, September 19, 2002

• Professor Ruth Wedgwood, Yale Law School

•Professor Jonathan Turley, George Washington University Law School

•Lee A. Casey, Baker & Hostetler

Practicing Law after September 11<sup>th</sup>: New Rules and Strategies for Lawyers and the Corporate World, January 16, 2002

•The Honorable Dick Thornburgh, Kirkpatrick & Lockhart, LLP (moderator)

•The Honorable Ed Bethune, Bracewell & Patterson, L.L.P.

•Thomas F. Cullen, Jones, Day, Reavis & Pogue

• Joseph E. diGenova, diGenova & Toensing

•Richard S. Levick, Esq., Levick Strategic Communications, Inc.

Implementing The New Anti-Terror Law: What Impact on Law Enforcement and Civil Liberties?, November 14, 2001

•The Honorable Viet D. Dinh, Assistant Attorney General of the United States

•George J. Terwilliger III, White & Case

•Victoria Toensing, diGenova & Toensing

•Ronald Weich, Zuckerman Spaeder LLP

The War on Terrorism: Risks and Rewards of Relying upon Criminal and International Law Principles, October 19, 2001

•The Honorable Dick Thornburgh, Kirkpatrick & Lockhart, LLP (moderator)

•Philip Allen Lacovara, Mayer, Brown & Platt

•Professor Ruth Wedgewood, Yale Law School

•Michael J. O'Neill, Preston Gates & Ellis

### **B.** Advocacy Ads

In 1998, WLF began running a series of opinion editorials on the op-ed page of the national edition of The New York Times called "In All Fairness." The op-ed has appeared well over 100 times, reaching over five million readers in 70 major markets and 90 percent of major newspaper editors. Titles and summaries of the op-eds published since September 11, 2001, relating to terrorism issues, include:



### Defending Our Own Civil Liberties

The September 11, 2001 attack on America was caused in large measure by the restrictions placed on our domestic and foreign intelligence gathering capabilities.

### Wanted: Public Interest Reality

Lawsuits by activists to block military training exercises, energy development, and economic growth, sacrifice national interests in favor of their narrow ideological agendas.

### Holiday Wishes

Attacks on the Administration's efforts to combat terrorism by so-called "civil libertarians" are misguided.

### Tampering With Our Lives

Activist groups opposing homeland security efforts and the war on terrorism threaten the safety of all Americans.

### Hijacking Liberties

Activists who attack law enforcement efforts to gather intelligence and instead seek to provide civil liberties protections to terrorists and their supporters harm our national security.

### Mirandize Our Foreign Enemies?

Efforts to extend civil liberties protections to suspected terrorists hamper our ability to combat terrorism and threaten our safety.

### No Blood For Oil

United States security requires less dependence on foreign oil and more development of domestic energy resources.

### Unwittingly Aiding Al-Qaeda

Activists who seek repeal of USA PATRIOT Act's anti-terrorism provisions and tough enforcement are ill-informed and help our enemies.

### The State of Our Union

Efforts to combat terrorism are under constant attack by misguided activists who use the courts to undermine our national security.

### "Civil Liberties" for Terrorists?

Activists are harming American interests by opposing major military activities overseas and domestic law enforcement efforts to fight the war on terrorism.

### Fueling National Insecurity

Energy development in America has been unnecessarily limited by activists and overly restrictive regulations.



### National Security and Energy

American dependence on foreign oil is the result of activists' efforts to prohibit domestic exploration and production.

### **C.** Public Appearances

WLF attorneys have appeared as featured panelists and speakers on national security issues before a wide variety of groups, and are frequently sought out by the electronic news media for interviews on national security issues coming before the courts. Public appearances made by WLF attorneys relating to national security issues, dating back to September 11, 2001, include:

### 2006

- \* June 29, WLF Chief Counsel Richard Samp was interviewed regarding the Supreme Court's decision in *Hamdan v. Rumsfeld* (which struck down the Bush Administration's plan to try alleged al Qaeda war criminals before military tribunals) by Fox News, ABC-Radio, CBS-Radio, NPR's "To the Point," Voice of America, and Court TV.
- \* June 21, Samp was interviewed on National Public Radio's nationally syndicated "Fresh Air" program, regarding the propriety of continued detention of "enemy combatants" at Guantanamo Bay, Cuba.
- \* April 4, Samp was interviewed on WBGO-Radio in Newark, New Jersey regarding a recent court decision that held that illegal immigrants who are injured on the job are entitled to recover damages for lost wages even though they would have had no right to continue to work in this country if they had not been injured.
- \* March 27, Samp participated in a debate, sponsored by the Cato Institute, against Charles Swift, the military attorney for Salim Hamdan, who faces a war crimes trial for his work as an aide to Osama bin Laden. Hamdan's challenge to the military tribunal process was being argued before the Supreme Court the next day. The debate, which was broadcast on C-SPAN, addressed whether the President has the authority to establish military tribunals to try war crimes suspects.
- \* March 2, Samp was interviewed on Radio Free Europe regarding U.S. immigration policy.

### 2005

\* September 19, Samp was interviewed on KFI-Radio in Los Angeles regarding New



York State's policy of granting in-state tuition rates to illegal aliens attending New York colleges, while denying those same rates to U.S. citizens living outside the State. Samp was interviewed on that same topic on Bloomberg Radio on October 21.

