ENVELOPE POSTMARK DATE NOV 15 2005

EXTENDED UNTIL NOVEMBER 15, 2005

Form **990**

Department of the Treasury
Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation)

▶ The organization may have to use a copy of this return to satisfy state reporting requirements

OMB No. 1545-0047

2004

Open to Public Inspection

A For the 2004 calendar year, or tax year beginning , 2004, and ending

B Check if applicable:
- ☐ Address change
- ☐ Name change
- ☐ Initial return
- ☐ Final return
- ☐ Amended return
- ☐ Application pending

Please use IRS label or print or type. See Specific Instructions

C Name of organization
WASHINGTON LEGAL FOUNDATION

Number and street (or P O box if mail is not delivered to street address) | Room/suite
2009 MASSACHUSETTS AVE., N.W.

City or town, state or country, and ZIP + 4
WASHINGTON, DC 20036

D Employer identification number
52-1071570

E Telephone number
(202)588-0302

F Accounting method: ☐ Cash ☒ Accrual ☐ Other (specify) ▶

- **Section 501(c)(3) organizations and 4947(a)(1) nonexempt charitable trusts must attach a completed Schedule A (Form 990 or 990-EZ).**

H *and* **I** *are not applicable to section 527 organizations.*

H(a) Is this a group return for affiliates? ☐ Yes ☒ No

H(b) If "Yes," enter number of affiliates ▶ N/A

H(c) Are all affiliates included? ☐ Yes ☐ No
(If "No," attach a list See instructions)

H(d) Is this a separate return filed by an organization covered by a group ruling? ☐ Yes ☒ No

G Website: ▶ WWW.WLF.ORG

J Organization type (check only one) ▶ ☒ 501(c) (3) ◀ (insert no) ☐ 4947(a)(1) or ☐ 527

K Check here ▶ ☐ if the organization's gross receipts are normally not more than $25,000 The organization need not file a return with the IRS, but if the organization received a Form 990 Package in the mail, it should file a return without financial data **Some states require a complete return.**

I Group Exemption Number ▶

M Check ▶ ☐ if the organization is **not** required to attach Sch B (Form 990, 990-EZ, or 990-PF)

L Gross receipts Add lines 6b, 8b, 9b, and 10b to line 12 ▶ 5,007,922.

Part I **Revenue, Expenses, and Changes in Net Assets or Fund Balances** (See page 18 of the instructions.)

Revenue	1	Contributions, gifts, grants, and similar amounts received		
	a	Direct public support	1a 3,879,110.	
	b	Indirect public support	1b 850,000.	
	c	Government contributions (grants)	1c	
	d	Total (add lines 1a through 1c) (cash $ 4,717,558. noncash $ 11,552.)		1d 4,729,110.
	2	Program service revenue including government fees and contracts (from Part VII, line 93)		2
	3	Membership dues and assessments		3
	4	Interest on savings and temporary cash investments		4 189,285.
	5	Dividends and interest from securities		5 41,302.
	6a	Gross rents	6a	
	b	Less rental expenses	6b	
	c	Net rental income or (loss) (subtract line 6b from line 6a)		6c
	7	Other investment income (describe ▶)		7
	8a	Gross amount from sales of assets other than inventory — (A) Securities 48,225.	8a	
	b	Less cost or other basis and sales expenses — (A) Securities 48,600.	8b	
	c	Gain or (loss) (attach schedule) — (A) Securities -375.	8c	
	d	Net gain or (loss) (combine line 8c, columns (A) and (B))		8d -375.
	9	Special events and activities (attach schedule) If any amount is from **gaming**, check here ▶ ☐		
	a	Gross revenue (not including $ _____ of contributions reported on line 1a)	9a	
	b	Less direct expenses other than fundraising expenses	9b	
	c	Net income or (loss) from special events (subtract line 9b from line 9a)		9c
	10a	Gross sales of inventory, less returns and allowances	10a	
	b	Less cost of goods sold	10b	
	c	Gross profit or (loss) from sales of inventory (attach schedule) (subtract line 10b from line 10a)		10c
	11	Other revenue (from Part VII, line 103)		11
	12	**Total revenue** (add lines 1d, 2, 3, 4, 5, 6c, 7, 8d, 9c, 10c, and 11)		12 4,959,322.
Expenses	13	Program services (from line 44, column (B))		13 2,255,886.
	14	Management and general (from line 44, column (C))		14 728,580.
	15	Fundraising (from line 44, column (D))		15 331,333.
	16	Payments to affiliates (attach schedule)		16
	17	**Total expenses** (add lines 16 and 44, column (A))		17 3,315,799.
Net Assets	18	Excess or (deficit) for the year (subtract line 17 from line 12)		18 1,643,523.
	19	Net assets or fund balances at beginning of year (from line 73, column (A))		19 14,509,824.
	20	Other changes in net assets or fund balances (attach explanation) STMT 1		20 144,492.
	21	Net assets or fund balances at end of year (combine lines 18, 19, and 20)		21 16,297,839.

For Privacy Act and Paperwork Reduction Act Notice, see the separate instructions. Form **990** (2004)

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Part II Statement of Functional Expenses All organizations must complete column (A) Columns (B), (C), and (D) are required for section 501(c)(3) and (4) organizations and section 4947(a)(1) nonexempt charitable trusts but optional for others (See page 22 of the instructions)

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
22 Grants and allocations (attach schedule) (cash $_____ noncash $_____)	22				
23 Specific assistance to individuals (attach schedule)	23				
24 Benefits paid to or for members (attach schedule)	24				
25 Compensation of officers, directors, etc	25	587,102.	241,649.	219,957.	125,496.
26 Other salaries and wages	26	834,457.	681,824.	107,307.	45,326.
27 Pension plan contributions	27	688,287.	447,125.	158,454.	82,708.
28 Other employee benefits	28	70,126.	45,555.	16,144.	8,427.
29 Payroll taxes	29	74,437.	48,356.	17,136.	8,945.
30 Professional fundraising fees	30				
31 Accounting fees	31	90,371.		90,371.	
32 Legal fees	32	25,371.	25,371.		
33 Supplies	33	44,109.	28,654.	10,155.	5,300.
34 Telephone	34	42,594.	27,670.	9,806.	5,118.
35 Postage and shipping	35	70,256.	42,154.	14,051.	14,051.
36 Occupancy	36				
37 Equipment rental and maintenance	37				
38 Printing and publications	38	545,752.	530,738.		15,014.
39 Travel	39	69,737.	51,134.	18,603.	
40 Conferences, conventions, and meetings	40				
41 Interest	41				
42 Depreciation, depletion, etc (attach schedule)	42	55,041.	35,756.	12,671.	6,614.
43 Other expenses not covered above (itemize) STMT 2	43a	118,159.	49,900.	53,925.	14,334.
b	43b				
c	43c				
d	43d				
e	43e				
44 **Total functional expenses** (add lines 22 through 43) *Organizations completing columns (B)-(D), carry these totals to lines 13-15*	44	3,315,799.	2,255,886.	728,580.	331,333.

Joint Costs. Check ▶ ☐ if you are following SOP 98-2.

Are any joint costs from a combined educational campaign and fundraising solicitation reported in (B) Program services? ▶ ☐ Yes ☒ No

If "Yes," enter (i) the aggregate amount of these joint costs $ _____, (ii) the amount allocated to Program services $ _____;

(iii) the amount allocated to Management and general $ _____, and (iv) the amount allocated to Fundraising $ _____

Part III Statement of Program Service Accomplishments (See page 25 of the instructions.)

What is the organization's primary exempt purpose? ▶ STMT 3

All organizations must describe their exempt purpose achievements in a clear and concise manner State the number of clients served, publications issued, etc Discuss achievements that are not measurable (Section 501(c)(3) and (4) organizations and 4947(a)(1) nonexempt charitable trusts must also enter the amount of grants and allocations to others)

Program Service Expenses (Required for 501(c)(3) and (4) orgs , and 4947(a)(1) trusts, but optional for others)

a LITIGATION, LEGAL PUBLIC POLICY ANALYSIS, CLINICAL LEGAL INTERN PROGRAM, BRIEFS AND RESEARCH DOCUMENTS, PUBLIC LEGAL ISSUES, AND MONOGRAPH SERIES.
(Grants and allocations $) 1,811,708.

b EDUCATIONAL MATERIAL DISTRIBUTED THROUGHOUT THE UNITED STATES AT NO CHARGE TO THE GENERAL PUBLIC. THESE MATERIALS DISCUSS BROAD ISSUES OF INTEREST TO ALL AMERICANS
(Grants and allocations $) 444,178.

c _____
(Grants and allocations $)

d _____
(Grants and allocations $)

e Other program services (attach schedule) (Grants and allocations $)

f **Total of Program Service Expenses** (should equal line 44, column (B), Program services) ▶ 2,255,886.

Part IV Balance Sheets (See page 25 of the instructions.)

	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
Assets	45 Cash - non-interest-bearing			583,642.	45	251,828.
	46 Savings and temporary cash investments			9,993,850.	46	11,305,236.
	47a Accounts receivable	47a				
	b Less: allowance for doubtful accounts	47b			47c	
	48a Pledges receivable	48a	NONE			
	b Less. allowance for doubtful accounts	48b		50,000.	48c	NONE
	49 Grants receivable				49	
	50 Receivables from officers, directors, trustees, and key employees (attach schedule)				50	
	51a Other notes and loans receivable (attach schedule)	51a				
	b Less. allowance for doubtful accounts	51b			51c	
	52 Inventories for sale or use				52	
	53 Prepaid expenses and deferred charges STMT 4			26,675.	53	18,045.
	54 Investments - securities (attach schedule) STMT 5 ▶ ☐ Cost ☒ FMV			2,046,328.	54	2,601,153.
	55a Investments - land, buildings, and equipment: basis	55a				
	b Less: accumulated depreciation (attach schedule)	55b			55c	
	56 Investments - other (attach schedule)				56	
	57a Land, buildings, and equipment: basis	57a	4,004,837.			
	b Less: accumulated depreciation (attach schedule)	57b	1,525,097.	2,403,936.	57c	2,479,740.
	58 Other assets (describe ▶ STMT 6)			249,995.	58	284,789.
	59 **Total assets** (add lines 45 through 58) (must equal line 74)			15,354,426.	59	16,940,791.
Liabilities	60 Accounts payable and accrued expenses			88,673.	60	87,852.
	61 Grants payable				61	
	62 Deferred revenue				62	
	63 Loans from officers, directors, trustees, and key employees (attach schedule)				63	
	64a Tax-exempt bond liabilities (attach schedule)				64a	
	b Mortgages and other notes payable (attach schedule)				64b	
	65 Other liabilities (describe ▶ STMT 7)			755,929.	65	555,100.
	66 **Total liabilities** (add lines 60 through 65)			844,602.	66	642,952.
Net Assets or Fund Balances	**Organizations that follow SFAS 117, check here** ▶ ☒ and complete lines 67 through 69 and lines 73 and 74.					
	67 Unrestricted			14,342,139.	67	16,175,770.
	68 Temporarily restricted			85,616.	68	40,000.
	69 Permanently restricted			82,069.	69	82,069.
	Organizations that do not follow SFAS 117, check here ▶ ☐ and complete lines 70 through 74					
	70 Capital stock, trust principal, or current funds				70	
	71 Paid-in or capital surplus, or land, building, and equipment fund				71	
	72 Retained earnings, endowment, accumulated income, or other funds				72	
	73 **Total net assets or fund balances** (add lines 67 through 69 **or** lines 70 through 72; column (A) **must** equal line 19; column (B) **must** equal line 21)			14,509,824.	73	16,297,839.
	74 **Total liabilities and net assets / fund balances** (add lines 66 and 73)			15,354,426.	74	16,940,791.

Form 990 is available for public inspection and, for some people, serves as the primary or sole source of information about a particular organization. How the public perceives an organization in such cases may be determined by the information presented on its return Therefore, please make sure the return is complete and accurate and fully describes, in Part III, the organization's programs and accomplishments.

Part IV-A Reconciliation of Revenue per Audited Financial Statements with Revenue per Return (See page 27 of the instructions.)

a	Total revenue, gains, and other support per audited financial statements ▶	a	5,103,814.
b	Amounts included on line a but not on line 12, Form 990:		
(1)	Net unrealized gains on investments $ 144,492.		
(2)	Donated services and use of facilities $		
(3)	Recoveries of prior year grants $		
(4)	Other (specify) $		
	Add amounts on lines (1) through (4) ▶	b	144,492.
c	Line a minus line b ▶	c	4,959,322.
d	Amounts included on line 12, Form 990 but not on line a:		
(1)	Investment expenses not included on line 6b, Form 990 $		
(2)	Other (specify) $		
	Add amounts on lines (1) and (2) ▶	d	
e	Total revenue per line 12, Form 990 (line c plus line d) ▶	e	4,959,322.

Part IV-B Reconciliation of Expenses per Audited Financial Statements with Expenses per Return

a	Total expenses and losses per audited financial statements ▶	a	3,315,799.
b	Amounts included on line a but not on line 17, Form 990:		
(1)	Donated services and use of facilities $		
(2)	Prior year adjustments reported on line 20, Form 990 $		
(3)	Losses reported on line 20, Form 990 $		
(4)	Other (specify) $		
	Add amounts on lines (1) through (4) ▶	b	
c	Line a minus line b ▶	c	3,315,799.
d	Amounts included on line 17, Form 990 but not on line a:		
(1)	Investment expenses not included on line 6b, Form 990 $		
(2)	Other (specify) $		
	Add amounts on lines (1) and (2) ▶	d	
e	Total expenses per line 17, Form 990 (line c plus line d) ▶	e	3,315,799.

Part V List of Officers, Directors, Trustees, and Key Employees (List each one even if not compensated, see page 27 of the instructions)

(A) Name and address	(B) Title and average hours per week devoted to position	(C) Compensation (If not paid, enter -0-.)	(D) Contributions to employee benefit plans & deferred compensation	(E) Expense account and other allowances
SEE STATEMENT 8		587,102.	291,044.	NONE

75 Did any officer, director, trustee, or key employee receive aggregate compensation of more than $100,000 from your organization and all related organizations, of which more than $10,000 was provided by the related organizations? ▶ ☐ Yes ☒ No

If "Yes," attach schedule - see page 28 of the instructions

Part VI Other Information (See page 28 of the instructions.)

			Yes	No
76	Did the organization engage in any activity not previously reported to the IRS? If "Yes," attach a detailed description of each activity	76		X
77	Were any changes made in the organizing or governing documents but not reported to the IRS? If "Yes," attach a conformed copy of the changes.	77		X
78a	Did the organization have unrelated business gross income of $1,000 or more during the year covered by this return?	78a		X
b	If "Yes," has it filed a tax return on **Form 990-T** for this year?	78b	N/A	
79	Was there a liquidation, dissolution, termination, or substantial contraction during the year? If "Yes," attach a statement	79		X
80a	Is the organization related (other than by association with a statewide or nationwide organization) through common membership, governing bodies, trustees, officers, etc , to any other exempt or nonexempt organization?	80a	X	
b	If "Yes," enter the name of the organization ▶ STMT 9 and check whether it is [X] exempt or [ ] nonexempt			
81a	Enter direct and indirect political expenditures See line 81 instructions. 81a			
b	Did the organization file **Form 1120-POL** for this year?	81b	N/A	
82a	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	X	
b	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) 82b			
83a	Did the organization comply with the public inspection requirements for returns and exemption applications?	83a	X	
b	Did the organization comply with the disclosure requirements relating to quid pro quo contributions?	83b	X	
84a	Did the organization solicit any contributions or gifts that were not tax deductible?	84a	N/A	
b	If "Yes," did the organization include with every solicitation an express statement that such contributions or gifts were not tax deductible?	84b	N/A	
85	*501(c)(4), (5), or (6) organizations* a Were substantially all dues nondeductible by members?	85a	N/A	
b	Did the organization make only in-house lobbying expenditures of $2,000 or less?	85b	N/A	
	If "Yes" was answered to either 85a or 85b, **do not** complete 85c through 85h below unless the organization received a waiver for proxy tax owed for the prior year			
c	Dues, assessments, and similar amounts from members 85c N/A			
d	Section 162(e) lobbying and political expenditures 85d N/A			
e	Aggregate nondeductible amount of section 6033(e)(1)(A) dues notices 85e N/A			
f	Taxable amount of lobbying and political expenditures (line 85d less 85e) 85f N/A			
g	Does the organization elect to pay the section 6033(e) tax on the amount on line 85f?	85g	N/A	
h	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/A	
86	*501(c)(7) orgs* Enter a Initiation fees and capital contributions included on line 12 86a N/A			
b	Gross receipts, included on line 12, for public use of club facilities 86b N/A			
87	*501(c)(12) orgs.* Enter a Gross income from members or shareholders 87a N/A			
b	Gross income from other sources (Do not net amounts due or paid to other sources against amounts due or received from them) 87b N/A			
88	At any time during the year, did the organization own a 50% or greater interest in a taxable corporation or 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	88		X
89a	*501(c)(3) organizations* Enter Amount of tax imposed on the organization during the year under section 4911 ▶ NONE , section 4912 ▶ NONE , section 4955 ▶ NONE			
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		X
c	Enter Amount of tax imposed on the organization managers or disqualified persons during the year under sections 4912, 4955, and 4958 ▶ NONE			
d	Enter Amount of tax on line 89c, above, reimbursed by the organization ▶ NONE			
90a	List the states with which a copy of this return is filed ▶ DC, FL, MN, NJ, NY			
b	Number of employees employed in the pay period that includes March 12, 2004 (See instructions) 90b 16			
91	The books are in care of ▶ TREASURER Telephone no ▶ (202)588-0302			
	Located at ▶ 2009 MASSACHUSSETTS AVE., NW, WASHINGTON ZIP + 4 ▶ 20036			
92	*Section 4947(a)(1) nonexempt charitable trusts filing Form 990 in lieu of* **Form 1041** - Check here ▶ [ ] and enter the amount of tax-exempt interest received or accrued during the tax year ▶ 92 N/A			

Part VII Analysis of Income-Producing Activities (See page 33 of the instructions.)