- \* September 19, Samp was a guest on the Kojo Nnamde Show on WAMU-Radio in Washington, D.C., discussing the U.S. military's detention of al Qaeda suspects at Guantanamo Bay, Cuba. Samp debated David Remes, a lawyer representing some of those detainees.
- \* August 24, Samp was interviewed on WBAL-Radio in Baltimore regarding Texas's policy of granting in-state tuition rates to illegal aliens attending Texas colleges, while denying those same rates to U.S. citizens living outside the State. WLF was interviewed on the same subject on KLBJ-Radio in Austin (Aug. 24), KTSA-Radio in San Antonio (Aug. 24), and KLIF-Radio in Dallas (Aug. 25).
- \* August 12, WLF Senior Executive Counsel Paul Kamenar was interviewed on KVT National Public Radio in Austin, Texas discussing WLF's petition challenging Texas's policy of granting in-state tuition to illegal aliens attending Texas colleges while denying those same lower rates to U.S. citizens living outside of the State.
- \* August 9, Samp was interviewed on National Public Radio regarding a lawsuit filed against top Bush Administration officials by a suspected al Qaeda terrorist; the suspect contends that he has been tortured while in U.S. custody.
- \* July 18, Samp was interviewed on the Chris Core Show on WMAL-Radio in Washington, D.C. regarding the military's decision to detain Jose Padilla, an American citizen accused of plotting with al Qaeda to blow up an American city; and regarding a recent court decision upholding his detention.
- \* May 23, Samp was interviewed on CBS Radio regarding the Supreme Court's decision in *Medellin v. Dretke*, a case in which a Texas prisoner is attempting to invoke international law to overturn his death sentence.
- May 16, Samp participated in a debate in Philadelphia, broadcast nationally on National Public Radio, regarding the U.S. military's detention of enemy combatants at Guantanamo Bay, Cuba. Samp debated against Thomas Wilner, an attorney representing many of the detainees.
- \* April 26, Kamenar was a featured guest on the FOX News "Big Story," hosted by Judge Andrew Napolitano. Kamenar discussed *Acree v. Iraq*, in which WLF is representing Senator George Allen and a bipartisan group of congressmen supporting a lawsuit by ex-POWs from the Gulf War suing Iraq and Saddam Hussein for torture.



- \* March 28, Samp was interviewed on CNN regarding *Medellin v. Dretke*, a Supreme Court case in which a convicted murderer is invoking international law in an effort to avoid execution.
- \* March 23, Samp was interviewed by Voice of America on the case of Jose Padilla, the alleged "dirty bomber" being held by the government as an enemy combatant.
- \* March 3, Samp was interviewed on NBC-TV Nightly News regarding *Clark v. Martinez*, the case in which the Supreme Court ordered the release of Mariel Cubans who have been convicted of violent crimes but cannot be deported back to Cuba.
- \* January 31, Samp was interviewed on CNN regarding lawsuits filed by foreigners being held at Guantanamo Bay, Cuba as "enemy combatants." Samp was also interviewed on January 31 by KLIF-Radio in Houston and on February 7 by KPCC-Radio in Denver on the same topic.

- \* November 9, 2004, Samp was interviewed on Voice of America regarding *Hamdan v*. *Rumsfeld*, a challenge to the Administration's plan to try alleged al Qaeda war criminals before military commissions.
- \* October 19, Samp was interviewed on KPCC-Radio in Los Angeles regarding antiterrorism measures enacted as part of the USA PATRIOT Act.
- \* June 3, Samp was interviewed by Azteca America, a Spanish-language television network, regarding detention of American citizens as "enemy combatants."
- \* May 25, Glenn Lammi, Chief Counsel of WLF's Legal Studies Division, discussed energy policy and the war on terrorism on the Pat Whitely Show, WRKO, Boston.
- \* May 17, Samp was interviewed on Fox News regarding pending lawsuits designed to force the U.S. government to build water stations in the Arizona desert to assist illegal aliens attempting to sneak into the country. Samp was interviewed on the same subject on Fox News' "The O'Reilly Factor" on June 9, and on WSBA-Radio in York, Pennsylvania on May 18.
- \* May 14, Samp was interviewed by Medill News Service (whose broadcasts are carried by numerous cable television companies) regarding the propriety of the federal government's detention of enemy combatants.
- \* April 29, WLF co-sponsored a briefing in Boston with Kirkpatrick & Lockhart LLP on "Homeland Security-Venture Capital Investment and Business Opportunities."





- \* April 12, Samp was interviewed on ABC-Radio regarding national security cases pending in the U.S. Supreme Court.
- \* March 3, Kamenar was the moderator at a seminar co-hosted by WLF, Kirkpatrick & Lockhart, and the Bureau of National Affairs (BNA) on legal and business issues involving Homeland Security. Other speakers included Joseph Whitley, General Counsel of the Department of Homeland Security; and U.S. Senator Pat Roberts, Chairman of the Senate Select Committee on Intelligence.
- \* February 24, Samp was interviewed on CBS Radio regarding U.S. v. Flores-Montano, a Supreme Court case that addressed constitutional limitations on the federal government's power to inspect vehicles entering the country.
- \* January 26, Samp was interviewed on CBS Radio regarding Sosa v. Alvarez-Machain, a Supreme Court case that addressed whether individuals may sue in federal court for alleged violations of international law.
- \* January 7, Kamenar was interviewed by Voice of America regarding capital punishment for terrorists and the refusal to extradite suspects by European countries which oppose the death penalty:

- \* December 18-22, Samp was interviewed on NBC-TV, ABC-Radio, NPR, and Democracy Now Radio Network on the court of appeals's decision in *Padilla v*. *Rumsfeld* regarding the detention of a suspected terrorist.
- \* September 12, Samp debated ACLU's Nadine Stroessen on CNBC on the USA PATRIOT Act and its enforcement.
- \* April 30, Samp appeared on CNBC's Buchanan & Press Show to discuss *Demore v*. *Kim*, a case that addressed the government's authority to detain alien felons pending completion of deportation proceedings.
- \* April 11, Samp was interviewed on CBC (Canadian television) on the *Rasul v. Bush* case involving detainees at Guantanamo Bay, Cuba.
- \* April 7, Kamenar debated Art Spitzer, Director of the ACLU's Washington, D.C. office, on "National Security and Civil Liberties" at a conference in Washington, D.C., sponsored by Panim el Panim for Jewish students from around the country.
- \* January 14, Samp discussed Demore v. Kim on National Public Radio.



### 2002

- \* December 6, Kamenar was the featured luncheon speaker before a group of 40 editorial page editors of major newspapers. The editors were attending a conference sponsored by the University of Maryland's Knight Journalism Center. The topic of the conference and Kamenar's remarks was "Civil Liberties in the Age of Terrorism."
- \* November 17, Samp spoke to the annual meeting of the Jewish Institute for National Security Affairs regarding WLF's efforts in the courts to defend the Bush Administration's war on terrorism.
- \* October 8, Samp spoke to a group of senior citizens visiting Washington under the auspices of the Close-Up Foundation, on legal challenges faced by the federal government in connection with the war on terrorism.
- \* September 12, Kamenar was a featured panelist at the Annual Symposium of the American Society of Access Professionals, an organization composed of government officials in charge of handling Freedom of Information Act requests. Kamenar discussed pending litigation involving the disclosure of the identities of aliens detained since the terrorist attack of September 11.
- \* August 15, Kamenar was a featured guest commentator on National Public Radio's "All Things Considered," discussing the ACLU lawsuit demanding the release of the names of aliens detained since September 11, 2001.
- \* January 16, Samp was interviewed by ABC Radio on the upcoming trial of John Walker Lindh, the accused American Taliban.

- \* December 31, Samp was interviewed on WLAC-Radio in Nashville on the Justice Department's plans to monitor conversations between suspected terrorists and their attorneys.
- \* December 21, Kamenar was a guest on CNBC television along with Newsweek reporter Michael Isakoff discussing the legal ramifications of prosecuting John Walker Lindh, the U.S. citizen captured for fighting with the Taliban.
- \* December 19, Kamenar was a guest on CNN television discussing the legality of military tribunals and alien detention proceedings.



- \* December 18, Kamenar was the featured guest on the award-winning Northern Virginia cable show "Law Weekly" hosted by noted attorney Glenn Lewis. The topic was the legality of military tribunals.
- \* December 17, Kamenar was the featured guest on the hour-long Tom Clark show aired by Wisconsin National Public Radio discussing the legality of anti-terrorism measures.
- \* December 7, Lammi discussed civil liberties and national securities issues on the "Ray Flynn Show" on WROL-Radio in Boston.
- \* December 6, Samp appeared on C-SPAN's Washington Journal, a half-hour call-in show, to discuss the Bush Administration's anti-terrorism measures, as well as on National Public Radio and Fox News Channel with a leading critic of Administration policy.
- \* November 16, Kamenar was a guest on National Public Radio along with ACLU President Nadine Stroessen and Dean Doug Kmiec of Catholic University Law School discussing the legality of military tribunals.
- \* November 9, Samp appeared on CNN to discuss federal government plans to monitor conversations between imprisoned terrorism suspects and their attorneys. Samp was interviewed on the same subject on Talk-Radio News Service.
- \* November 8, Samp was interviewed on WFM-Radio in Tampa regarding government detention of illegal aliens suspected of terrorism.
- \* September 25, Lammi debated Harvard Law School's Alan Dershowitz on civil liberties and national security on CNN's "Talkback Live."

### **III. PUBLICATIONS**

WLF's Legal Studies Division is the preeminent publisher of persuasive, expertly researched, and highly respected legal papers. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDERS covering current developments affecting the American legal system, to comprehensive Monographs providing law-review-length inquiries into significant legal issues.

Since its inception fifteen years ago, WLF's Legal Studies Division has produced a library of publications of considerable size and depth. The publications explore a wide-variety of legal topics. Since the 9/11 terrorist attacks, a significant number of WLF's publications have focused on national security issues. Notable WLF authors on national security issues



include: former Attorney General Richard Thornburgh, University of Virginia Law Professor John Norton Moore, and former Deputy Solicitor General Philip Lacovara.

Activist Suits Challenging Terrorist Surveillance Should Be Dismissed By Andrew C. McCarthy, the head of the Center for Law and Counterterrorism at the Foundation for the Defense of Democracies. LEGAL BACKGROUNDER, June 2, 2006, 4 pages

**Congress Enacts Substantial Liability Protections For Public Health Emergencies** By John M. Clerici, a partner with the law firm McKenna Long & Aldridge LLP in its government contracts practice and government affairs group; Frank M. Rapoport, also a partner and focuses on government contracts, information technology, federal litigation and public health law; and Douglas B. Farry, a Managing Director in the firm's Government Affairs practice.

LEGAL OPINION LETTER, February 10, 2006, 2 pages

### Hamdan v. Rumsfeld: High Court Should Uphold Executive Wartime Powers

By Andrew C. McCarthy, a Senior Fellow at the Foundation for Defense of Democracies. LEGAL OPINION LETTER, December 16, 2005, 2 pages

### Federal Role Essential For Terrorism Risk Insurance

By John T. Leonard, President and CEO of Maine Employers' Mutual Insurance Company (MEMIC) and MEMIC Indemnity Company of New Hampshire. LEGAL BACKGROUNDER, October 7, 2005, 4 pages

### **Ruling Expands Judiciary's Role In Transfer of Terror Detainees**

By **Robert Chesney**, Associate Professor of Law at Wake Forest University School of Law. LEGAL BACKGROUNDER, August 26, 2005, 4 pages

### Military Commissions For Terrorists On Solid Constitutional Grounds

By **Bradford A. Berenson**, who served as Associate Counsel to President George W. Bush from January 2001 through January, 2003 and is currently a partner with the law firm Sidley Austin Brown & Wood LLP, and **Christian M.L. Bonat**, an associate at Sidley Austin Brown & Wood LLP. LEGAL BACKGROUNDER, September 17, 2004, 4 pages

### Deciding The Rules For Detainees: Wars Are Not Criminal Prosecutions

By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw. LEGAL OPINION LETTER, March 19, 2004, 2 pages





Foreign "War Crimes" Lawsuits Against American Soldiers Threaten National Security By Margaret D. Stock, Assistant Professor, Department of Law, United States Military Academy, West Point, New York. LEGAL BACKGROUNDER, August 22, 2003, 4 pages

Courts, Military Detainees, And The War On 21st Century Terrorism By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw. LEGAL OPINION LETTER, May 9, 2003, 2 pages

President Has Clear Authority To Designate Detainees As "Enemy Combatants" By Robert L. Siriani, Jr., a Fall 2002 student in the Washington Legal Foundation's Economic Freedom Clinic at the George Mason University School of Law. LEGAL BACKGROUNDER, March 2003, 4 pages

### No Absolute Right To Open Deportation Hearings

By John Williams, a Fall 2002 student in the Washington Legal Foundation's Economic Freedom Clinic at the George Mason University School of Law. LEGAL BACKGROUNDER, March 2003, 4 pages

### **Court Should Uphold Citizenship Requirement For Airport Security Screeners**

By S. Alexander Fiske, a Fall 2002 student in the Washington Legal Foundation's Economic Freedom Clinic at the George Mason University School of Law. LEGAL BACKGROUNDER, March 2003, 4 pages

### Vaccine Liability Law Clarification Protects Lives And Resources

By Victor E. Schwartz, chairman of the Public Policy Group at the law firm Shook, Hardy & Bacon L.L.P., and Leah Lorber, of counsel to the firm. LEGAL BACKGROUNDER, January 10, 2003, 4 pages

### **Courts Must Respect President's Authority In Times Of War**

By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw. LEGAL OPINION LETTER, September 6, 2002, 2 pages

### **Chemical Risk Data Remains Dangerously Available To The Public**

By Emily Cochran, Institute for Human Studies Fellow at the Washington Legal Foundation. LEGAL BACKGROUNDER, August 23, 2002, 4 pages

### **Courts Must Not Meddle In Military Detainment Decisions**

By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw. LEGAL OPINION LETTER, June 7, 2002, 2 pages

### Flaws Undermine Use Of Alien Terrorist Removal Court

By Steven R. Valentine, a partner in the law firm Preston Gates Ellis & Rouvelas Meeds LLP, Washington, D.C.

LEGAL BACKGROUNDER, February 22, 2002, 4 pages



### Securing Personal Information Key To Anti-Terror Efforts

By **Barnaby Zall**, Of Counsel to the law firm of Weinberg & Jacobs, LLP, in Rockville, Maryland.

LEGAL BACKGROUNDER, January 11, 2002, 4 pages

### "Anticipatory" Self-Defense Against Terrorism Is Legal

By Lee A. Casey and David B. Rivkin, Jr., partners in the Washington, D.C. office of the law firm Baker & Hostetler. LEGAL OPINION LETTER, December 14, 2001, 2 pages

Court Should Dismiss Activists' Misguided Missile Defense Suit By David A. Codevilla, an attorney in the Environmental Group in the Washington, D.C. office of the law firm Kirkland & Ellis. LEGAL OPINION LETTER, December 14, 2001, 2 pages

### What Role For The United Nations In Responding To Terrorism?

By **The Honorable Richard Thornburgh**, Counsel to the law firm Kirkpatrick & Lockhart LLP, who previously served as Under-Secretary-General of the United Nations, U.S. Attorney General, and Governor of Pennsylvania. LEGAL BACKGROUNDER, November 6, 2001, 4 pages

**Courts Should Uphold Detention Of Aliens Accused Of Terrorist Acts** 

By Richard A. Samp, Washington Legal Foundation's Chief Counsel. LEGAL OPINION LETTER, October 19, 2001, 2 pages

### U.S. And International Laws Support Our War On Terrorism

By **Professor John Norton Moore**, Director of the Center for National Security Law at the University of Virginia and former Counselor on International Law to the Department of State. LEGAL OPINION LETTER, October 19, 2001, 2 pages

### **Criminal Or Military Justice For Captured Terrorists?**

By **Philip Allen Lacovara**, a partner with the law firm Mayer, Brown, Rowe & Maw, LLP in New York City and a former Deputy Solicitor General of the United States. LEGAL BACKGROUNDER, October 5, 2001, 4 pages

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Since 1977, The Washington Legal Foundation (WLF) has been defending individual and economic freedom in America's federal and state courts. Established as a charitable nonprofit organization, WLF is a public interest law and policy center devoted to the defense and promotion of the American free enterprise system.