Note: *Enter gross amounts unless otherwise indicated.*	Unrelated business income		Excluded by section 512, 513, or 514		(E) Related or exempt function income
	(A) Business code	(B) Amount	(C) Exclusion code	(D) Amount	
93 Program service revenue					
a					
b					
c					
d					
e					
f Medicare/Medicaid payments					
g Fees and contracts from government agencies					
94 Membership dues and assessments					
95 Interest on savings and temporary cash investments			14	189,285.	
96 Dividends and interest from securities			14	41,302.	
97 Net rental income or (loss) from real estate:					
a debt-financed property					
b not debt-financed property					
98 Net rental income or (loss) from personal property					
99 Other investment income					
100 Gain or (loss) from sales of assets other than inventory			18	-375.	
101 Net income or (loss) from special events					
102 Gross profit or (loss) from sales of inventory					
103 Other revenue: a					
b					
c					
d					
e					
104 Subtotal (add columns (B), (D), and (E))				230,212.	
105 **Total** (add line 104, columns (B), (D), and (E)) ▶					230,212.

Note: *Line 105 plus line 1d, Part I, should equal the amount on line 12, Part I*

Part VIII Relationship of Activities to the Accomplishment of Exempt Purposes (See page 34 of the instructions.)

Line No. ▼	Explain how each activity for which income is reported in column (E) of Part VII contributed importantly to the accomplishment of the organization's exempt purposes (other than by providing funds for such purposes)

Part IX Information Regarding Taxable Subsidiaries and Disregarded Entities (See page 34 of the instructions.)

(A) Name, address, and EIN of corporation, partnership, or disregarded entity	(B) Percentage of ownership interest	(C) Nature of activities	(D) Total income	(E) End-of-year assets
N/A	%			
	%			
	%			
	%			

Part X Information Regarding Transfers Associated with Personal Benefit Contracts (See page 34 of the instructions.)

(a) Did the organization, during the year, receive any funds, directly or indirectly, to pay premiums on a personal benefit contract? . . . . . ☐ Yes ☒ No

(b) Did the organization, during the year, pay premiums, directly or indirectly, on a personal benefit contract? ☐ Yes ☒ No

Note: *If "Yes" to (b), file Form 8870 and Form 4720 (see instructio*

Please Sign Here

Under penalties of perjury, I declare that I have examined this re
and belief, it is true, correct, and complete Declaration of prep

Daniel J Popeo
Signature of officer

DANIEL J. POPEO
Type or print name and title

Paid Preparer's Use Only

Preparer's signature

Firm's name (or yours if self-employed), address, and ZIP + 4

BOND BEEBE, P.C.
4600 EAST-WEST HWY.
BETHESDA, MD

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SCHEDULE A (Form 990 or 990-EZ)

Department of the Treasury
Internal Revenue Service

Organization Exempt Under Section 501(c)(3)

(Except Private Foundation) and Section 501(e), 501(f), 501(k), 501(n), or Section 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

2004

Name of the organization

WASHINGTON LEGAL FOUNDATION

Employer identification number

52-1071570

Part I Compensation of the Five Highest Paid Employees Other Than Officers, Directors, and Trustees

(See page 1 of the instructions. List each one. If there are none, enter "None.")

(a) Name and address of each employee paid more than $50,000	(b) Title and average hours per week devoted to position	(c) Compensation	(d) Contributions to employee benefit plans & deferred compensation	(e) Expense account and other allowances
JAMES T. GALLAGHER 2009 MASSACHUSETTS AVE., N.W. WASHINGTON, DC 20036	DIR. OF ADMIN. 45 HOURS	60,000.	6,024.	NONE
PAUL D. KAMENAR 2009 MASSACHUSETTS AVE., N.W. WASHINGTON, DC 20036	SENIOR EXEC. COUNSEL 45 HOURS	135,000.	110,460.	NONE
GLENN G. LAMMI 2009 MASSACHUSETTS AVE., N.W. WASHINGTON, DC 20036	CHIEF COUNS./LEGAL 45 HOURS	138,000.	14,436.	NONE
DAVID A. PRICE 2009 MASSACHUSETTS AVE., N.W. WASHINGTON, DC 20036	SENIOR VICE PRES 45 HOURS	114,400.	6,024.	NONE
RICHARD A. SAMP 2009 MASSACHUSETTS AVE., N.W. WASHINGTON, DC 20036	CHIEF COUNSEL 45 HOURS	135,000.	24,995.	NONE
Total number of other employees paid over $50,000 ▶	NONE			

Part II Compensation of the Five Highest Paid Independent Contractors for Professional Services

(See page 2 of the instructions. List each one (whether individuals or firms). If there are none, enter "None.")

(a) Name and address of each independent contractor paid more than $50,000	(b) Type of service	(c) Compensation
BOND BEEBE, P.C. BETHESDA, MD 20814-3423	ACCOUNTING	82,740.
Total number of others receiving over $50,000 for professional services ▶ NONE		

Part III 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.)*			
a	Sale, exchange, or leasing of property?	2a		X
b	Lending of money or other extension of credit?	2b		X
c	Furnishing of goods, services, or facilities?	2c		X
d	Payment of compensation (or payment or reimbursement of expenses if more than $1,000)? STMT 10	2d	X	
e	Transfer of any part of its income or assets?	2e		X
3a	Do you make grants for scholarships, fellowships, student loans, etc ? (If "Yes," attach an explanation of how you determine that recipients qualify to receive payments)	3a		X
b	Do you have a section 403(b) annuity plan for your employees?	3b		X
4a	Did you maintain any separate account for participating donors where donors have the right to provide advice on the use or distribution of funds?	4a		X
b	Do you provide credit counseling, debt management, credit repair, or debt negotiation services?	4b		X

Part IV Reason for Non-Private Foundation Status (See pages 3 through 6 of the instructions.)

The organization is not a private foundation because it is (Please check only **ONE** applicable box.)

- 5 ☐ A church, convention of churches, or association of churches Section 170(b)(1)(A)(i)
- 6 ☐ A school Section 170(b)(1)(A)(ii) (Also complete Part V)
- 7 ☐ A hospital or a cooperative hospital service organization Section 170(b)(1)(A)(iii)
- 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** ▶ _____
- 10 ☐ An organization operated for the benefit of a college or university owned or operated by a governmental unit Section 170(b)(1)(A)(iv) (Also complete the **Support Schedule** in Part IV-A)
- 11a ☒ An organization that normally receives a substantial part of its support from a governmental unit or from the general public Section 170(b)(1)(A)(vi). (Also complete the **Support Schedule** in Part IV-A)
- 11b ☐ A community trust Section 170(b)(1)(A)(vi) (Also complete the **Support Schedule** in 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 organization after June 30, 1975 See section 509(a)(2) (Also complete the **Support Schedule** in Part IV-A)
- 13 ☐ An organization that is not controlled by any disqualified persons (other than foundation managers) and supports organizations described in **(1)** lines 5 through 12 above, or **(2)** section 501(c)(4), (5), or (6), if they meet the test of section 509(a)(2). (See section 509(a)(3))

Provide the following information about the supported organizations (See page 5 of the instructions)

(a) Name(s) of supported organization(s)	(b) Line number from above

- 14 ☐ An organization organized and operated to test for public safety. Section 509(a)(4) (See page 5 of the instructions)

Part IV-A Support Schedule (Complete only if you checked a box on line 10, 11, or 12.) ***Use cash method of accounting.***

Note: *You may use the worksheet in the instructions for converting from the accrual to the cash method of accounting.*

Calendar year (or fiscal year beginning in) ▶	(a) 2003	(b) 2002	(c) 2001	(d) 2000	(e) Total
15 Gifts, grants, and contributions received (Do not include unusual grants See line 28)	5,972,010.	4,349,270.	3,861,579.	3,896,412.	18,079,271.
16 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	226,231.	262,129.	37,509.	451,512.	977,381.
19 Net income from unrelated business activities not included in line 18					
20 Tax revenues levied for the organization's benefit and either paid to it or expended on its behalf					
21 The value of services or facilities furnished to the organization by a governmental unit without charge Do not include the value of services or facilities generally furnished to the public without charge					
22 Other income Attach a schedule Do not include gain or (loss) from sale of capital assets	STMT 11 5,989.	8,056.	12,281.		26,326.
23 Total of lines 15 through 22	6,204,230.	4,619,455.	3,911,369.	4,347,924.	19,082,978.
24 Line 23 minus line 17	6,204,230.	4,619,455.	3,911,369.	4,347,924.	19,082,978.
25 Enter 1% of line 23	62,042.	46,195.	39,114.	43,479.	

26 Organizations described on lines 10 or 11: a Enter 2% of amount in column (e), line 24	26a	381,660.
b Prepare a list for your records to show the name of and amount contributed by each person (other than a governmental unit or publicly supported organization) whose total gifts for 2000 through 2003 exceeded the amount shown in line 26a **Do not file this list with your return.** Enter the total of all these excess amounts	26b	1,938,360.
c Total support for section 509(a)(1) test Enter line 24, column (e)	26c	19082978.
d Add Amounts from column (e) for lines 18 977,381. 19 ____ 22 26,326. 26b 1,938,360.	26d	2,942,067.
e Public support (line 26c minus line 26d total)	26e	16140911.
f **Public support percentage (line 26e (numerator) divided by line 26c (denominator))**	26f	84.5828 %

27 Organizations described on line 12: a For amounts included in lines 15, 16, and 17 that were received from a "disqualified person," prepare a list for your records to show the name of, 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

(2003) _____ (2002) _____ (2001) NOT APPLICABLE (2000) _____

b For any amount included in line 17 that was received from each person (other than "disqualified persons"), prepare a list for your records to show the name of, and amount received for each year, that was more than the **larger** of **(1)** the amount on line 25 for the year or **(2)** $5,000 (Include in the list organizations described in lines 5 through 11, as well as individuals) **Do not file this list with your return.** After computing the difference between the amount received and the larger amount described in **(1)** or **(2),** enter the sum of these differences (the excess amounts) for each year

(2003) _____ (2002) _____ (2001) _____ (2000) _____

c Add Amounts from column (e) for lines 15 ____ 16 ____ 17 ____ 20 ____ 21 ____	27c	
d Add Line 27a total ____ and line 27b total ____	27d	
e Public support (line 27c total minus line 27d total)	27e	
f Total support for section 509(a)(2) test Enter amount from line 23, column (e)	27f	
g **Public support percentage (line 27e (numerator) divided by line 27f (denominator))**	27g	%
h **Investment income percentage (line 18, column (e) (numerator) divided by line 27f (denominator))**	27h	%

28 Unusual Grants: For an organization described in line 10, 11, or 12 that received any unusual grants during 2000 through 2003, prepare a list for your records to show, for each year, the name of the contributor, the date and amount of the grant, and a brief description of the nature of the grant **Do not file this list with your return.** Do not include these grants in line 15

Part V **Private School Questionnaire** (See page 7 of the instructions.) NOT APPLICABLE
(To be completed ONLY by schools that checked the box on line 6 in Part IV)

			Yes	No
29	Does the organization have a racially nondiscriminatory policy toward students by statement in its charter, bylaws, other governing instrument, or in a resolution of its governing body?	29		
30	Does the organization include a statement of its racially nondiscriminatory policy toward students in all its 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?	31		
	If "Yes," please describe, if "No," please explain (If you need more space, attach a separate statement)			
32	Does the organization maintain the following.			
a	Records indicating the racial composition of the student body, faculty, and administrative staff?	32a		
b	Records documenting that scholarships and other financial assistance are awarded on a racially nondiscriminatory basis?	32b		
c	Copies of all catalogues, brochures, announcements, and other written communications to the public dealing 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:			
a	Students' rights or privileges?	33a		
b	Admissions policies?	33b		
c	Employment of faculty or administrative staff?	33c		
d	Scholarships or other financial assistance?	33d		
e	Educational policies?	33e		
f	Use of facilities?	33f		
g	Athletic programs?	33g		
h	Other extracurricular activities?	33h		
	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		
	If you answered "Yes" to either 34a or b, please explain using an attached statement.			
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		

Part VI-A Lobbying Expenditures by Electing Public Charities (See page 9 of the instructions.)
(To be completed **ONLY** by an eligible organization that filed Form 5768) NOT APPLICABLE

Check ▶ a ☐ if the organization belongs to an affiliated group Check ▶ b ☐ if you checked "a" and "limited control" provisions apply.

Limits on Lobbying Expenditures (The term "expenditures" means amounts paid or incurred.)		(a) Affiliated group totals	(b) To be completed for ALL electing organizations
36 Total lobbying expenditures to influence public opinion (grassroots lobbying)	36		
37 Total lobbying expenditures to influence a legislative body (direct lobbying)	37		
38 Total lobbying expenditures (add lines 36 and 37)	38		
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 — 20% of the amount on line 40			
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 — $1,000,000			
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		
44 Subtract line 41 from line 38. Enter -0- if line 41 is more than line 38	44		

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 11 of the instructions.)

Calendar year (or fiscal year beginning in) ▶	(a) 2004	(b) 2003	(c) 2002	(d) 2001	(e) Total
	Lobbying Expenditures During 4-Year Averaging Period				
45 Lobbying nontaxable amount					
46 Lobbying ceiling amount (150% of line 45(e))					
47 Total lobbying expenditures					
48 Grassroots nontaxable amount					
49 Grassroots ceiling amount (150% of line 48(e))					
50 Grassroots lobbying expenditures					

Part VI-B Lobbying Activity by Nonelecting Public Charities NOT APPLICABLE
(For reporting only by organizations that did not complete Part VI-A) (See page 11 of the instructions.)

During the year, did the organization attempt to influence national, state or local legislation, including any attempt to influence public opinion on a legislative matter or referendum, through the use of	Yes	No	Amount
a Volunteers			
b Paid staff or management (Include compensation in expenses reported on lines c through h.)			
c Media advertisements			
d Mailings to members, legislators, or the public			
e Publications, or published or broadcast statements			
f Grants to other organizations for lobbying purposes			
g Direct contact with legislators, their staffs, government officials, or a legislative body			
h Rallies, demonstrations, seminars, conventions, speeches, lectures, or any other means			
i Total lobbying expenditures (Add lines c through h.)			

If "Yes" to any of the above, also attach a statement giving a detailed description of the lobbying activities.

Part VII **Information Regarding Transfers To and Transactions and Relationships With Noncharitable Exempt Organizations** (See page 11 of the instructions.)

51 Did the reporting organization directly or indirectly engage in any of the following with any other organization described in section 501(c) of the Code (other than section 501(c)(3) organizations) or in section 527, relating to political organizations?

		Yes	No
a Transfers from the reporting organization to a noncharitable exempt organization of:			
(i) Cash	51a(i)		X
(ii) Other assets	a(ii)		X
b Other transactions:			
(i) Sales or exchanges of assets with a noncharitable exempt organization	b(i)		X
(ii) Purchases of assets from a noncharitable exempt organization	b(ii)		X
(iii) Rental of facilities, equipment, or other assets	b(iii)		X
(iv) Reimbursement arrangements	b(iv)		X
(v) Loans or loan guarantees	b(v)		X
(vi) Performance of services or membership or fundraising solicitations	b(vi)		X
c Sharing of facilities, equipment, mailing lists, other assets, or paid employees	c	X	

d If the answer to any of the above is "Yes," complete the following schedule Column (b) should always show the fair market value of the goods, other assets, or services given by the reporting organization If the organization received less than fair market value in any transaction or sharing arrangement, show in column (d) the value of the goods, other assets, or services received

(a) Line no	(b) Amount involved	(c) Name of noncharitable exempt organization	(d) Description of transfers, transactions, and sharing arrangements
51C		BUSINESS CIVIL LIBERTIES, INC. (501(C)(4))	ONE FILE DRAWER OF ADMINISTRATIVE FILES LOCATED IN THE ADMINISTRATIVE OFFICE

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? ▶ [X] Yes [ ] No

b If "Yes," complete the following schedule:

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

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.