WLF understands that a thorough knowledge of complex policy and regulatory issues is the best defense against misguided government bureaucrats and activist lawyers who are eager to tread on even the most basic tenets of our economic rights. WLF disseminates astute perspectives through its Legal Studies Division — the preeminent publisher of persuasive, expertly researched, and highly respected legal papers. Since its establishment in 1986, WLF's Legal Studies Division has produced and distributed more than 1,800 publications.

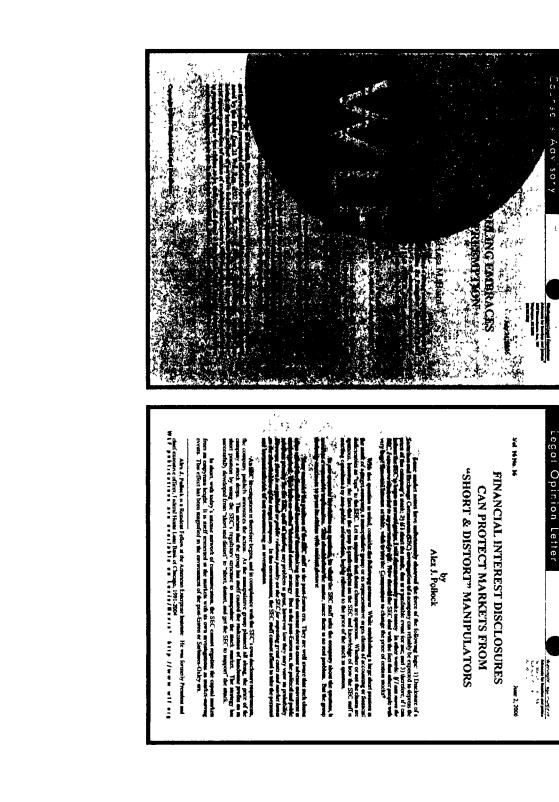
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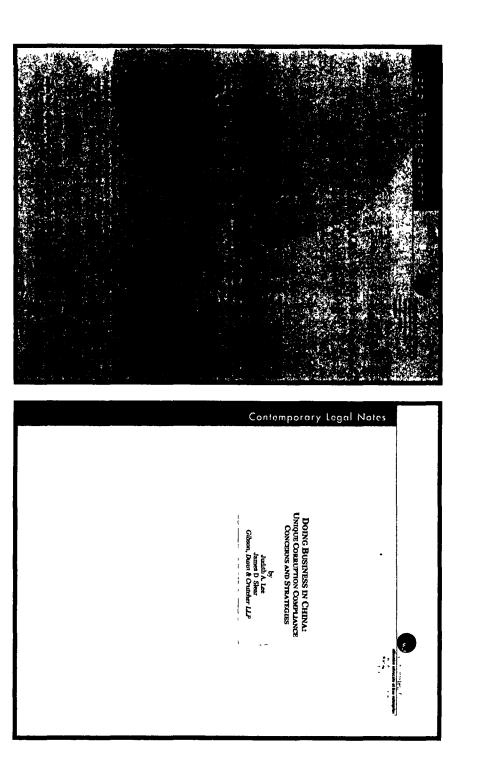


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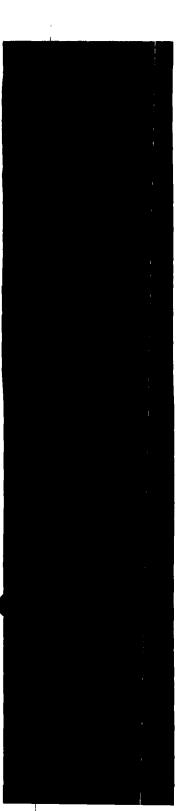
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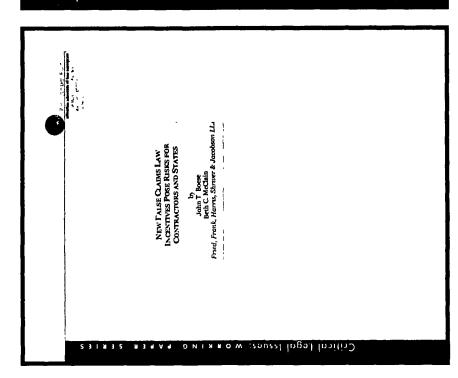
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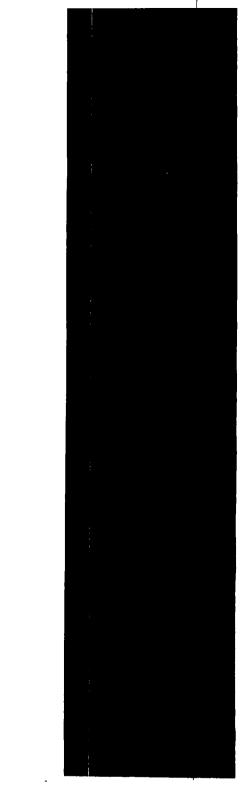
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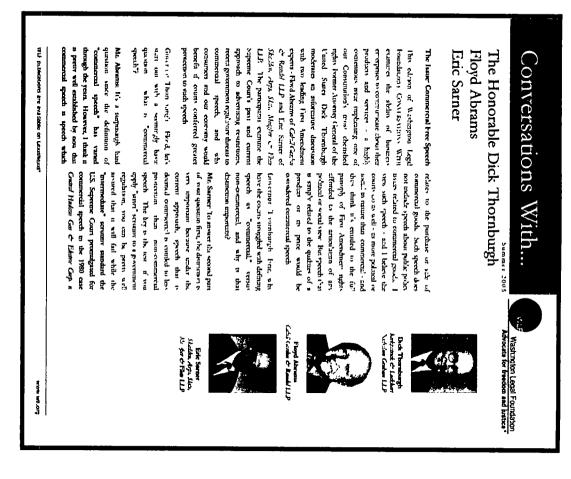
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### Educational Program Speakers