CONFIDENTIAL

REPORT

to the

WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

WLF ACTIVITIES
IN OPPOSITION TO
EXCESSIVE GOVERNMENT REGULATION

November 29, 2004

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CONFIDENTIAL

NOVEMBER 29, 2004

REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

WLF ACTIVITIES IN OPPOSITION TO EXCESSIVE GOVERNMENT REGULATION

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 freest, wealthiest, and fairest nation in the world.

Throughout its 27 years, the Washington Legal Foundation has devoted a significant portion of its resources to ensuring that our free-enterprise system is not strangled by excessive government regulation. WLF attorneys regularly appear before both federal and state regulatory bodies to ensure that they understand that protecting the "public interest" does not simply mean preventing fraudulent and unsafe practices by the business community, but also means promoting a climate in which entrepreneurs are not encumbered by red tape and thus are left free to innovate for the benefit of the consuming public. Bureaucrats all too often overlook this second portion of their mission; WLF stands ready to provide them with frequent reminders -- both by appearing directly before administrative bodies and, when necessary, bringing them into court.

WLF has worked to achieve those objectives through its precedent-setting litigation, its involvement in government regulatory proceedings, its publication of timely articles on speech-related issues, and its tireless advocacy for free-market solutions in the news media and other public forums. Through those activities, WLF has acquired significant expertise in the workings of many of the major federal regulatory bodies. This report highlights some of WLF's more significant efforts to influence decision-making at those regulatory agencies over the past seven 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 who have been the victims of excessive government regulation.

A. Alcohol and Tobacco Tax and Trade Bureau

The Alcohol and Tobacco Tax and Trade Bureau (TTB), a branch of the Treasury Department, has, as it name implies, extensive authority over the marketing of tobacco products and alcoholic beverages. WLF has long been a strong supporter of the First Amendment rights of the business community. Accordingly, for many years it has worked actively to ensure that TTB regulation of product marketing does not infringe on First Amendment rights. (NOTE: TTB recently went through a reorganization and name change. It used to be known as the Bureau of Alcohol, Tobacco, and Firearms, but changed its name after its law-enforcement functions were transferred to the Justice Department in 2003.) What follows are some of the TTB proceedings in which WLF has been actively engaged in recent years.

Flavored Malt Beverages. On October 21, 2003, WLF filed comments in opposition to proposed TTB regulations that would impose excessive and unjustified restrictions on statements in 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. WLF noted that the U.S. 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.

Labeling of "Alcopops." On July 23, 2001, WLF filed comments with TTB, 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 TTB 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.

Health Warnings on Alcoholic Beverages. On August 17, 2001, WLF filed comments with TTB, in opposition to proposals to require manufacturers to more prominently display the congressionally mandated health warning statement required to appear on the labels of all containers of alcoholic beverages. WLF argued that such warning labels are already prominently displayed and that the health warnings are seen and understood by almost all consumers. WLF noted that forcing manufacturers to include a government statement on their product raises serious First Amendment concerns. WLF argued that at some point, the important government interests served by mandating inclusion of health warnings are outweighed by manufacturers' First Amendment rights not to be compelled to speak. WLF argued that that point would be reached if TTB mandated the more-prominent health warnings being proposed by some so-called consumer groups.

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.

B. Army Corps of Engineers

For generations, the U.S. Army Corps of Engineers focused almost all of its efforts on government construction projects, such as building dams. But in recent years, it has attempted to reinvent itself as a protector of the environment; in particular, it has taken on a role in enforcing wetlands regulations issued pursuant to the Clean Water Act (CWA). In that new role, the Army Corps has often lost sight of the rights of private property owners who, in some cases, are being told that their dry lands are federally protected "wetlands" and thus may not be developed. WLF has been a frequent critic of the Army Corps's CWA enforcement policy and has regularly gone to court, when necessary, to prevent the Army Corps from exceeding its mandate. Some of WLF's efforts in this regard are listed below.

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 -- raised by WLF in its brief -- of whether Congress has authority under the Commerce Clause to regulate such isolated wetlands simply because migratory birds were observed on the parcel. In this case a local government agency in Illinois purchased a 533-acre parcel of land to be used as a landfill. Originally, the Army Corps determined that the parcel, which contained a few ponds and puddles, did not constitute "waters of the United States" under the CWA. However, the Corps changed its position and asserted jurisdiction over the isolated wetland when it was discovered that migratory birds were spotted on the property. In its brief, WLF argued that the Corps' so-called "migratory bird rule" exceeded 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.

American Mining Congress v. U.S. Army Corps of Engineers. On June 25, 1998, the U.S. Court of Appeals for the District of Columbia Circuit unanimously upheld a lower court decision, in which WLF participated, that struck down a wetland regulation that asserted federal jurisdiction over the land clearing, excavation, and dredging of wetlands because the rule was inconsistent with the language and intent of the Clean Water Act. WLF argued in its brief that the agencies lacked authority under the Clean Water Act to promulgate the rule, and that its implementation would impose an unfair burden on property owners who would be required to go through yet another bureaucratic procedure to get pre-approval for land clearing and other normal land use activities.

Comments on Wetland Regulation. On April 16, 2003, WLF filed comments with the EPA and the U.S. Army Corps of Engineers regarding the regulatory implications of the U.S. Supreme Court's decision in *Solid Waste Agency of Northern Cook County (SWANCC) v. U.S. Army Corps of Engineers.* In *SWANCC*, the Court ruled that the Corps lacked jurisdiction to regulate isolated wetlands that were not connected to navigable waters. WLF urged the agencies to revise their regulations to reflect the Court's decision that the agencies' jurisdiction over wetlands is limited in scope.

C. Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services, administers federal government health care programs for the elderly and indigent. CMS has an obvious interest in holding down costs; unfortunately, that interest often leads CMS to block patient access to important but expensive medications. WLF attorneys regularly appear before CMS to ensure that the agency does not inappropriately second-guess the decisions of physicians that their patients be treated with an FDA-approved medication.

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 benefits 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.

Coverage of Cancer Drugs. On February 10, 2004, WLF filed a petition with the CMS, 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.

PhRMA v. Thompson. 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; it also upheld CMS's and HHS's decision to approve the Michigan program. 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 CMS 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.

Privacy of Health Information. On March 30, 2001, WLF filed comments with HHS and CMS, urging them to give serious consideration to substantially revising the health privacy rules adopted in the waning days of the Clinton administration. WLF argued that the rules were adopted too hastily without providing interested parties with sufficient opportunity to digest and comment upon the rule's extremely wide-ranging provisions. WLF noted its particular objection to the provision that attempts to regulate oral communications; WLF argued that that provision exceeds HHS's statutory authority and would unnecessarily chill communications among care givers; communication that is vital to effective health care.

WLF also objected to the unnecessarily broad patient consent and authorization provisions, which, by requiring all consents to information disclosure to be in writing, will interfere with the doctor-patient relationship to an unwarranted degree. Although HHS announced that it would go forward with the Clinton Administration's timetable for implementing the regulation, it is considering possible revisions.

D. Commerce Department

The U.S. Department of Commerce exercises regulatory authority over several types of commercial activity, including fishing. The department also conducts the decennial census. Both of the activities have drawn WLF's attention from time to time, when Department of Commerce officials have failed to abide by their congressional mandates.

U.S. House of Representatives v. U.S. Dep't of Commerce. On January 25, 1999, the U.S. Supreme Court handed WLF an important win when it ruled that the Clinton Administration acted illegally in seeking to abolish the 200-year tradition of attempting to count all citizens in decennial censuses. In its brief, WLF urged the Court to uphold a lower-court decision prohibiting the government from abandoning the traditional headcount. The Court decision prohibited the Census Bureau from carrying out its plan to adjust the results of the 2000 Census by boosting population totals in areas thought to contain disproportionate numbers of undercounted minority group members. WLF's brief argued (and the Supreme Court agreed) that the Clinton Administration's plan to adjust census totals violated the Census Act. WLF noted that no prior American census adjusted population totals from the number of citizens actually counted, and that using statistical sampling to adjust census totals would open the census process to the danger of political manipulation. WLF filed its brief at the request of the leadership of the U.S. House of Representatives, and did so on behalf of a coalition of 23 non-profit organizations and two individuals.

Regulation of Maine Lobster Fishing. WLF has fought for years to prevent the National Marine Fisheries Service ("NMFS," a division of the Department of Commerce) from imposing overly strict regulations on Maine lobster fishing. The NMFS regulations issued in 2000 were less severe than originally proposed, thanks in part to WLF's efforts. WLF's filings with NMFS expressed its concerns over proposed lobster restrictions designed to reduce the possible danger posed to four large whale stocks incidental to certain East Coast fisheries. The proposed rule included time and area closures for lobstering, anchored gillnet and shark drift gillnet fisheries, gear requirements, including a general prohibition on having line floating at the surface in these fisheries, and a prohibition on storing inactive gear at sea. WLF's filings expressed concerns regarding the rule's impact on the Maine lobster industry. WLF commented that NMFS's proposed gear marking system for lobster gear, even as revised, would provide little informational value for assessing whale entanglements, with incommensurate costs to the lobster industry. WLF also requested NMFS to perform a Regulatory Flexibility Act analysis to ensure that the rule would not have a significant detrimental impact on small businesses.

E. Environmental Protection Agency

Americans can be justly proud of their efforts over the past several decades in cleaning up the environment. Thanks in part to the federal Clean Water Act and Clean Air Act, our nation's lakes and rivers, as well as the air we breathe, are considerably cleaner than they once were.

Overseeing the clean-up effort has been the Environmental Protection Agency (EPA). Unfortunately, overzealous EPA bureaucrats all to often have overlooked their responsibility to balance the need for a healthy environment with the need to allow the business community to carry out the innovations necessary to maintain our prosperous and healthy standard of living. WLF has stood ready to combat EPA officials on those occasions when they ignore their congressional mandate.

Riverdale Mills Corp. v. United States. WLF is representing a small business and its owner in a lawsuit against the federal government and two EPA agents. The suit alleges that the defendants violated their civil rights by maliciously filing false criminal charges against them. WLF's suit arises in the aftermath of a failed criminal prosecution against Riverdale Mills Corp. and its owner based on alleged violations of the Clean Water Act. The charges fell apart after a court found that EPA agents forged evidence. In the ensuing WLF lawsuit, Riverdale Mills and its owner allege that the defendants engaged in selective prosecution and violated their Fourth Amendment rights to be protected against unreasonable searches and seizures. The claims are now pending before the U.S. Court of Appeals for the First Circuit, which must determine (among other issues) whether the individual EPA agents are entitled to immunity from suit.

Massachusetts v. EPA. On November 2, 2004, WLF filed a brief in the U.S. Court of Appeals for the District of Columbia Circuit, urging the court to reject an effort by environmentalists and several States to force the EPA to begin regulating carbon dioxide as a "pollutant." The level of carbon dioxide in the atmosphere in recent decades has increased somewhat, and some environmentalists contend that that increase could lead to long-term warming of the environment. In its brief, WLF argued that Congress has never authorized the EPA to take steps to reduce emissions of carbon dioxide into the air. WLF noted that any serious efforts to reduce emissions would require a drastic overhaul of our industrial society; and argued that if Congress had intended to require the EPA to control carbon dioxide emissions, one would have expected some indication in the legislative record of such an intent. WLF argued that in the absence of any such indication, it cannot be true that Congress mandated EPA regulation of carbon dioxide.

United States v. Alcan Aluminum Corporation. On January 12, 2004, the Supreme Court denied review in this important case. On December 15, 2003, WLF filed a brief in the U.S. Supreme Court in support of a petition for review filed by Alcan Aluminum Corporation (Alcan) seeking review and reversal of an adverse U.S. Court of Appeals for the Second Circuit ruling, which required Alcan to pay $13 million in cleanup costs of two EPA Superfund sites in upstate New York. Alcan's allegedly "hazardous substance" was essentially nothing more than water; 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 business clients.

"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 has regularly gone to court to oppose that distorted interpretation of Title VI; its litigation efforts culminated in a near-total victory in 2001 when the Supreme Court ruled in *Alexander v. Sandoval* that private litigants are not empowered to bring "environmental justice" lawsuits under Title VI.

However, *Alexander v. Sandoval* left open the possibility that federal agencies, such as EPA, could invoke this "disparate impact" Title VI theory to enforce activists' notions of "environmental justice" (EJ).

Accordingly, WLF has intervened in numerous EPA proceedings in which activists have filed EJ complaints. To date, WLF has succeeded in persuading the EPA not to block *any* development projects on the basis of an EJ claim. WLF has also sought to prevent the EPA from adopting regulations that would give undue credence to the theory underlying the EJ movement. For example, on August 28, 2000, WLF filed comments opposing the EPA's Draft Revised Guidance for Investigating Title VI Administrative Complaints Challenging Permits. Although the guidance ostensibly provided a framework for processing complaints filed under the EPA's discriminatory effects regulations, WLF pointed out that the entire concept of enforcing EJ under those regulations is legally flawed because Title VI prohibits only *intentional* discrimination. WLF argued that the guidance document also likely would cause a significant, unjustified shifting of permit decision-making authority from the states to the federal government. In response to criticisms from WLF and others, the EPA withdrew the document and in its place in December 2003 issued its EJ "Toolkit" to assist companies in complying with EJ regulations. WLF continues to work within the EPA to ensure that the agency never seeks to enforce its EJ regulations, with the ultimate goal of repealing them altogether.

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 EPA's 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.

Petition Governing EPA Inspections. On May 14, 2001, WLF filed a formal petition for rulemaking with the Environmental Protection Agency (EPA) that would require the EPA to provide regulated companies and businesses with a "Statement of Rights of Owners and Operators" before any EPA agents can enter and inspect the premises for possible violations of the myriad environmental laws and regulations administered by the EPA. The petition is pending before the EPA.

United States v. Vertac Chemical Corp. On April 11, 2001, WLF scored a major victory for itself and WLF's clients, a group of prominent scientists and organizations, when the United States Court of Appeals for the Eighth Circuit vacated a $100 million Superfund liability ruling by the U.S. District Court for the Eastern District of Arkansas, and remanded the case to the district court to determine whether the Hercules company is liable, and if so, to what extent, for the costly cleanup of a Superfund site containing dioxins. On January 24, 2000, WLF filed a brief with the court on behalf of itself and a group of prominent scientists and organizations urging the court to reverse a district court ruling that upheld the EPA's arbitrary 1980 measure of dioxin's cancer potency factor. The EPA's misguided regulation of the chemical has resulted in the unnecessary expenditure of billions of dollars to remediate so-called "Superfund" sites that were not shown to pose hazards to human health.

American Trucking Associations, Inc. v. Browner. On February 27, 2001, the U.S. Supreme Court upheld the EPA's method of revising standards for the permissible levels of ground-level ozone and particulate matter. In doing so, the High Court rejected arguments by WLF and the regulated industry that the EPA, in setting the standards, had to factor in the costs of their implementation, and that the failure to do so would result in an unconstitutional delegation of legislative power from Congress to the EPA. At the same time, however, the Court struck down the EPA's ozone implementation plan as violative of the Clean Air Act (CAA), and sent it back to the U.S. Court of Appeals for the District of Columbia Circuit for further consideration.

Harmon Industries, Inc. v. Browner. On January 24, 2000, the U.S. Court of Appeals for the Eighth Circuit denied a petition for rehearing en banc, thereby leaving intact WLF's victory in this case. WLF's victory came about when the Eighth Circuit declared unlawful the EPA's controversial practice of "overfiling," whereby the EPA seeks additional penalties against companies for certain environmental violations, even though State authorities have resolved the matter. WLF argued in its brief, and the court of appeals agreed, that RCRA's statutory structure and principles of federalism preclude the EPA from enforcing Missouri law.

United States v. Bestfoods. On June 8, 1998, the Supreme Court unanimously ruled that a parent corporation cannot be held liable for its subsidiary's violation of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA"), otherwise known as the "Superfund" law, simply because the parent company owns or operates the subsidiary. Rather, the government must show that the parent company actually operated its subsidiary's chemical facility. WLF had filed a brief in the case on February 20, 1998, urging the Court to uphold a precedent-setting court of appeals decision that parent corporations cannot be held liable as an "owner or operator" under CERCLA unless the "corporate veil" of the subsidiary can be pierced under state law rather than under federal common law.

Etcheverry v. Tri-Ag Services. On March 8, 2000, the California Supreme Court ruled that a federal pesticide labeling law preempts lawsuits filed in California courts under state law that claim that the labels on the chemicals did not adequately warn purchasers of the possible adverse effects of the product. In doing so, the California Supreme Court handed a victory to WLF which had argued that the state claims were preempted by federal law, and dealt a blow to the EPA, which had argued the opposite. WLF's January 1999 brief urged the court to disregard an informational notice issued by the EPA which took the position that state law tort claims against manufacturers of pesticide chemicals are not preempted by federal law administered by the EPA. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA requires manufacturers to provide specific information on the labels of such products. In the U.S. Supreme Court in a subsequent case, the EPA confessed error and agreed with WLF's position.