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# **Publications Directory**

# ■ ALTERNATIVE DISPUTE RESOLUTION (ADR)

Federal Court Rejects Class Action Waivers In Arbitration Clauses By Donald M. Falk and Archis A Parasharami, a partner and an associate, respectively, at the firm Mayer Brown Rowe & Mawe LLP COUNSEL'S ADVISORY, October 6, 2006, 1 page

# State High Court Condemns Arbitration Provisions That Don't Allow Class Actions

By Donald M. Falk, a partner in the Supreme Court and Appellate Practice Group of the law firm Mayer Brown Rowe & Maw LLP, resident in the Palo Alto office, and Archis A. Parasharami, an associate in the firm's Washington, D C office LEGAL BACKGROUNDER, March 24, 2006, 4 pages

U.S. Supreme Court Gives Employers A Chance To Avoid Costly Litigation

By Michael J. Connolly, a member of the Detroit office of Riley Roumell & Connolly, PC, and Clifford J Scharman, a member of the firm's Washington, D C office

LEGAL BACKGROUNDER, June 29, 2001, 4 pages

California High Court Lays Out Mandatory Arbitration Guidelines By William J. Emanuel, a partner, and Harry I Johnson, III, an associate, in the Los Angeles office of the law firm Jones Day LEGAL BACKGROUNDER, November 17, 2000, 4 pages

# ANTITRUST & CONSUMER PROTECTION REGULATION

English Court Permits "Forum Shopping" In Private Antitrust Suits

By David Marks, a partner at the law firm CMS Cameron McKenna LLP

COUNSEL'S ADVISORY, July 21, 2006, 1 page

Supreme Court Should Rule Pleading Standards For Antitrust Mega-Litigation

By Roy T Englert Jr, a founding partner of Robbins, Russell, Englert, Orseck & Untereiner LLP in Washington, D C LEGAL OPINION LETTER, May 19, 2006, 2 pages

High Court Hears Key Case On Antitrust And Joint Ventures By William Kolasky, a partner, and Steven Lehotsky, an associate at Wilmer Cutler Pickering Hale and Dorr LLP, in the firm's Washington and Boston offices, respectively Mr Kolasky was previously Deputy Assistant Attorney General for International Enforcement in the Antitrust Division of the U S Department of Justice LEGAL BACKGROUNDER, January 6, 2006, 4 pages

Closer Judicial Scrutiny Will Alter Antitrust Review Of Mergers In Europe

By Denise L Díaz, a former trial attorney of the Antitrust Division of the U S Department of Justice who practices in California, specializing in antitrust law

LEGAL BACKGROUNDER, July 1, 2005, 4 pages

#### Court Finds Patent Creates Presumption Of Market Power In Antitrust Tying Actions

By Connie Robinson and Peter Boyle, partners, and Saadeh Al-Jurf, an associate, of the Washington, D C office of the law firm Kilpatrick Stockton LLP

LEGAL OPINION LETTER, March 11, 2005, 2 pages

The European Commission's Decision In The Microsoft Case An Economic Perspective By Peter Passell, a senior fellow at The Milken Institute WORKING PAPER, August 2004, 38 pages

An Expanded European Union New Competition Rules And Challenges For U.S Companies

By Donald Falk, Hans-Georg Kamann and Peter Scher, partners with the law firm Mayer, Brown, Rowe & Maw LEGAL BACKGROUNDER, July 23, 2004, 4 pages

Europe Should Learn From Recent U.S. Court Ruling In Microsoft By Robert A. McTamaney, a partner in the New York City law firm Carter, Ledyard, & Milburn where he is Co-Chair of the Corporate Department

COUNSEL'S ADVISORY, July 9, 2004, 2 pages

Innovation At A Crossroads' Microsoft, Mario Monii & Media Players

By Robert A McTamaney, a partner in the New York City Law Firm of Carter, Ledyard & Milburn where he is Co-Chairman of the Corporate Department.