Revocation of Invalid Rules. On March 13, 2002, the EPA finally revoked a pair of regulations that had been struck down by the courts almost two years earlier. This action came as a victory for WLF which had petitioned the EPA in late 2001, demanding that the EPA formally revoke the invalid regulations that the agency had improperly kept on the books. The Office of Management and Budget (OMB), acting upon a related WLF petition, ordered all regulatory agencies to review all of their regulations and to revoke those that have been declared invalid by the courts.

Opposing Petition To Regulate Greenhouse Gas Emissions from Automobiles. For the past five years, WLF has spearheaded opposition to a proposal submitted by a broad array of environmental groups requesting EPA to regulate carbon dioxide emissions from automobiles. On November 29, 1999, WLF's Working Group To Oppose Expanded EPA Authority filed a 45-page opposition with the EPA challenging a petition by several activist groups to regulate so-called "greenhouse gas" emissions, such as carbon dioxide, from new motor vehicles. On May 22, 2001, WLF filed supplemental comments in response to the EPA's January 3, 2001 formal notice of the petition. Environmental groups contend that regulation is required by Section 202 of the Clean Air Act. In its 45-page response, WLF's Working Group argued that the 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 the EPA did have the authority to regulate greenhouse gas emissions, there was no sound scientific basis for doing so and that 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.

Because WLF convinced the EPA not to begin regulation in this area, environmental groups have now brought their fight to federal court. WLF is monitoring the litigation and has entered the fray in support of the EPA at appropriate opportunities (*see, e.g., Massachusetts v. EPA, supra*).

Petition to Adopt Guidelines Governing the Publication of Environmental Data Via the Internet. On May 15, 2001, WLF petitioned the EPA to adopt certain guidelines for publicizing environmental information via the Internet. First, WLF recommended that the EPA prohibit the release of data unless expressly authorized for publication by statute. Second, WLF recommended that the EPA clearly state on its website when particular activities are authorized by law, regulation, or permit. Third, WLF recommended that the EPA explain the nature of each environmental violation and its impact (or non-impact) on the local community. Fourth, WLF urged the EPA to include sites favorable to free enterprise alongside those that advocate environmental litigation. And fifth, WLF asked the EPA to prohibit the release of trade secrets and confidential business information.

Comments on Wetland Regulation. On April 16, 2003, WLF filed comments with the EPA and the U.S. Army Corps of Engineers regarding the regulatory implications of the U.S. Supreme Court's decision in *Solid Waste Agency of Northern Cook County (SWANCC) v. U.S. Army Corps of Engineers.* In *SWANCC*, the Court ruled that the Corps lacked jurisdiction to regulate isolated wetlands that were not connected to navigable waters. WLF urged the agencies to revise their regulations to reflect the Court's decision that the agencies' jurisdiction over wetlands is limited in scope.

Rules on Dioxin Reporting. On September 5, 1997, WLF filed comments with the EPA opposing its proposed rule to add dioxin and 27 so-called "dioxin-like" compounds to the reporting requirements of Section 313 of the Emergency Planning and Community Right-to-Know Act. WLF argued that the proposed rules lacked sound scientific basis and would impose unnecessary and costly burdens on American industry. The rules were adopted in final form at the tail end of the Clinton Administration.

Toxic Release Inventory Program. On February 27, 1997, WLF filed comments with the EPA opposing efforts by that agency to expand the Toxic Release Inventory Program (TRI) on the grounds that the EPA lacked statutory authority to expand TRI, and that the huge costs of such a program would outweigh the negligible benefits. No further action was ever taken by the EPA on the matter.

Changes in BEN Model. On June 18, 1999, in partial response to WLF's efforts, the EPA announced changes in its "BEN model" -- a computer model used by the EPA to assist in computation of civil enforcement fines. When a company is found to have violated environmental laws, EPA policy is to impose a fine that is at least as large as the economic benefit the company derived as a result of its violation. The BEN Model is EPA's attempt to quantify the extent of that benefit. In comments filed on April 1, 1997, WLF criticized the Model for producing wildly inflated "benefit" calculations. WLF also argued that the EPA needs to be less secretive regarding how it undertakes such calculations, and that fines should be based on the amount necessary to deter future noncompliance -- an amount that in some instances may be considerably less than the EPA's calculation of the "benefit" of past noncompliance. The EPA has now agreed to make public both the current BEN Model and EPA's user manual. That last concession was in response to a successful 1997 WLF lawsuit that had forced the EPA to release numerous formerly secret documents that discussed how the BEN model operated.

***Washington Legal Foundation v. EPA* ["*EPA I*"].** In October 1997, the Environmental Protection Agency (EPA), facing possible contempt sanctions, filed a long overdue report to Congress on the Clean Air Act.

On June 30, 1997, WLF won a major courtroom victory when the U.S. District Court entered a judgment requiring the EPA to file a cost/benefit report on the Clean Air Act. The EPA filed its first of many such reports in October 1997. In 1996, WLF filed suit on behalf of itself and ten U.S. Senators and Representatives against the EPA, its Administrator, and two EPA advisory committees for EPA's failure to submit to Congress cost/benefit studies of the Clean Air Act as required by law. The initial cost/benefit report was due to Congress in 1991, with updated reports in 1992 and 1994; but none were filed until after WLF filed suit.

***Washington Legal Foundation v. EPA* ["*EPA II*"].** On January 21, 1998, the U.S. Court of Appeals for the District of Columbia Circuit granted EPA's motion to dismiss WLF's lawsuit seeking review of the EPA's Clean Air Act rules on ozone and particulate matter; the court agreed with the EPA that WLF lacked standing to sue. WLF had filed the lawsuit on September 16, 1997. In filing suit, WLF joined several dozen major industry associations, as well as a number of small business groups, attacking rules that would cost industry billions of dollars without adequate scientific evidence showing that the rules were necessary. WLF challenged the rules as arbitrary and capricious; as a violation of the Small Business Regulatory Enforcement Fairness Act (SBREFA); and as being the product of a biased agency proceeding. The bias charge was based on a 22-page petition WLF filed in early 1997 with the EPA alleging that EPA Administrator Carol Browner had made numerous public statements on the rules before the close of the public comment period, demonstrating that she had already made up her mind to adopt the new standards.

"Cluster Rule" to Strengthen Regulatory Control Over the Pulp and Paper Industry. For four years, WLF fought EPA's plans to adopt this rule before its eventual adoption in 1998. WLF opposed the rule on the grounds that it represented a draconian regulatory standards on the paper and pulp industry concerning pollutants when, by the EPA's own admission, it lacked data regarding the impacts of those standards. The final rule is known as the "cluster rule" because it combines both air and water pollution standards. WLF had urged the EPA to carefully evaluate the rules since they could have severe negative impacts on the American economy.

United States v. Montrose Chemical Corp. of California. On January 16, 1997, the U.S. Court of Appeals for the Ninth Circuit reinstated a lawsuit filed by the federal government against chemical companies for releasing certain chemicals into the environment between 1947 and 1982. The decision was a setback for WLF, which filed a brief urging that the district court's dismissal of the case be upheld. WLF argued that the suit -- brought under CERCLA (the Comprehensive Environmental Response, Compensation and Liability Act) -- was barred by CERCLA's three-year statute of limitations. WLF argued that the statute of limitations began to run in 1986 (four years before suit was filed), when the federal government issued its final rules regarding implementation of CERCLA.

United States v. Olin Corp. On March 25, 1997, the U.S. Court of Appeals for the Eleventh Circuit reinstated a suit filed by the EPA under CERCLA, whereby the EPA was seeking to require a property owner to pay the cost of cleaning up hazardous substances on the property. The decision was a setback for WLF, which filed a brief (on behalf of 17 Members of Congress) urging that the district court's dismissal of the suit be upheld. WLF argued that CERCLA does not impose liability for the release of hazardous substances before the law's enactment in 1980. WLF also argued that the district court was correct that CERCLA exceeds Congress's power under the Commerce Clause as applied in this case, because the substances released at the defendant's property had no effect on commerce or the channels of commerce.

Virginia v. Browner. On January 27, 1997, the U.S. Supreme Court declined to review this case, bringing an end to Virginia's challenge to the EPA's efforts to rewrite Virginia court rules.

The EPA ruled in 1994 that Virginia would lose large amounts of federal funding unless it changed its court rules to make it easier for environmental groups to file state-court challenges to decisions granting permits under the Clean Air Act. WLF filed briefs in support of Virginia in both the appeals court and the Supreme Court, arguing that the Clean Air Act (CAA) does not require states to grant a right of judicial review to anyone who has commented on a CAA permit application, at least when the commentator would not have standing to sue under otherwise-applicable state court rules. WLF also argued that any federal law that attempts to interfere in that manner with state court proceedings is of doubtful constitutionality.

F. False Claims Act

When WLF opposes excessive federal government regulation, it usually can identify a specific federal agency that is the culprit. But that is not true when private citizens invoke the False Claims Act and seek to utilize a provision in that Act which allows them to take on the role of a "private attorney general." 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 attorney generals" 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 November 26, 2003, WLF filed a brief in the U.S. Court of Appeals for the Sixth Circuit, urging the court not to permit individuals litigants to file suits designed to second-guess decisions of the FDA authorizing the sale of drugs or medical devices. 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. WLF argued that federal law prohibits damage suits based on claims that a manufacturer obtained FDA approval for its product by defrauding the FDA. WLF argued that the FDA should be the sole judge of whether it has been defrauded. WLF argued that plaintiffs should not be permitted to evade this preemption rule by (as here) recasting their suits as claims arising under the federal False Claims Act, which permits *qui tam* suits by private individuals who allege that the federal government has been defrauded. WLF achieved a preliminary victory in this case in September 2003 when, in response to a previous brief filed by WLF, the appeals court agreed to review a trial court determination that the case should be allowed to go forward. A final decision is expected in early 2005.

U.S. ex rel. Merena v. SmithKline Beecham Clinical Labs., Inc. On March 4, 2000, WLF scored a victory when the U.S. Court of Appeals for the Third Circuit reversed a district court decision that awarded an unprecedented "bounty" of approximately $52 million to plaintiffs who filed False Claims Act (FCA) lawsuits, even though much of the alleged wrongdoing was already under investigation by the government and had been reported by the media by the time that the suits were filed. The United States intervened in the cases and subsequently reached a settlement with SmithKline for $325 million. The district court ruled that the plaintiffs were entitled to 17% of that amount. The Third Circuit agreed with WLF that the plaintiffs' recovery should be limited to a percentage of those claims that were not public knowledge at the time the plaintiffs filed suit.

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.

G. Federal Communications Commission

The Federal Communications Commission (FCC) regulates, among other things, radio and television broadcasting. WLF has regularly appeared before the FCC, to ensure that the agency respects both First Amendment rights and the privacy rights of individuals. The following items note some of WLF's recent appearances before the FCC.

Restrictions on Alcohol Advertisements. At various times in the past decade, the FCC has considered whether to adopt limits on the advertising of distilled spirits on television. WLF has made repeated filings with the FCC in opposition to such limits. In one recent filing, WLF argued that the Supreme Court's commercial speech decisions have made it absolutely clear that restrictions on truthful commercial speech are rarely, if ever, an effective or appropriate way for the government to achieve its asserted policy goals. Specifically, the Court has held that a restriction or ban on truthful commercial speech about a lawful product is lawful only where the restriction "significantly" advances the government's interest and is "no more extensive than necessary." WLF argued that the government's interest in reducing underage drinking cannot justify an ad ban because there is little or no evidence that an ad ban would have a significant effect on underage drinking.

Barring Broadcast of Telephone Conversations Without Consent. On November 5, 2001, WLF filed comments with the FCC, urging the Commission to rule that a radio station may not broadcast a telephone conversation if the broadcaster knows or has reason to know that at least one party to the conversation has not consented to the broadcast. WLF noted that FCC rules already explicitly prohibit such broadcasts where the telephone conversation was taped by the radio station itself. In response to the FCC's request for comments on the issue, WLF urged the FCC to make clear that its rule also applies where the tape of the telephone conversation is supplied to the broadcaster by a third party. WLF argued that whatever First Amendment interests a radio station may have in broadcasting such conversations, those interests are far outweighed by individuals' privacy interest in not having their personal phone calls broadcast for the whole world to hear.

H. Federal Deposit Insurance Corporation (and other federal banking regulators)

A variety of federal agencies regulate the banking industry in this country. When those agencies devote their attention to ensuring that the American banking system remains safe and fair for consumers, WLF rarely has any objections to these agencies' actions. But WLF has been quick to enter the fray whenever one of these agencies seek to impose regulations that are based on considerations unrelated to the safety of the banking system. In general, WLF has opposed government efforts to protect borrowers from themselves. WLF believes that when banks fully disclose the terms of their loans, consumers ought to be given more credit for being able to understand those terms, and should be free to accept reasonable terms that have been fully explained to them.

Definition of "Small Bank" under Community Reinvestment Act. On October 20, 2004, WLF filed formal comments in general support of the Federal Deposit Insurance Corporation's (FDIC) proposed changes to 12 CFR Part 345 that would increase the asset size limit of banks eligible for the streamlined small-bank Community Reinvestment Act (CRA) examination. FDIC's proposed changes would do three things: 1) change the definition of "small bank" to raise the asset threshold to $1 billion regardless of holding company affiliation; 2) add a community development activity criterion to the streamlined evaluation method for small banks with assets greater than $250 million and up to $1 billion; and 3) expand the definition of "community development" to encompass a broader range of activities in rural areas.

National Bank Preemption. On October 6, 2003, WLF filed comments with the Office of the Comptroller of the Currency (OCC) urging the agency to adopt an amended version of its proposal to increase the nationwide uniformity of legal requirements for OCC-regulated banks. OCC's proposal, issued on August 5, 2003, would clarify the applicability of state law to the activities of national banks. The proposal would preempt any state law that obstructs a national bank's authority to lend or take deposits, making clear that OCC has exclusive power to regulate those activities. WLF argued in its comments that the increased consolidation in the banking industry and the rapid growth of interstate banking – in response to technological improvements, increased mobility of consumers, and state and federal legal reforms – have created a greater need for national rules to govern banking products and operations. For banks operating in numerous states, WLF argued, a patchwork of inconsistent state legal requirements creates inordinate compliance burdens and undue obstacles to the provision of new banking products and services on a national level. WLF urged OCC to amend one provision of the proposal, however, concerning predatory real estate lending. The proposal would prohibit a national bank from making a loan secured by real estate where the loan is "based predominantly on the value of the borrower's collateral, without regard to the borrower's repayment ability." WLF's comments stated that the proposed rule does not take account of proper lending practices under which collateral is typically a crucial element of the decision to grant credit.

Proposal on "Payday Lending." On March 14, 2003, WLF filed comments regarding the FDIC's proposed guidelines for banks that engage in "payday lending" -- small, short-term loans repayable at the borrower's next payday. WLF stated that the guidelines are generally reasonable, given that payday loans are a form of subprime lending and as such involve a fair degree of risk by banks that engage in such loans. Nonetheless, WLF urged the FDIC to revise its guidelines to give formal recognition to payday loans as an appropriate practice that meets a growing and legitimate demand by consumers for short-term credit. WLF argued that by overstating the risks of such loans, the FDIC may drive up their costs, thereby making them less attractive to consumers. The FDIC issued its guidelines in final form in June 2003.

Expanded Guidance for Subprime Lending Programs. On May 7, 2001, WLF submitted comments with the Office of the Comptroller of the Currency, the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision in response to a document entitled, "Expanded Guidance for Subprime Lending Programs." WLF urged these organizations to withdraw the guidance document and to replace it with guidelines that more fully take into account the concerns of consumers, businesses, and the financial services industry. In particular, WLF argued that the guidance mistakenly focused on the distinction between "prime" and "subprime" lending rather than on identifying lending practices rightly characterized as "predatory." WLF also pointed out that increasing capital requirements will hurt consumers by driving capital out of poor communities. WLF further said that the guidance document unfairly requires financial services institutions to choose between violating the law by neglecting to meet the needs of the poor or accepting the burden of higher capital requirements for "subprime" lending.

Proposed Rulemaking Regarding Electronic Banking. On April 3, 2000, WLF filed comments supporting the Office of the Comptroller of the Currency's (OCC) efforts to ensure that regulations governing electronic banking aid and not obstruct the growth of electronic commerce. The OCC ultimately adopted several of the proposed changes in its electronic banking regulations recommended by WLF.

Proposed Rules on Disclosure of Personal Information by Banks. On March 31, 2000, WLF filed comments urging the Office of the Comptroller of the Currency (OCC) to amend its proposed rules governing the disclosure of nonpublic personal information by financial institutions. WLF argued that the OCC's proposed rules ought to be amended in two ways. First, the rules should contain at least two examples of privacy disclosure notices that the OCC regards as acceptably clear. Second, the rules should leave no doubt that letting states erect greater privacy protections for consumers than what federal law affords does not mean that states may infringe on businesses' free speech rights.

Atherton v. FDIC. On January 14, 1997, the U.S. Supreme Court ruled that state law establishes the standard of conduct for officers and directors of federally-insured savings institutions; accordingly, federal bank regulators may not impose liability on bank officials under federal common law. The decision was a victory for WLF, which filed a brief urging the court to rule against regulators' power to establish common-law liability rules for alleged "simple negligence." The Court agreed with WLF's argument that bank officials may not be found liable under federal common law because there is simply no common law to apply.

I. Federal Trade Commission

The Federal Trade Commission oversees numerous aspects of the private sector's business practices, such as advertising and compliance with the antitrust laws. While we often find ourselves in agreement with the FTC's pro-competitive policies, WLF on numerous occasions has gone before the FTC and the courts to protest FTC missteps.

Schering-Plough Corp. v. FTC. On June 9, 2004, WLF filed a brief in the U.S. Court of Appeals for the Eleventh Circuit, urging it to overturn an FTC decision that condemned a patent settlement agreement as an antitrust violation. The agreement settled a contentious dispute involving generic drug companies who wished to manufacture a drug for which Schering-Plough Corp. claimed to have a patent. The FTC held that the settlement unreasonably restrained trade by inducing the generic companies to delay their entry into the market. WLF argued that patents always entail some restraints on commerce, but that those restraints are warranted in light of the large benefits derived from the patent system. WLF argued that parties ought to be encouraged to settle patent disputes, but that by increasing the possibility that settlements will be held to violate antitrust laws, the FTC is unnecessarily discouraging settlements. WLF also filed a brief in the case when it was before the FTC.

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.

Novartis Corp. v. Federal Trade Comm'n. On August 18, 2000, the U.S. Court of Appeals for the D.C. Circuit issued a short and disappointing opinion holding that the FTC validly ordered Novartis Corp., a pharmaceutical company, to include a governmentally-dictated message in its advertising. The court ruled that the FTC had sufficient evidence on which to base its order and that the First Amendment posed no bar to the FTC's so-called corrective advertising order.

WLF had filed a brief urging the D.C. Circuit to set aside the FTC's corrective advertising order. The case arose when the FTC filed a complaint against Novartis, the manufacturer of Doan's Pills, alleging that advertisements for Doan's had been misleading insofar as they suggested that Doan's offers more effective relief for back pain than other pain relievers. A divided FTC ordered 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 appeals court, WLF argued that correcting *possible* misimpressions based on past advertising is not a sufficient First Amendment justification for ordering "corrective" statements in advertising.

Kraft, Inc. v. FTC. 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" cheese constituted false advertising by implying false claims. WLF had filed a brief urging the Court to grant review in order to reverse what WLF believes is the FTC's unnecessarily restrictive view of First Amendment rights to advertise. The advertisements were literally true, but the FTC held that the ads could be prohibited because some consumers might misconstrue the ads as implying other claims not actually made. WLF argued that the First Amendment prohibits the FTC from censoring an advertisement based on claims that some consumers *might* be misled, unless it can show that *some* consumers *actually* were misled.

False Asbestos Claims. On July 7, 2004, WLF petitioned the FTC to investigate attorney-sponsored mass screening programs that improperly generate large numbers of claims for asbestos injury on behalf of claimants who have not been injured. WLF's petition pointed to evidence from judicial proceedings and the news media indicating that asbestos claims have been improperly generated in large numbers in violation of federal law, with the intention and effect of deceiving courts and defrauding defendant businesses.

Product Placement. On March 26, 2004, WLF filed comments with the FTC and the Federal Communications Commission in opposition to a proposed rule on product placement from Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert had petitioned the FTC and the FCC to adopt new regulations that would mandate an on-screen warning for all instances of product placement on television. WLF's comments in opposition to Commercial Alert noted that television product placement dates to the medium's earliest days. WLF also 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. WLF further argued that the proposed regulations would violate First Amendment free speech rights.

Regulation of Contingency Fees. On August 14, 2001, WLF filed a petition urging the FTC to crack down on abuses of the contingency fee system by attorneys. The petition was actually a supplement to one filed with the FTC in 1999; the new petition provided additional details regarding the widespread abuses of contingency fee agreements, and additional reasons why an FTC response to those deceptive practices is appropriate. 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 response to WLF's petition, the FTC in 2002 published a booklet for consumers advising them on how to retain an attorney, and noting that contingency fee rates are negotiable.

Defending Corporate Speech on Food Irradiation. On August 7, 2003, WLF filed comments with the FTC, 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.

Petition of Physicians Committee for Responsible Medicine. On March 13, 2000, WLF filed a brief 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. In its brief, WLF argued that PCRM's petition should be rejected for three reasons. First, the petition improperly invited the FTC to revisit Congress's decision to promote the consumption of milk. Second, PCRM's complaints did not satisfy the legal test for categorizing an advertisement as "false." Third, WLF argued that the FTC lacked authority to second-guess the advertisements because they had been authorized by the U.S. Department of Agriculture. The FTC ultimately dismissed the PCRM's 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 brief, WLF argued that advertisements being run by makers of chips containing Olestra have been 100% accurate. WLF argued that CSPI's hysterical campaign is merely an attempt to scare consumers away from Olestra-containing products. It also noted that health experts (as well as CSPI) have been stressing for years that Americans need to reduce fat consumption, and that substituting Olestra-containing chips for regular snack foods (which invariably are high in saturated fats) is one effective way to improve overall nutrition. The FTC later dismissed the CSPI complaint.

Alcoholic Beverage Advertisements. On October 13, 1998, WLF filed comments with the FTC, urging it to reconsider a pair of proposed consent agreements against two companies regarding the advertising of their products. The FTC claimed that the 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 do 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.

"Green Advertising" Guidelines. On October 11, 1996, the FTC issued its revised guidelines for "green" advertising; that is, marketing claims that extol a company's environmental record. The guidelines were a substantial improvement over a previous FTC proposal, thanks in significant part to WLF's criticisms of the previous version. In its comments to the agency, WLF recommended that the FTC eliminate the following unwarranted requirements: (1) that the manufacturer conduct testing of every product it intends to claim is "recyclable," even when the product is already know to be recyclable; (2) that the labeling and advertisement containing a "recyclable" claim include a disclaimer that the product can be recycled only in areas where appropriate recycling facilities exist -- a point that should be obvious to all consumers; and (3) that a manufacturer may not make truthful "ozone friendly" claims unless the product is also harmless "to the atmosphere as a whole."

J. Fish and Wildlife Service

The U.S. Fish and Wildlife Service (F&WS) is charged with enforcing several federal environmental laws, most prominently the Endangered Species Act (ESA). Certainly, all Americans support Congress's goal in adopting the ESA: to ensure that well-recognized animal species do not become extinct. But in many instances, the F&WS has gone far beyond its congressional mandate by: (1) placing obscure plants and insects on the endangered species list when they are not even generally recognized as a separate species; (2) prohibiting development of private land where a listed species *might* be located, often without evidence that those prohibitions will do anything to protect the species; and (3) refusing to provide compensation to property owners whose property suffers precipitous plunges in value due to F&WS-imposed restrictions on property use. Throughout the past decade, WLF has battled to ensure that F&WS administers the ESA in a reasonable manner.

GDF Realty Investments v. Norton. On September 6, 2004, WLF filed a brief in the U.S. Supreme Court, urging it to review (and ultimately reverse) a decision that would give the F&WS 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. In this case, F&WS 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. The developer even offered to donate portions of the land to a nonprofit conservation group, but was rebuffed by government officials. WLF argued that the F&WS is inappropriately applying the ESA to a matter that has no connection whatsoever to interstate commerce.

Rancho Viejo, LLC v. Norton. On March 2, 2004, the U.S. Supreme Court declined to review an appeals court decision that effectively removes any limits on Congress to regulate development under the Commerce Clause of the Constitution. The decision was a setback for WLF, which had filed a brief urging review. The appeals court upheld the F&WS's application of the Endangered Species Act to a small residential developer that had erected a fence on its property. The F&WS claimed that the fence would interfere with the southwestern arroyo toad, a federally listed endangered 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 ignored Commerce Clause limitations on the federal government's authority to regulate local land use.

Gibbs v. Babbitt. On June 7, 2000, the U.S. Court of Appeals for the Fourth Circuit upheld a regulation promulgated by the F&WS that greatly restricts the rights of property owners to defend themselves and their property against the threat posed by the red wolf, an endangered species. In its brief challenging the regulation, WLF argued that the Endangered Species Act (ESA), as applied in this case, exceeds the power of Congress under the Commerce Clause of the Constitution to regulate interstate commerce. The wolves were released into the North Carolina area by the F&WS and soon found their way onto private property where they attacked livestock, pets, and humans. The federal government claimed that it had Commerce Clause power over the wolves because they cross state lines and a few tourists travel to North Carolina to hear wolf "howling" events. WLF argued that this interstate commerce connection was too tenuous and would allow the federal government to regulate almost all local land use activity.

National Association of Home Builders v. Babbitt. On June 24, 1998, the U.S. Supreme Court declined to review this important Endangered Species Act (ESA) case. The decision was a setback for WLF, which filed a brief urging that review be granted.

In December 1997, the U.S. Court of Appeals for the District of Columbia Circuit ruled that the ESA, as applied by the F&WS to a subspecies of a fly found in only two California counties, is a proper exercise of federal power under the Commerce Clause of the Constitution. In seeking review of that decision, WLF argued that under the Supreme Court's decision in *United States v. Lopez* -- which struck down a federal law banning gun possession near schools as exceeding federal power under the Commerce Clause -- Congress has no authority to regulate local land use activity with regard to the fly. Otherwise, Congress could regulate almost everything, WLF argued.

Bennett v. Spear. On March 18, 1997, the U.S. Supreme Court ruled unanimously that those adversely affected by decisions made by government officials under the ESA have legal standing to challenge those decisions in federal court. The decision was a victory for WLF, which filed a brief urging the Court to reinstate a suit filed by two Oregon ranchers who were challenging an F&WS decision that required that water in Oregon reservoirs not be used for irrigation but rather be maintained at high levels for the benefit of several species of fish. The Court agreed with WLF that *anyone* adversely affected by a decision implementing the ESA has standing to challenge the decision, not merely those interested in greater preservation of species (as the appeals court had held).

Proposed Listings of Plants and Animals as Endangered or Threatened. For more than a decade, WLF has regularly opposed F&WS efforts to add species to the endangered species list when the listing is not warranted by scientific evidence. On more than a few occasions, WLF's objections have caused the listing decision to be reversed. WLF's filings often point out that the species for which the F&WS propose a listing are not generally recognized as separate species at all, but rather is simply a geographically distinct population of an otherwise un-endangered species, and/or that the ESA does not permit a species to be listed as endangered when the threat it faces will at most affect only a small portion of the species' range. Among the many listings to which WLF has objected are: St. Andrew's beach mouse, Preble's meadow jumping mouse, the flat-tailed horned lizard, the yellow larkspur, the bog turtle, the San Diego fairy shrimp, and the black legless lizard.

Proposed Special Rule To Protect the Northern Spotted Owl on Non-Federal Lands. WLF has worked for years to minimize disruptions caused by the F&WS's decision to place the northern spotted owl on the endangered species list. For example, WLF worked with F&WS to promote adoption of a "special rule," applicable to non-federal forest lands in California and Washington -- to replace the blanket prohibitions against the incidental "take" of spotted owls. WLF has also urged the F&WS to reconsider the need to prohibit any timber harvest activities on non-federal lands inhabited by the owls.

Application of Environmental Rules to Combat Training Exercises. On August 2, 2004, WLF filed comments with the F&WS in partial support of a proposed rule that would give the Department of Defense (DoD) authority in some instances to override otherwise applicable provisions of environmental laws. The rule would permit DoD to determine that a proposed or ongoing military activity is permissible despite the likelihood that it would result in a significant adverse effect on the sustainability of a population of a migratory bird species of concern. WLF's comments supported giving DoD authority to make determinations regarding a "significant adverse effect," which is defined as "an effect that could result in a population no longer being maintained at a 'biologically viable level for the long term.'" However, WLF did not support the proposed rules on suspension and withdrawal of DoD's authorizations because they are in conflict with the intent of 2003 congressional legislation, and otherwise infringe on the President's Commander-in-Chief powers.

NPS Implementation of NAGPRA. WLF has also repeatedly appeared before another branch of the Interior Department, the National Parks Service (NPS), when that agency has sought to exercise its regulatory authority in an unauthorized fashion.

For example, the NPS is charged with implementing the Native American Grave Protection and Repatriation Act of 1990 (NAGPRA), a law designed to preserve Indian artifacts. The NPS has been implementing NAGPRA in a manner that unnecessarily interferes with the property rights of museums and imposes unnecessarily harsh penalties on museums that fail to comply with the NPS's interpretation of NAGPRA. WLF has worked actively to relax NAGPRA regulations adopted by the NPS. WLF has been particularly critical of the manner in which the government has applied NAGPRA to the "Kennewick Man" controversy -- a controversy that frustrated scientists' hopes to study the bones of a pre-historic man uncovered in Kennewick, Washington. WLF has also opposed unwarranted NPS regulations that ban snowmobiling in many national parks; in comments filed with the NPS, WLF has argued that such bans prevent thousands of potential visitors from enjoying the parks during the winter months.

Kootenai Tribe of Idaho v. Veneman; State of Idaho v. U.S. Forest Service. The Forest Service is another federal agency that has, on occasion, inappropriately interfered with private property rights. On December 12, 2002, the U.S. Court of Appeals for the Ninth Circuit overturned an injunction enjoining implementation of the Clinton Administration's Roadless Area Conservation Rules. The decision was a setback for WLF, which (on behalf of itself and U.S. Senators Larry E. Craig of Idaho and Mark Dayton of Minnesota) had filed a brief urging the court to uphold the injunction. The rules, adopted in the closing days of the Clinton Administration, 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.

K. Food and Drug Administration

For more than a decade, WLF has been the leading advocate for reform of the Food and Drug Administration (FDA), an agency with regulatory jurisdiction over more than 1/4 of the American economy. Thanks in part to WLF's successful litigation and administrative efforts, FDA has changed considerably: it now recognizes much more than it used to that it is fully subject to First Amendment constraints, that excessive caution in approving new therapies often leads to much greater loss of life than does expeditious approval of those products, and that the successful American pharmaceutical industry is an asset to be treasured, not an enemy to be slain. This lengthy list of WLF accomplishments before the FDA represents only a small fraction of the work WLF has undertaken at FDA on behalf of healthcare patients.

Abigail Alliance for Better Access to Investigational Drugs v. McClellan. For the past year, WLF has been engaged in litigation against FDA on behalf of itself and the Abigail Alliance, a nonprofit group with numerous members who are suffering from terminal illness or who have lost family members to terminal illness. Filed in the U.S. District Court for the District of Columbia on July 28, 2003, the lawsuit challenges FDA restrictions that prevent the terminally ill from obtaining new medicines that have shown safety and efficacy during clinical trials. Under FDA regulations, the vast majority of patients with life-threatening illnesses do not gain entry into clinical trials, and thus do not have access to promising new medications during the years of clinical testing and review required by the FDA. The drugs remain unavailable to patients even though there is evidence of the drugs' safety and efficacy, and even though the patients have no alternative to the drugs other than to wait for their own death. In the lawsuit, WLF and the Abigail Alliance contend that these regulations violate the constitutional rights of terminally ill patients who have no other treatment options. The suit is now before the U.S. Court of Appeals for the District of Columbia Circuit, on the issue of whether such a constitutional right exists.

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.

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. 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 repeated their criticisms of the proposed restrictions at several well-attended ACCME-related forums in 2003 and 2004. The ACCME board of directors approved the rules, with slight revisions, on April 1, 2004, and they took effect in September 2004. WLF is considering what responses to take to this affront to First Amendment values.

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 in the coming year.

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.

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 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. The result of that change is that television advertising of prescription drugs has increased substantially over the past six years, and consumers have received significantly more information about these products.

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.

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.

FDA Proposals to Regulate Food Labeling. WLF has long been in 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.

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.

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.

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 human-tissue 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. 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.

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.

FDA v. Brown & Williamson Tobacco Co. On March 21, 2000, the U.S. Supreme Court struck down the Food and Drug Administration's (FDA) attempts to regulate tobacco as a "drug." The decision was a major victory for WLF, which had filed a brief arguing that Congress never authorized FDA to regulate tobacco. The Supreme Court held that FDA's assertion that tobacco qualified as a "drug" was contrary to clear statutory language. The Court agreed with WLF's argument that federal law authorizes FDA to regulate tobacco products as "drugs" only when the manufacturer claims that the products have a beneficial effect on a person's health. WLF also argued that if federal law were interpreted in the broad manner suggested by FDA, it would be unconstitutional, because it would then amount to an improper, wholesale delegation of power from Congress to FDA to take whatever actions FDA believes would promote public health.