LEGAL BACKGROUNDER, April 2, 2004, 4 pages

Rulings Invite Antitrust Suits In U.S. Based On Overseas Conduct By Marinn Carlson, a partner in the Washington, D C office of Sidley Austin Brown & Wood LLP, and Larry Fullerton, also a partner with the firm

LEGAL OPINION LETTER, July 18, 2003, 2 pages

State Competition Law Imposes Tax On Businesses And Consumers

By William L Stern, a partner with the San Francisco law firm Morrison & Foerster, LLP

LEGAL OPINION LETTER, February 14, 2003, 2 pages

The Proposed Microsoft Decree And Past Antitrust Remedies<sup>1</sup> A Systematic Comparison

By Robert W Crandall, a senior fellow at the Brookings Institution in Washington, D C

WORKING PAPER, November 2002, 56 pages

FTC Administrative Judge Rejects Commission's View Of Drug Patent Settlements

By Geraldine M Alexis and Zorah Braithwaite, a partner and an associate, respectively, with the law firm Bingham McCutchen LLP in its San Francisco office

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By Timothy J. Muris, Of Counsel to O'Melveny & Myers LLP, where he co-chairs the firm's antitrust and competition practice Mr Muris is also a George Mason University Foundation Professor of Law, and from 2001-04 he was Chairman of the Federal Trade Commission

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By Clark S. Judge, the Managing Director of White House Writers Group, a communications and policy consulting firm based in Washington, D C

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A Corporate Counsel's Guide To Discovery In The Information Age By David E Dukes, James K. Lehman, Michael W. Hogue, and Jason Sprenkle, attorneys with the South Carolina law firm Nelson Mullins Riley & Scarborough, LLP Foreword by The Honorable Shira A Scheindlin of the US District Court for the Southern District of New York, Introduction by Thomas Y Allman, former Senior Vice President and General Counsel, BASF Corporation MONOGRAPH, November 2001, 61 pages

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By Gilbert L. Ross, M.D., Medical and Executive Director of The American Council on Science and Health, a consumer-education organization based in New York Prior to that, he practiced internal medicine for over twenty years

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By The Honorable Arthur J. Schwab, U.S. District Court for the Western District of Pennsylvania and past Chair of Litigation in the Pittsburgh law firm Buchanan Ingersoll, PC, and David J Porter, a shareholder with Buchanan Ingersoll, PC Foreword by Laura Stein, Senior Vice President and General Counsel of The Clorox Company, Introduction by John K. Williamson, former Assistant General Counsel, Intellectual Property, PPG Industries and currently a partner in the Pittsburgh office of the law firm Kirkpatrick & Lockhart Nicholson Graham LLP

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Lawyers And Experts Risk Malpractice Suits From Peddling Junk Science

By Rolin P. Bissell, a partner with the Philadelphia law firm Schnader Harrison Segal & Lewis LLP, specializing in complex commercial litigation, including antitrust, RICO, securities, financial fraud, and corporate governments litigation, and James M. Holston, also a partner at Schnader Harrison Segal & Lewis LLP, specializing in complex commercial and tort litigation WORKING PAPER, June, 2001, 25 pages

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New Procedure Extends Public Access To Government Science By U S. Senator Richard Shelby (R-AL), who serves as Chairman of the Senate Committee on Appropriations' Subcommittee on Transportation, and Chairman of the Senate Select Committee on Intelligence

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By Steven S Scholes, a partner in the Trial Department of the law firm McDermott, Will & Emery LLP, resident in its Chicago office, and co-chair of the firm's Securities Litigation Practice Group, as well as its SEC Defense Group

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Once Again .Ohio Legislators Approve Comprehensive Tort Reform

By Kurtis A Tunnell, Anne Marie Sferra Vorys and Miranda Creviston Motter who have all worked extensively on tort reform efforts in Ohio Mr Tunnell is a partner with Bricker & Eckler LLP and serves as legal counsel to the Ohio Alliance for Civil Justice (OACJ) Ms Sferra Vorys is a partner in the firm's litigation department Ms Creviston Motter is an Associate in the firm's government relations department

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Department of the Treasury

(Rev April 2007)

## Application for Extension of Time To File an Exempt Organization Return

. . .

Internal Revenue Service	File a separate application for each return	
<ul> <li>If you are filing for a</li> </ul>	n Automatic 3-Month Extension, complete only Part I and check this box	• x
	In Additional (not automatic) 3-Month Extension, complete only Part II (on page 2 of this form). Inness you have already been granted an automatic 3-month extension on a previously filed Form 8868.	
Part I Automatic 3	-Month Extension of Time. Only submit original (no copies needed).	
Section 501(c) corpora	tions required to file Form 990-T and requesting an automatic 6-month extension - check this box	

Section 501(c) corporations required to file Form 990-T and requesting an automatic 6-month extension - check this box and complete Part Lonly

All other corporations (including 1120-C filers), partnerships, REMICs, and trusts must use Form 7004 to request an extension of time to file income tax returns.

**Electronic Filing (e-file).** Generally, you can electronically file Form 8868 if you want a 3-month automatic extension of time to file one of the returns noted below (6 months for section 501(c) corporations required to file Form 990-T). However, you cannot file Form 8868 electronically if (1) you want the additional (not automatic) 3-month extension or (2) you file Forms 990-BL, 6069, or 8870, group returns, or a composite or consolidated From 990-T. Instead, you must submit the fully completed and signed page 2 (Part II) of Form 8868. For more details on the electronic filing of this form, visit www irs.gov/efile and click on e-file for Charities & Nonprofits.