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.

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. FDA is expected to rule in the near future.

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.

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.

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.

Proposed 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 went too far in this regard. FDA proposed 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 was 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.

L. Government Contracting Regulations

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 on many occasions participated in government contracts litigation, as well as regulatory proceedings, to ensure that the rules that develop in this area are fair both to taxpayers and to contractors.

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.

Opposing Proposed Rule To Debar Government Contractors. On November 8, 1999, WLF submitted formal comments opposing proposed Government Service Administration (GSA) rules that would debar government contractors from doing business with the government for minor regulatory infractions. WLF opposed the proposal on numerous grounds. In particular, WLF argued that the proposal would violate the due process rights of contractors and put contracting officials in the unfamiliar role of judging compliance with complex and confusing federal statutes ranging from the Internal Revenue Code to environmental and labor law. WLF also argued that the proposed regulation was anti-competitive and could result in increased costs to the federal taxpayer. The GSA eventually scrapped the proposed rule.

Krygoski Constr. Co. v. United States. On May 12, 1997, the U.S. Supreme Court declined to review a lower court decision that held that the United States may arbitrarily terminate a contract for its convenience without having to compensate the contractor for its damages. The decision was a setback for WLF, which had filed a brief urging the Court to grant review. The case involved a contract to demolish and remove structures at an old government missile facility. When large amounts of asbestos were found at the site (a discovery which would have entitled the contractor to significant price increases to complete the contract), the government opted to terminate the contract. The court of appeals agreed with the federal government that the government has an automatic right to terminate a contract without providing compensation whenever cost overruns exceed 25% of the contract price.

In its brief urging review, WLF argued that in the absence of an explicit contract provision absolving the government from contract damages, the general rule ought to be that the government should pay all damages incurred as a result of its termination of a contract.

M. Justice Department

Politicians from both political parties like to score points by appearing to be "tough" on crime, and they particularly enjoy being perceived as "tough" on corporate wrongdoers. WLF shares prosecutors' desire to bring criminals to justice. However, WLF worries that federal prosecutors, in their desire to create a favorable public image, too often have filed criminal charges in business-related cases that either should have been handled as a civil matter or involved business people totally innocent of any wrongdoing. WLF has regularly provided assistance to business people wrongly caught up in criminal proceedings, and has also worked with the Department of Justice to establish guidelines to prevent the "over-criminalization" of business matters.

Decriminalization of Regulatory Offenses. On June 25, 2001, WLF petitioned the Department of Justice (DOJ) to update a 1983 study 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's petition argued that our current regulatory system is an extensive morass of complicated, confusing, and burdensome statutes, rules, and regulations. This situation is further exacerbated, WLF argued, by the fact that many of these laws, rules, and regulations provide for criminal penalties for companies and employees who violate them, often without requiring proof of intent. WLF argued that U.S. Attorneys have increasingly initiated criminal investigations and prosecutions arbitrarily for minor regulatory offenses when administrative and civil remedies would clearly be more appropriate. WLF noted that criminal prosecutions in such cases against individuals often have exaggerated consequences because the U.S. Sentencing Guidelines result in the imposition of substantial prison sentences for even minor infractions by first-time offenders. WLF called on DOJ to undertake a substantial overhaul of its entire criminal justice system as it applies to enforcement of business regulations.

Environmental Regulatory Offenses. On June 6, 2003, WLF sent a follow-up petition to DOJ, expanding on its June 2001 petition (see above) and focusing on over-criminalization of environmental regulations. WLF attorneys have since had several meetings with senior DOJ officials to discuss their reform proposals.

Principles of Federal Prosecution. On June 28, 2001, WLF petitioned DOJ to publicly recommit itself to adhering to its own *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 guidelines should lead DOJ to eschew prosecution for minor regulatory offenses when administrative or civil remedies would be more appropriate. By doing so, WLF argued, DOJ would encourage voluntary compliance with the law. WLF's petition has been favorably received by DOJ personnel.

Blandford v. United States. On February 25, 2004, the Supreme Court denied review of WLF's petition for review in this important case of over-criminalization of business activities. WLF filed the petition on behalf of its clients; three seafood importers convicted of importing "illegal" seafood and facing sentences of up to *eight years* in prison.

In a case that has ramifications for all regulated businesses, the seafood dealers were convicted under the Lacey Act for importing lobster tails from Honduras because they allegedly violated an obscure Honduran regulation requiring that frozen seafood be shipped in cardboard boxes instead of clear plastic bags, and because about three percent of the shipment consisted of lobster tails that were shorter than allowed under another Honduran regulation. Because the seafood was shipped in clear plastic bags instead of opaque boxes, they were also charged with "smuggling," even though the shipments regularly went through Customs inspections and testing by the FDA. Furthermore, because the seafood importers paid for the seafood they purchased in a normal commercial transaction, they were charged with money laundering. More importantly, the Honduran courts later declared null and void the Honduran regulations that served as the predicate for the charges. DOJ persisted with its prosecution, despite a plea by the Honduran government in the U.S. Supreme Court that the entire federal prosecution was based on a misunderstanding of Honduran law.

Hanousek v. United States. On January 10, 2000, the Supreme Court declined to review this important environmental criminal case. That decision was a setback for WLF, which filed a brief with the Court urging it to review and reverse the criminal conviction and prison sentence of a supervisor for the negligent violation of the Clean Water Act (CWA). The decision sets a dangerous precedent, allowing prosecution for environmental accidents without having to prove criminal intent to violate the CWA. The case raised important issues under the responsible corporate officer doctrine. Justices O'Connor and Thomas dissented from the denial of review.

United States v. Hansen. On June 16, 2002, the U.S. Supreme Court declined to review this important case involving DOJ criminal enforcement of environmental laws. The decision was a setback for WLF, which filed a brief urging the High Court to grant review. WLF also filed a brief before the federal appeals court whose decision WLF sought to have reviewed. On August 24, 2001, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta affirmed the convictions and 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). Several years after the plant shut down, the officers were indicted and convicted of knowing endangerment, even though no employee was ever injured. They were convicted under the "responsible corporate officer" theory of liability and given prison sentences of up to nine years. WLF argued that such convictions and sentences are wholly unwarranted in the absence of evidence that anyone was injured by the regulatory infractions, and because the evidence showed that the defendants shut down the plant once they realized that they were unable to stop continued infractions.

United States v. Ahmad. On November 27, 1996, the U.S. Court of Appeals for the Fifth Circuit reversed the criminal conviction of a small business owner who had been sentenced to 21 months in prison for discharging pollutants in violation of the Clean Water Act (CWA). The decision was a victory for WLF, which filed a brief in support of the business owner. The appeals court agreed with WLF that the trial court erred in holding that the defendant could be convicted even in the absence of evidence that he knew that his conduct violated the CWA. WLF argued that because the CWA's criminal provision is limited to "knowing" violations, a conviction cannot be based merely on proof that the defendant knew what his employees were doing; the Justice Department must also prove that the defendant had reason to know that those actions violated the law.

N. Occupational Safety and Health Administration

The Occupational Safety and Health Administration (OSHA) is the federal agency charged with ensuring the safety of America's workers. As can happen with any large bureaucracy, OSHA on occasion loses sight of the need to avoid imposing cumbersome regulations that accomplish little besides entangling employers in red tape.

WLF has long recognized that employers are just as interested in a safe workplace as are government regulators; employers realize that a safe workplace is a profitable workplace. But employers cannot take effective steps to promote job safety if they are hamstrung by vague and often conflicting government work rules. WLF attorneys have striven for 28 years to ensure that OSHA adopt only clearly written rules and only after demonstrating that the rules directly promote workplace safety.

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-before-used Congressional Review Act to repeal OSHA's 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. On December 7, 2000, WLF filed a lawsuit against OSHA in the U.S. Court of Appeals for the District of Columbia Circuit, 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.

Paid OSHA Ergonomics Consultants. On September 30, 2000, WLF filed a Freedom of Information Act request with OSHA seeking documents relating to OSHA's payments to their expert witnesses to testify in favor of OSHA's ergonomics rule, and OSHA's suspected coaching of their witnesses to tailor their testimony in favor of the rule. WLF's investigation indicated that OSHA, far from being a dispassionate investigator of whether the scientific evidence supported adoption of an ergonomics rule, was acting as a partisan proponent of a proposed rule that drew heavy criticism from a sizeable segment of the scientific community.

Regulation of Home Offices. Thanks to intense pressure from WLF and others, in July 2000, OSHA backed off its previously announced intention to hold employers fully responsible for the safety of "home offices" used by employees who work in their own homes. WLF responded strongly to OSHA's initial announcement, arguing forcefully in submissions to OSHA that it was unrealistic to expect employers to begin inspecting their employees' homes for safety concerns. OSHA responded to the initial criticism by announcing a new standard that exempted home offices from OSHA inspections and stated that businesses should not be held liable for injuries occurring in the home. WLF responded on March 29, 2000, with comments requesting that OSHA extend and formalize those exemptions. OSHA agreed and ultimately amended its guidelines to provide merely that if OSHA receives a complaint about a home office, it *may* informally let employers know of complaints about home office conditions, but will not follow up with the employer or employee. OSHA nonetheless refused to exempt home offices from its injury and illness reporting requirements on the ground that such records "provide important information about the work environment that is useful to employers and employees alike."

Injury and Illness Recording and Reporting Requirements. WLF was a leading proponent of a rule, finally adopted by OSHA in 2001, to streamline some of its injury and illness reporting requirements. Nonetheless, in comments submitted to the agency, WLF questioned OSHA's efforts to expand the scope of some aspects of those requirements. In particular, WLF opposed OSHA's requirement that general contractors in the construction industry maintain records that duplicate records already being maintained by subcontractors. WLF also urged OSHA to define employee injuries and illnesses as "work-related" only if work was a major contributor to them.

Metzler v. Arcadian Corp. On April 28, 1997, the U.S. Court of Appeals for the Fifth Circuit in New Orleans rejected efforts by OSHA to drastically increase fines imposed on employers for alleged violations of workplace safety. The decision was a victory for WLF, which filed a brief in the case in opposition to OSHA. The court agreed with WLF that OSHA should not be permitted to turn a single alleged safety violation into 87 (thereby increasing the potential fine from $70,000 to $4.4 million) by bringing a separate charge for each of the 87 employees that were exposed to a single hazardous condition. The court held that Congress's $70,000-per-violation limitation on fines would be rendered meaningless if OSHA were permitted to manipulate the definition of "violation" to such a great extent, and that it is dangerous to give a federal agency virtually unfettered power to determine fine levels.

Privilege For Self-Critical Health and Safety Audits. On May 8, 1998, OSHA declined to grant WLF's petition for rulemaking that urged the agency to adopt a policy against seeking employers' internal evaluations or audits of workplace conditions. WLF argued in its petition that OSHA policy should reflect that these self-evaluations are indispensable to improving the health and safety of American workers. In WLF's view, OSHA has created a powerful barrier to such initiatives by failing to recognize a privilege of confidentiality for employers' self-critical audits of workplace conditions. The petition also pointed out that OSHA has extensive record-keeping requirements and inspection powers with which to identify violations, without the need to deter self-audits. WLF's proposal was more hospitably received on Capitol Hill: on June 10, 1998, the House Committee on Education and the Workforce approved a bill that addressed this issue.

Eastern Enterprises v. Apfel. On June 25, 1998, the U.S. Supreme Court struck down as unconstitutional a 1992 federal law requiring a coal company to pay millions of dollars in health benefits for employees who last worked for the company 30 years previously. The decision was a victory for WLF, which filed a brief urging that the law be struck down as applied to the plaintiff. WLF argued that the retroactive law violated the plaintiffs' constitutional rights under both the Takings Clause and the Due Process Clause. The company faced liabilities of up to $100 million after Congress, in an effort to ensure health benefits for retired miners who used to work for companies that had since ceased operations, passed a law allocating responsibility for the benefits to other companies. The decision calls into question the constitutionality of other "reach back" laws, such as certain environmental laws, that impose retroactive liability.

O. Postal Service

Congress has decreed that the U.S. Postal Service (USPS), although it continues to be owned by the government, should be run just like a for-profit enterprise -- it should seek to earn a profit by charging competitive rates for providing services to the public. The USPS has responded by branching out to provide numerous services other than its traditional mail-delivery service. WLF applauds that move as a potential boon to consumers. But WLF also believes that once the USPS begins to compete with the private sector, it should be bound by the same rules that its competitors must observe. WLF has worked to ensure that the USPS is not allowed to compete unfairly by gaining exemptions from normal business rules.

USPS v. Flamingo Industries. On February 25, 2004, the U.S. Supreme Court overturned a lower court ruling that federal antitrust laws are applicable to the USPS for all of its commercial activities that are not part of its statutory monopoly for mail delivery. The decision was a setback for WLF, which filed a brief urging that the USPS be subject to the antitrust laws. 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. WLF argued that there is no reason to give the USPS a competitive advantage by exempting it from restraints applicable to everyone in the private sector.

Petition to Regulate Commercial Activities of U.S. Postal Service On January 30, 2003, WLF filed formal comments in support of a petition filed with the Postal Rate Commission (PRC) by Consumer Action and PRC's Office of Consumer Advocate to institute a proceeding to determine (1) whether the Commission has jurisdiction over fourteen specified services offered to the public without a prior request by the Postal Service for a recommended decision under 39 U.S.C. §§ 3621, 3622, and 3623 of the Postal Reorganization Act ("PRA"); and (2) to establish rules that would require a full accounting by the Postal Service of the costs and revenues of non-jurisdictional domestic services so as to ensure that they are not being cross-subsidized by jurisdictional domestic services. Currently, the Postal Service engages in a variety of commercial activities in addition to selling postage, such as offering online payments services, phone cards, and other merchandise and services.

Deceptive Advertising by U.S. Postal Service. On June 24, 2003, WLF filed comments in support of a complaint submitted to the Federal Trade Commission on April 17, 2003 by Council of Citizens Against Government Waste (CCAGW). WLF requested that the FTC initiate an investigation to determine whether the USPS's Priority Mail advertising campaign complied with federal laws governing deceptive advertising. The print and television ads gave the public the false impression that the USPS's Priority Mail service can deliver packages in two days and thus is comparable to services offered by private delivery services. However, the evidence showed that the Priority Mail service is inferior, even in comparison to the less expensive First Class mail service. WLF further argued that the USPS is not exempt from the deceptive advertising laws. On September 26, 2003, the FTC closed its investigation after the USPS agreed to discontinue the ads.

Comments on Report on Postal Service Regulation. On March 13, 2003, WLF filed comments with the White House Commission on the U.S. Postal Service, providing a critique of a study entitled "*Who Has the Advantage? -- Evaluating the Playing Field Facing Parcel Competitors in the United States.*" WLF argued that the report did not fairly compare the differences between the regulatory framework governing the U.S. Postal Service with that governing the private sector.

P. Securities and Exchange Commission

There can be no doubt that the Securities and Exchange Commission's (SEC) regulation of American securities markets has helped to make those markets among the fairest and safest markets in the world. Nonetheless, WLF has not hesitated to step in when the SEC fails to uphold basic constitutional rights of market participants. For example, WLF has worked to protect the First Amendment rights of market participants to speak truthfully about securities-related issues. WLF has also worked to ensure that plaintiffs' lawyers are not permitted to use the court system to duplicate regulations already imposed by the SEC. Finally, through its Investor Protection Project, WLF has sought to make the SEC aware of various means that plaintiffs' lawyers use to manipulate the securities markets, for the purpose of advantaging their clients to the detriment of investors.

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.

Relaxing Restrictions on Speech about Securities. On December 20, 1995, WLF filed a petition for rulemaking with the 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.

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.

Petition Regarding Disclosure of Clinical Trial Results. On December 28, 1995, WLF filed a joint petition for rulemaking with FDA and the SEC, urging those agencies to exempt from 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 and the SEC have 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.

In re: Complaint on Short-Selling and Class Actions. On December 19, 2003, WLF filed a complaint with the 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.

In re: 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.

Hedge Fund Regulation. On April 30, 2003, WLF submitted comments to the SEC 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 its 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. The hedge funds short the stock and reap profits when the suit is filed due to the subsequent 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.

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 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.

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 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 regulation-related topics. Recent media briefings (dubbed media "noshes") on such issues have included the following:

Courts, Commerce & Regulation: How The Judiciary Can Help (And Hinder) Free Enterprise in America, June 22, 2004

- **The Honorable Randall T. Shepard**, Supreme Court of Indiana
- **Lawrence H. Mirel**, District of Columbia Department of Insurance, Banking & Securities
- **Peter A. Bisbecos**, National Association of Mutual Insurance Companies

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

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

Antitrust on the World Stage: Microsoft, Mario Monti, and Future of Harmonizing Competition Policy, April 28, 2004

- **Charles F. (Rick) Rule**, Fried, Frank, Harris, Shriver & Jacobson
- **William J. Kolasky**, Wilmer Cutler Pickering LLP
- **Albert A. Foer**, American Antitrust Institute

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

"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

New Source Review: How Will New Rules and Lawsuits Impact Energy and the Environment?, November 12, 2003

- **Robert M. Sussman**, Latham & Watkins
- **Eric V. Schaeffer**, Director, Environmental Integrity Project
- **William Wehrum**, Environmental Protection Agency
- **Steve Lomax**, Edison Electric Institute

EU Regulatory Policy: Barriers To U.S. – European Trade and Opportunities for Cooperation, October 30, 2003

- **The Honorable Stuart E. Eizenstat**, Covington & Burling
- **Jane C. Luxton**, King & Spalding
- **Hal S. Shapiro**, Miller & Chevalier

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

An Optional Federal Charter: The Future of Insurance Regulation?, May 29, 2003

- **Wayne F. White, CPA**, Home Mutual Fire Insurance Co.
- **Chairman Mike Pickens**, Arkansas Insurance Department
- **Bradford W. Rich**, USAA
- **Craig A. Berrington**, American Insurance Association

Health Care and Antitrust Law: The Latest Developments and a Forecast for 2003, November 20, 2002

- **James F. Rill**, Howrey Simon Arnold & White LLP
- **Willard K. Tom**, Morgan, Lewis & Bockius LLP
- **Daniel L. Wellington**, Fulbright & Jaworski L.L.P.

Copyrights in a Digital Age: Government or Market Solutions "Piracy" of Entertainment Content?, October 21, 2002

- **Professor Richard A. Epstein**, University of Chicago Law School
- **Mitch Glazier**, Recording Industry Association of America
- **Chris Jay Hoofnagle**, Electronic Privacy Information Center

Implementing Sarbanes-Oxley: What Lies Ahead for SEC and DOJ?, September 5, 2002

- **Ira Lee Sorkin**, Carter, Ledyard & Milburn
- **Eugene I. Goldman**, McDermott, Will & Emery
- **Linda L. Griggs**, Morgan, Lewis & Bockius LLP

Agencies' Use of "Sound" Science: A New Front Opens on the Federal Regulatory Battlefield, June 4, 2002

- **Paul Noe**, Office of Management and Budget
- **Alan Charles Raul**, Sidley Austin Brown & Wood LLP
- **Rena I. Steinzor**, Natural Resources Defense Council and University of Maryland Law School

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

Priorities for the New FDA Commissioner, October 3, 2001

- **Alan Slobodin**, House Energy and Commerce Committee
- **John W. Bode**, Olsson, Frank & Weeda
- **Larry R. Pilot**, McKenna Long & Aldridge

Government Sponsored Enterprises: Is a More Rigorous Regulator Needed for Fannie Mae and Freddie Mac?, June 13,2001

- **John Taylor**, National Community Reinvestment Coalition
- **Deborah Lucas**, Congressional Budget Office
- **James C. Miller III**, Law & Economics Consulting Group
- **Bert Ely**, Ely & Co.

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

- **Willard K. Tom**, Morgan, Lewis & Bockius
- **Robert Goldbergh, Ph.D.**, National Center for Policy Analysis
- **Frank M. Rapoport**, McKenna Long & Aldridge
- **Michie I. Hunt, Ph.D.**, Michie I. Hunt & Associates

HHS's Medical Privacy Rule: What Impact Will it Have on Patients and Quality of Care?, April 18, 2001

- **Mary R. Grealy**, Healthcare Leadership Council
- **Chris Hoofnagle**, Electronic Privacy Information Center
- **Donald W. Moran**, The Moran Company

Copyrights in Cyberspace: Are Intellectual Property Rights Obsolete in the Digital Economy?, March 28, 2001

- **The Honorable Dick Thornburgh**, Kirkpatrick & Lockhart LLP (moderator)
- **The Honorable Edward J. Damich**, U.S. Court of Federal Claims
- **Manus Cooney**, Napster, Inc.
- **Charles J. Cooper**, Cooper & Kirk
- **David M. Young**, Hunton & Williams

The FCC and Communications Policy: What Does the Future Hold in a New Era of Deregulation?, March 21, 2001

- **Richard E. Wiley**, Wiley, Rein & Fielding (moderator)
- **Nicholas Allard**, Latham & Watkins
- **Charles H. Kennedy**, Morrison & Foerster
- **David R. Poe**, LeBoeuf Lamb Greene & MacRae

Regulating Online Software Transactions: Should the States Adopt UCITA?, January 24, 2001

- **Scott C. Oostdyk**, McGuire Woods (Moderator)
- **Carlyle C. Ring**, Ober, Kaler, Grimes & Shriver
- **Professor Charles Shafer**, University of Baltimore School of Law
- **Jonathan Band**, Morrison & Foerster
- **Douglas Koelemay**, Northern Virginia Technology Counsel

Universal Service Fees: Who Pays to Close the "Digital Divide?", February 15, 2000

- **The Honorable Harold Furchtgott-Roth**, Federal Communications Commission (moderator)
- **Stanley M. Gorinson**, Preston Gates Ellis & Rouvelas Meeds, LLP
- **Mark Cooper**, Consumer Federation of America

***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

Is Rhetoric or Reality Driving the Debate Over Federal "Climate Change" Policy?, April 24, 2000

- **Fredrick D. Palmer**, Western Fuels Association
- **Professor William H. Lash, III**, George Mason University School of Law

Does FCC's "Public Interest Mandate" Inhibit Our Freedom to Communicate?, May 2, 2000

- **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

Consumer Privacy on the Internet: Government Controls or Self-Regulation?, July 18, 2000

- **Marc Rotenberg**, Electronic Privacy Information Center
- **Mark E. Plotkin**, Covington & Burling
- **James Halpert**, Piper Rudnick

Open Access to Broadband Cable: Will Government or the Free Market Lead the Way to High-Speed Internet?, October 17, 2000

- **The Honorable Harold Furchtgott-Roth**, Federal Communications Commission (moderator)
- **John Frantz**, Verizon Communications
- **David A. Irwin**, Irwin, Campbell & Tannenwald
- **Daniel Brenner**, National Cable Television Association

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.

B. Advocacy Ads

In 1998, Washington Legal Foundation began running a series of opinion editorials, called "In All Fairness," on the op-ed page of the national edition of ***The New York Times***. The op-ed has appeared over 100 times, reaching over five million readers in 70 major markets as well as 90 percent of major newspaper editors. The need for government regulatory reform has been the focus of a number of "In All Fairness" columns:

Bureaucrats Practicing Medicine, April 26, 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
(WLF suit against HHS and FDA challenges policy that prevents cancer patients from having access to life-saving drug therapies)

Anti-Consumer Protection, July 29, 2003
(Lawsuits by so-called "consumer" activists against companies which make or market disfavored products reduces consumer choice and imposes a litigation tax on products)

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)

Unfriendly Skies for Consumers?, March 11, 2003
(Department of Transportation's revision of Computer Reservation Systems regulations for purchasing airline tickets are harmful to consumers)

Stealing Consumer Choice, February 24, 2003
(Regulatory efforts to eliminate short-term lending practices for consumers is paternalistic and limits consumer choices)

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

Eating Away at Our Freedoms, April 15, 2002
(Attacks by consumer activists against certain food products harm consumer choice and result in costly regulations and taxes)

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

Targeting American Prosperity, July 9, 2001
(Activists are handicapping the U.S. economy and energy production with excessive environmental restrictions)

WARNING: Please Don't Eat the Dirt!, May 21, 2001
(Environmental hazards can be overblown and lead to absurd legal requirements, such as EPA regulations that forced a company to spend millions so that dirt at a Superfund site would be clean enough for children to eat small amounts for 245 days a year)

Who Turned Out the Lights?, March 19, 2001
(Blame for the California energy crisis should be laid at the feet of environmental extremists and their allies in government, who have made it virtually impossible to develop the energy resources needed by millions of residents now suffering from rolling blackouts)

regulatoryoverkill@osha.gov, January 22, 2001
(OSHA's ergonomics rule, which governs matters as picayune as the height of your desk, should be scrapped; because OSHA failed to show that ergonomic injuries necessarily result from workplace hazards, making businesses pay for such injuries would be unfair)

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)

Who Elected the EPA?, October 2, 2000
(The EPA should not be allowed to use its power to reduce air pollution as an excuse to impose massively burdensome regulations regardless of their cost; unless it is stopped, the EPA will continue to usurp power that rightly belongs to our elected representatives)

Leaving Patients Behind, September 11, 2000
(Maine's law imposing price controls on prescription drugs will ultimately hurt the very patients it was intended to help, because the law ignores the connection between free enterprise and technological innovation)

EPA Needs a Cleanup, July 17, 2000
(EPA has revealed its anti-business bias by withholding or falsifying evidence in its attacks on legitimate companies, while turning a blind eye to the serious health risks caused by government polluters)

Bad Medicine for Consumers, June 12, 2000
(Price controls should not be placed on drugs because the free market, not a new bureaucracy, is most suited to determining how much drugs ought to cost and because price controls stifle innovation)

Gagging Free Enterprise, March 20, 2000
(Courts and regulators should demonstrate more sensitivity for the constitutional implications of restricting businesses' speech)

21st Century Luddites, January 24, 2000
(Environmental activists are wrong to attack genetically modified foods when biotechnology holds the potential for eliminating world hunger)

Rule of Law, Not Lawyers, December 6, 1999
(Regulation by litigation instead of by elected lawmakers subverts the Rule of Law by placing decisionmaking in the hands of activist lawyers and judges)

Geppetto's Apprentices, November 26, 1999
(Activists and EPA use junk science to scare public about alleged danger of dioxin and other chemicals)

When Radicals Regulate, November 22, 1999
(EPA's efforts to hold everyone within a geographical area of a stream or river responsible for water pollution is unfair and exceeds EPA's regulatory authority)

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)

The World Turned Upside Down, August 16, 1999
(Plaintiffs' lawyers and activists have turned judicial and regulatory decisionmaking upside down where logic and the rule of law are sacrificed for special interest agendas)

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

Can't We All Just Get Along, May 10, 1999
(Activist environmental groups are trying to deny access to national parks and wilderness areas by campers, fishermen, and vacationers)

Better Living Through Activism?, April 12, 1999
(Activists, regulators, and plaintiffs' lawyers ultimately harm consumers and the economy through excessive regulation and litigation)

Can the Public Trust Government Science?, October 19, 1998
(Government agencies should not use "junk science" to justify regulating products, businesses, and the environment)

Environmental Injustice, August 24, 1998
(The latest attack on free enterprise by activists claims racial discrimination against businesses for locating their facilities in low-income or minority neighborhoods)

WARNING: Excessive Activism May Be Hazardous, July 6, 1998
(Prop 65 lawsuits seeking money awards against companies that fail to disclose chemicals in their products are more about greed than consumer protection)

When Government Plays Monopoly, May 25, 1998
(U.S. Postal Service unfairly uses its monopoly power against private businesses)

Taking Environmentalism to the Extreme, March 30, 1998
(Frivolous lawsuits by activists and bureaucrats thwart responsible economic development)

These and other "In All Fairness" columns can be accessed from WLF's comprehensive Web site, www.wlf.org.

C. Public Appearances

WLF attorneys have appeared as featured panelists and speakers on regulatory reform issues before such groups 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 the Medical Device Manufacturers Association. What follows are highlights of the numerous public appearances that WLF attorneys have made in the past nine years, to address regulatory reform issues:

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, WLF Chief Counsel Richard 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.

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 24, 2003, WLF Chairman and General Counsel Daniel J. 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.

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.

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, WLF Senior Executive Counsel Paul 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.

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."

October 2, 2002, Popeo was the featured speaker at the Community Financial Services Association's Banking Committee meeting in Washington, D.C.

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."

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 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 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.

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

May 23, 2000, WLF Legal Studies Division Chief Counsel Glenn Lammi was interviewed on Russia's State TV regarding the Justice Department's antitrust suit against Microsoft.

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."

March 21, 2000, Samp was interviewed on CNN regarding *FDA v. Brown & Williamson,* in which the Supreme Court determined that the Food and Drug Administration acted improperly in asserting jurisdiction over tobacco products.

November 29, 1999, Samp was a guest on C-SPAN's "Washington Watch," along with former U.S. Solicitor General Walter Dellinger, to discuss *FDA v. Brown & Williamson*, in which the Supreme Court decided that FDA lacked statutory authority to regulate tobacco products. Samp was interviewed on Fox News on September 29 on the same topic.

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, 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, 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?"

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-to-consumer 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 regulation topics. WLF's publications in this area include the following:

A. AGRICULTURE/BIOTECHNOLOGY REGULATION

Engineering Legal Risk Management Into Agricultural Biotechnology
By **Thomas P. Redick**, a member of the law firm Gallop, Johnson & Neuman, L.C. in St. Louis.
LEGAL BACKGROUNDER, January 16, 2004, 4 pages

New EU Rules On "GMO" Food And Feed : Details And Analysis
By **Mark Mansour**, a partner with the law firm of Morgan Lewis, LLP and **Sara Key**, an associate with the firm.
CONTEMPORARY LEGAL NOTE, April 2004, 22 pages

Excessive "Precaution" Threatens Food Consumers And Foreign Trade
By **Mark Mansour**, a partner in the Washington D.C. law firm Keller and Heckman L.L.P.
LEGAL BACKGROUNDER, October 19, 2001, 4 pages

Agriculture Biotechnology: Will Regulatory "Precaution" Expand Liability Risks?
By **Thomas P. Redick**, an attorney with the St. Louis law firm Gallop, Johnson & Neuman, L.C., specializing in product liability prevention for technology clients. Foreword by **Representative Nick Smith**, Chairman of the U.S. House of Representatives Subcommittee on Basic Research.
MONOGRAPH, January 2001, 50 pages

Why Safe And Effective Food Biotechnology Is In The Public Interest
By **Dr. Martina McGloughlin**, Director of the Biotechnology Program at UC Davis and Director of the UC Systemwide Life Sciences Informatics Program.
WORKING PAPER, December 2000, 27 pages

Regulation Of Biotech Foods: Obstacles And Opportunities
By **Mark Mansour** and **Jennifer B. Bennett**, who is an associate, in the Washington D.C. law firm Keller and Heckman L.L.P.
LEGAL BACKGROUNDER, July 14, 2000, 4 pages

"Precautionary Principle" Stalls Advances In Food Technology
By **Henry I. Miller**, a Senior Research Fellow at Stanford University's Hoover Institution, and **Gregory Conko**, Director of Food Safety Policy at the Competitive Enterprise Institute.
LEGAL BACKGROUNDER, May 26, 2000, 4 pages

Science And Reason Must Guide Decisions On Biotech Food
By **U.S. Senator Kit Bond**, who has served the state of Missouri in the United States Senate since 1987.
LEGAL BACKGROUNDER, May 26, 2000, 4 pages

Mandated Biotech Food Labeling Ineffective And Legally Suspect
By **John W. Bode**, a principal in the Washington, D.C. law firm Olsson, Frank & Weeda, which specializes in food and drug law.
LEGAL OPINION LETTER, March 3, 2000, 2 pages

Informed Debate Can Break Down Barriers To Biotechnology
By **Daniel L. Spiegel**, a senior partner in the Washington D.C. office of Akin, Gump, Strauss, Hauer & Feld, L.L.P., and **Laura M. Reifschneider**, counsel in the firm's Brussels office.
LEGAL BACKGROUNDER, January 7, 2000, 4 pages

B. ANTITRUST AND COMPETITION POLICY

U.S. And European Merger Policies Move Towards Convergence
By **Stanley M. Gorinson**, a partner in the Washington, DC, office of the law firm Kilpatrick Stockton LLP, where he chairs the firm's antitrust practice, and **Robert Pambianco**, Esq.
LEGAL BACKGROUNDER, August 9, 2002, 4 pages

"Mission Creep" At FTC?: Use Of Disgorgement Remedy Signals Desire To Prosecute
By **Pamela J. Auerbach** and **Alex Dimitrief**, partners in the Washington, D.C. and Chicago offices, respectively, of the law firm Kirkland & Ellis.
LEGAL BACKGROUNDER, April 5, 2002, 4 pages

Appraising DOJ's New Initiative For Pre-Merger Review
By **Joe Sims**, a partner in the Washington, D.C. office of the law firm Jones Day Reavis & Pogue.
LEGAL BACKGROUNDER, February 8, 2002, 4 pages

FTC Improperly Injects Itself Into Drug Patent Settlements
By **Geraldine M. Alexis** and **Zorah Braithwaite**, a partner and an associate, respectively, with the law firm Bingham McCutchen in its San Francisco office.
LEGAL BACKGROUNDER, November 2, 2001, 4 pages