Type or	Name of Exempt Organization	Employer ident	ification n	umber			
print	WASHINGTON LEGAL FOUNDATION	52-10715	570				
File by the	Number, street, and room or suite no If a P O box, see instructions						
due date for filing your	2009 MASSACHUSETTS AVE., N.W.		_				
return See	um See City, town or post office, state, and ZIP code For a foreign address, see instructions						
Instructions	WASHINGTON, DC 20036						
<u>Che</u> ck type o	f return to be filed (file a separate application for each return):						
<u>X</u> Form 990	Form 990-T (corporation)	rm 4720					
Form 990	-BL Form 990-T (sec. 401(a) or 408(a) trust) For	rm 5227					
Form 990	EZ Form 990-T (trust other than above) For	rm 6069					
Form 990	PF Form 1041-A For	rm 8870					
The books	are in the care of <a>CONSTANCE C. LARCHER</a>		_				
Telephone	No. ▶ <u>202 588-0302</u> FAX No ▶		_				
If this is for	ization does not have an office or place of business in the United States, check this box a Group Return, enter the organization's four digit Group Exemption Number (GEN)	· · · · · · · · · · ·	If this				
-	roup, check this box ▶ If it is for part of the group, check this box ▶	and attach a lis	t with th	1e			
until	an automatic 3-month (6 months for a section 501(c) corporation required to file Form 9 08/15,2007, to file the exempt organization return for the organization nan organization's return for:	•					
► X ►	calendar year 2006 or tax year beginning, and ending	,	·				
2 If this tax	year is for less than 12 months, check reason:	Change in ac	counting	period			
•	plication is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax,	less any	[				
	table credits. See instructions.		\$	NONE			
•	plication is for Form 990-PF or 990-T, enter any refundable credits and estimated tax p lude any prior year overpayment allowed as a credit.	ayments 3b	\$	NONE			
c Balance	Due. Subtract line 3b from line 3a. Include your payment with this form, or, if required			•			
	o coupon or, if required, by using EFTPS (Electronic Federal Tax Payment Syste		2				
instructio		3c	\$	NONE			
Caution. If you	are going to make an electronic fund withdrawal with this Form 8868, see Form 8453-E	O and Form 887	9-EO				
for payment in							
For Privacy A	and Paperwork Reduction Act Notice, see Instructions.	Form	8868 (Re	ev 4-2007)			

Form 8868 (Rev 4-2007)

Page 2 • If you are filing for an Additional (not automatic) 3-Month Extension, complete only Part II and check this box.... ► x Note. Only complete Part II if you have already been granted an automatic 3-month extension on a previously filed Form 8868

If yo	you are filing for an Automatic 3-Month Extension, complete only Part I (on page	
Part	t II Additional (not automatic) 3-Month Extension of Time. You r	nust file original and one copy.
Туре о	Name of Exempt Organization	Employer identification number
print	WASHINGTON LEGAL FOUNDATION	52-1071570
File by th		For IRS use only
extended due date	ate for ZUU9 MASSACHUSETTS AVE., N.W.	
filing the return Se	he City, town or post office, state, and ZIP code For a foreign address, see instructions	
Instructio		
Check	ck type of return to be filed (File a separate application for each return).	
x	Form 990 Form 990-PF	Form 1041-A Form 6069
	Form 990-BL Form 990-T (sec 401(a) or 408(a) trust)	Form 4720 Form 8870
	Form 990-EZ Form 990-T (trust other than above)	Form 5227
STOP	P! Do not complete Part II if you were not already granted an automatic 3-m	onth extension on a previously filed Form 8868.
• Th	he books are in the care of  CONSTANCE C. LARCHER	
	elephone No ▶ 202 588-0302 FAX No. ▶	
	he organization does not have an office or place of business in the United States,	check this box
	his is for a Group Return, enter the organization's four digit Group Exemption Num	
	he whole group, check this box 🕨 🔲 If it is for part of the group, check this be	
	es and EINs of all members the extension is for	
	I request an additional 3-month extension of time until	11/15,20.07
	For calendar year 2006, or other tax year beginning	and ending202020
	If this tax year is for less than 12 months, check reason Initial return	Final return Change in accounting period
	State in detail why you need the extension	
	ADDITIONAL TIME IS REQUIRED TO ASSEMBLE THE INFORMATIC	ON TN ORDER TO
	FILE A COMPLETE AND ACCURATE RETURN.	
	If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter th	ne tentative tax, less any
	nonrefundable credits. See instructions.	8a \$NONE
-	If this application is for Form 990-PF, 990-T, 4720, or 6069, enter any refundal	
	tax payments made. Include any prior year overpayment allowed as a cred	
	previously with Form 8868	8b \$ NONE
	Balance Due. Subtract line 8b from line 8a. Include your payment with this forr	
	with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax	
	Instructions:	8c \$ _ NONE
	Signature and Verification	on
	penalties of perjury, I declare that I have examined this torm, including accompanying schedules	and statements, and to the best of my knowledge and belief,
it is true,	ue, correct, and completer and that fam authonzed to prepare this form	,
Signatur	ture toto i for Title Coa	Date ► 8/13/07
	Notice to Applicant. (To Be Complete	
$\square$	We have approved this application Please attach this form to the organization's return	
<b>F</b> -1	We have not approved this application. However, we have granted a 10-day grace pe	riod from the later of the date shown below or the due
ت	date of the organization's return (including any prior extensions) This grace period is otherwise required to be made on a timely return Please attach this form to the organizat	considered to be a valid extension of time for elections.
	We have not approved this application. After considering the reasons stated in item 7	
<u> </u>	to file We are not granting a 10-day grace period	
$\square$	We cannot consider this application because it was filed after the extended due date of	the return for which an extension was requested
$\vdash$	Other	······
ت		
	Ву	
Directo		Date
Alterr	rnate Mailing Address. Enter the address if you want the copy of this application	for an additional 3-month extension
	rned to an address different than the one entered above.	
	Name	
	BOND BEEBE	
Туре о	or Number and street (include suite, room, or apt. no.) or a P.O. box number	
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