AOL/Time Warner Case Signals Need To Update Merger Guidelines
By **Joseph Kattan**, a partner in the Washington office of the law firm Gibson, Dunn & Crutcher.
LEGAL BACKGROUNDER, June 1, 2001, 4 pages

Online "Business-to-Business" Enterprises Raise Antitrust Issues
By **Richard E. Donovan**, a partner and chair of the Antitrust & Trade Regulation Practice Group with the law firm Kelley Drye & Warren LLP in New York City.
LEGAL OPINION LETTER, August 11, 2000, 2 pages

Assessing Antitrust Guidelines For Competitor Collaborations
By **Peter C. Ward**, a Shareholder specializing in antitrust and trade regulation matters in the Nashville office of the law firm Baker, Donelson, Bearman & Caldwell.
LEGAL BACKGROUNDER, March 17, 2000, 4 pages

FTC Quietly Advances Regulatory Agenda In Alcohol Advertising Report
By **Glenn G. Lammi**, Chief Counsel to WLF's Legal Studies Division.
COUNSEL'S ADVISORY, October 15, 1999, 1 page

FTC Treads On Free Speech Rights With Corrective Advertising Order
By **Barry J. Cutler**, a partner in the Washington, D.C. office of the law firm Baker & Hostetler.
LEGAL BACKGROUNDER, July 23, 1999, 4 pages

FTC's Quest For Money Damages: An Unauthorized Power Grab
By **Michael S. Kelly**, a partner in the Washington, D.C. office of the law firm Morgan Lewis LLP, and **Bilal Sayyed**, an attorney-advisory to Federal Trade Commission Chairman Timothy Muris.
LEGAL BACKGROUNDER, June 11, 1999, 4 pages

Market Concentration As An Antitrust Standard: Does It Make Sense?
By **Stanley M. Gorinson**, a partner in the Washington, D.C. office of the law firm Kilpatrick Stockton, and **William H. Davenport**, an attorney with the Enforcement Division of the Federal Communications Commission.
LEGAL BACKGROUNDER, February 19, 1999, 4 pages

FTC's Expansion Of "Unfairness" Jurisdiction Imperils Speech Rights
By **D. John Hendrickson**, a partner in the Los Angeles office of the law firm Katten Muchin & Zavis.
LEGAL BACKGROUNDER, January 22, 1999, 4 pages

Surviving Antitrust Agencies' Scrutiny During "Merger Mania"
By **Kevin J. Arquit**, a partner with the law firm Simpson, Thatcher & Bartett, and **Steven A. Newborn**, a partnes with the law firm Weil, Gotshal & Manges.
LEGAL BACKGROUNDER, June 5, 1998, 4 pages

New Law Expands Paperwork Burden And Liability Threat For Employers
By **Mark R. Hornak**, a partner with the Pittsburgh law firm Buchanan Ingersoll.
LEGAL BACKGROUNDER, February 6, 1998, 4 pages

Does Office "Superstore" Merger Rejection Begin "A New Wave Of FTC Activism"?
By **Greg Kinzelman**, an attorney with the Washington, D.C. office of the law firm Hunton & Williams.
LEGAL BACKGROUNDER, August 22, 1997, 4 pages

FTC Should Continue Careful Approach On "Unfair" Alcohol Advertising Charges
By **Deborah Owen**, General Counsel of Armstrong World Industries and a former Commissioner of the Federal Trade Commission.
LEGAL BACKGROUNDER, February 21, 1997, 4 pages

The FTC's Global Competition Report: Will It Alter Scrutiny Of Mergers?
By **Joseph Kattan**, a partner with the Washington, D.C. office of the law firm Gibson, Dunn & Crutcher.
LEGAL BACKGROUNDER, September 20, 1996, 4 pages

When Intellectual Property And Antitrust Law Collide: FTC Must Tread Lightly
By **Robert A. Skitol**, a partner with the Washington, D.C. office of Drinker Biddle & Reath.
WORKING PAPER, September 1996, 26 pages

Will New Guidelines Clarify Role Of Antitrust Law In Health Care?
By **Bruce R. Stewart** and **E. John Steren**, shareholders in the Washington, D.C. office of Ober, Kaler, Grimes & Shriver.
LEGAL BACKGROUNDER, June 21, 1996, 4 pages

C. BANKING AND FINANCIAL SERVICES

Regulation And Self-Policing Will Influence Consumers' Access To "Payday Loans"
By **Charles M. Horn**, a partner in the Washington, D.C. office of the law firm of Mayer, Brown, Rowe & Maw LLP.
LEGAL BACKGROUNDER, November 14, 2003, 4 pages

Proposal On "Predatory" Lending: One Step Forward, One Step Back?
By **James M. Rockett**, a partner and co-head of the Financial Institutions Corporate and Regulatory practice of Bingham McCutchen LLP, San Francisco.
LEGAL OPINION LETTER, September 19, 2003, 2 pages

Regulation And Self-Policing Will Influence Consumers' Access To "Payday Loans"
By **Charles M. Horn**, a partner in the Washington, D.C. office of the law firm of Mayer, Brown, Rowe & Maw LLP.
LEGAL BACKGROUNDER, November 14, 2003, 4 pages

Defiant Freddie And Fannie: Sketchy Financial Disclosure Harms Investors And Taxpayers
By **Bert Ely**, a financial institutions and monetary policy consultant and the principal in Ely & Company, Inc., Alexandria, Virginia.
LEGAL OPINION LETTER, October 4, 2002, 2 pages

In Defense Of Moderation: Avoiding Overregulation Of "Special Purpose Entities"
By **Charles M. Horn**, a partner in the Washington, D.C. office of the law firm Mayer, Brown, Rowe & Maw.
LEGAL BACKGROUNDER, September 20, 2002, 4 pages

Federal Court Holds Bank Regulators Accountable For Breaching Contracts
By the late **Warren L. Dennis**, a senior litigation partner, and **Amybeth García-Bokor**, a senior litigation associate, in the Washington, D.C. office of Proskauer Rose LLP.
LEGAL BACKGROUNDER, July 13, 2001, 4 pages

Fed Proposal To Identify Loan Applicants' Race Misguided
By **James M. Rockett**, a partner with the San Francisco law firm Bingham McCutchen.
LEGAL OPINION LETTER, March 31, 2000, 2 pages

Do Community Lending Advocates Wield Too Much Influence Over Bank Regulation?
By **Albert V. De Leon**, a Vice President and General Counsel for Compliance with Skadinaviska Enskilda Banken.
LEGAL BACKGROUNDER, October 18, 1996, 4 pages

Settlements Display DOJ Activism On Fair Lending Enforcement
By the late **Warren L. Dennis**, a partner, and **Christine D. Bachman**, an associate, in the Washington, D.C. office of the law firm Proskauer Rose Goetz & Mendelsohn.
LEGAL OPINION LETTER, March 29, 1996, 2 pages

Government's New Activism In Equal Credit Enforcement Threatens Consumer Lending
By the late **Warren L. Dennis**, a partner, and **Christine D. Bachman**, an associate, in the Washington, D.C. office of the law firm Proskauer Rose Goetz & Mendelsohn.
WORKING PAPER, July 1995, 32 pages

Fair Lending Enforcement: How The Government Micromanages Banking
By **David J. McPherson**, a partner with the Washington, D.C. office of the law firm Morgan Lewis LLP. Features a foreword by **Bernard H. Clineburg**, President and CEO of George Mason Bank.
MONOGRAPH, June 1995, 60 pages

D. COMMUNICATIONS AND INFORMATION TECHNOLOGY LAW

Understanding and Complying With The "CAN-SPAM" Act
By **Kristen J. Mathews**, an associate in the New York office of the law firm Brown Raysman Millstein Felder & Steiner LLP.
CONTEMPORARY LEGAL NOTE, September 2004, 45 pages

"Digital Rights Management" Best Left To Private Contract
By **Professor Richard A. Epstein**, James Parker Hall Distinguished Service Professor of Law, The University of Chicago, and Peter and Kirsten Bedford Senior Fellow at The Hoover Institution.
LEGAL BACKGROUNDER, November 15, 2002, 4 pages

Anti-Terror Law Will Impact Telecom And Internet Providers
By **Theresa M.B. Van Vliet**, a partner in the Ft. Lauderdale office of the law firm Ruden McClosky Smith Schuster & Russell, PA.
COUNSEL'S ADVISORY, November 16, 2001, 1 page

Landmark Speech Ruling Curtails FCC Cable Regulation
By **Jeffrey P. Cunard**, a partner, and **Rebecca Tushnet**, an associate, in the Washington, D.C. office of Debevoise & Plimpton.
LEGAL BACKGROUNDER, June 15, 2001, 4 pages

FCC's Agenda Should Place Priority On Broad Reform
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By **U.S. Senator George Allen**, former Governor of Virginia and a partner with the Richmond law firm of McGuire, Woods, Battle & Boothe LLP, and **Scott C. Oostdyk**, a partner in the commercial litigation section of the law firm McGuire, Woods in its Pittsburgh office.
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Should The FTC Regulate Privacy On The Internet?
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Comment On Proposed Incentives For Private Species Protection Plans
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Of Mice And Men . . . Surviving Endangered Species Litigation
By **David T. Hardy**, a former Department of Interior lead legal advisor to the Fish & Wildlife Service and currently an Attorney At Law in Tucson, Arizona. Foreword by **Congressman Charles W. Stenholm** (D-TX). Introduction
by **Kirk Fordice**, former governor of the State of Mississippi.
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Federal Regulation Of States' Drinking Water Unconstitutional
By **The Honorable Don Stenberg**, Attorney General of Nebraska since January, 1991.
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By **Robert E. Roberts**, Administrator of the Environmental Protection Agency's Region 8 in Denver, and formerly the Executive Director of the Environmental Council of the States.
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By **Craig E. R. Jakubowics**, Director of Environmental Legal Affairs for Edison Electric Institute in Washington, D.C.
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By **William H. Lash, III**, Assistant Secretary for Market Access and Compliance at the U.S. Department of Commerce and formerly a professor at George Mason School of Law.
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By **Russell J. Harding**, Director of the Michigan Department of Environmental Quality, and **G. Tracy Mehan, III**, Assistant Administrator for the Environmental Protection Agency's Office for Water Programs
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By **Congressman Joe Knollenberg**, a Junior Member from Michigan's 11th District who serves on the House of Representatives VA-HUD Subcommittee on Appropriations.
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Six Shortcomings Create Imperfect Environment For EPA's Mission
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By **Russell J. Harding**, Director of the State of Michigan's Department of Environmental Quality.
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By **E. Bruce Harrison** of Ruder Finn in New York, and **Joseph G. Wojtecki**, former Vice President, of E. Bruce Harrison Company.
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By **James H. Burnley, IV**, and **Warren E. Hoemann**, an attorney serving as Vice President, Government Relations, Yellow Corp. and Chairman, California Trucking Association FIP Task Force.
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By **Frank B. Cross**, an associate professor of business regulation at the University of Texas.
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Clinton Administration Should Not Punish Business With International Treaty's Junk Science-Based Air Quality Demands
By **Edward C. Krug, Ph.D.**, the Director of Environmental Projects for the Committee for a Constructive Tomorrow and an internationally respected and published soil and environmental scientist.
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Wetlands Decision Argues Federal Courts Should Review Regulatory Actions That Legislate Crimes
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The Federal Government Flunks Test For Regulating Wetlands On Oregon School District Property
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More Absurdity From Washington: EPA's "Scarlet Letter" Ozone Warning
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By **William T. Huston**, Chairman of both the Los Angeles Community Air Quality Task Force and Watson Land Company.
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A Guide To Understanding The Clean Air Act
By **Dr. Stanley A. Millan**, a corporate attorney and professor at Loyola University School of Law.
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EPA Right-To-Know Law Is Constitutionally Suspect
By **Paul D. Kamenar**, Washington Legal Foundation's Senior Executive Counsel.
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New Wetlands Regulation Further Dampens Economy
By **W. Lawrence Wallace**, formerly a partner in the McLean, Virginia office of the law firm Hazel & Thomas.
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Playing By the Rules: Surviving Tougher Civil And Criminal Enforcement Of The Clean Air Act Amendments
By **Scott M. DuBoff**, a partner with the Washington, D.C law firm Wright & Talisman, P.C., and **Andreas Leskovsek**, an attorney with the Washington, D.C. office of Winston & Strawn.
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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.
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By **James Dabney Miller,** a partner with the law firm King & Spalding LLP.
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By **Richard A. Samp,** Chief Counsel to the Washington Legal Foundation.
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By **Kathleen M. Sanzo** and **Stephen Paul Mahinka**, partners in the Washington, D.C. office of the law firm of Morgan Lewis, LLP.
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FDA Limits On Dual Trademarks Tread On Patient Safety And Law
By **Marc J. Scheineson,** a partner in the law firm of Alston & Bird, LLP in Washington, D.C. where he heads the firm's food and drug practice.
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By **James Dabney Miller**, a partner with the law firm King & Spalding LLP in its Washington, D.C. office.
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By **Marc J. Scheineson**, a partner in the law firm of Alston & Bird, LLP and **Robert J. Kaufman**, then a third year law student at Harvard Law School.
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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.
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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.
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By **David M. Hoffmeister**, a partner with the law firm Wilson Sonsini Goodrich & Rosati, and **Wayne L. Pines**, a consultant and President of Regulatory Services and Healthcare at APCO Worldwide.
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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.
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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.
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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.
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By **Alan Slobodin**, Senior Oversight Counsel at the House Energy and Commerce Committee.
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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.
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By **Drew L. Kershen**, the Earl Sneed Centennial Professor of Law at the University of Oklahoma College of Law.
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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.
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Activists Use Mad Cow Scare To Advance Ideological Agendas
By **David Martosko**, Director of Research for The Guest Choice Network.
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By **Richard A. Samp**, Chief Counsel to the Washington Legal Foundation.
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By **George M. Burditt**, a partner with the Chicago law firm Bell, Boyd & Lloyd.
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By **Mark Boulding**, General Counsel and Vice President, Regulatory Affairs for Medscape Inc.
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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.
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By **The Honorable Robert H. Bork**, who served as Circuit Judge, United States Court of Appeals for the District of Columbia Circuit, from 1982 to 1988, and as Solicitor General of the United States, Department of Justice, from 1973 to 1977.
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By **Neil Kahanovitz, M.D.**, a practicing orthopedic surgeon and founder and President of Center for Patient Advocacy.
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By **William C. MacLeod**, a partner with the Washington, D.C. law firm of Collier Shannon Scott.
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By **Jeffrey N. Gibbs**, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
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By **Alan H. Magazine**, former President of the Health Industry Manufacturers Association.
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By **James M. Johnstone**, a Washington, D.C. lawyer.
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By **Richard A. Samp**, Washington Legal Foundation Chief Counsel.
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By **Glenn G. Lammi**, Chief Counsel of WLF's Legal Studies Division.
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By **Alan M. Slobodin**, former President of WLF's Legal Studies Division, and **Roman P. Storzer**, a former WLF Fellow.
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By **Alan M. Slobodin**, former President of WLF's Legal Studies Division.
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By **Richard A. Samp**, Washington Legal Foundation Chief Counsel.
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By **Paul B. Jacoby**, a Washington, D.C. attorney, and **James Baller**, a partner with the Washington, D.C. law firm of Baller Hammett, P.C.
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By **Dr. James T. Bennett**, a Professor of Economics at George Mason University.
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By **Richard A. Merrill**, Dean of the University of Virginia School of Law and Special Counsel to the Washington, D.C. law firm of Covington & Burling.
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By **Robert G. Hibbert**, a partner with the law firm of McDermott, Will & Emery, Washington, D.C.
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By **Stuart M. Pape**, a partner in the Washington, D.C. law firm of Patton Boggs specializing in food and drug law.
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By **Glenn G. Lammi**, Chief Counsel to WLF's Legal Studies Division.
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By **Melinda L. Sidak**, an attorney with the Washington, D.C. office of Covington & Burling.
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By **Hugh Latimer**, a partner in the Washington, D.C. office of Wiley, Rein & Fielding.
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By **Edward Dunkelberger**, formerly a partner in the Washington, D.C. office of Covington & Burling.
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H. HEALTH CARE

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.
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By **David Price**, Senior Vice President, Legal Affairs, of the Washington Legal Foundation.
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By **Glenn Lammi,** Chief Counsel of the Washington Legal Foundation's Legal Studies Division.
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By **Mark E. Nagle**, a partner in the Washington, D.C. office of the law firm Sheppard, Mullin, Richter and Hampton 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.
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By **Richard Samp**, Chief Counsel of the Washington Legal Foundation.
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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.
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By **Alan R. Bennett** and **Dr. Gregory J. Glover**, partners with the law firm Ropes & Gray in its Washington, D.C. office.
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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.
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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.
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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.
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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.
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By **Daly D.E. Temchine**, a partner in the Washington, D.C. office of Epstein, Becker & Green, P.C. ("EB&G"), where he heads up the Health Law Litigation Department.
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By **Garret G. Rasmussen**, a partner with the Washington law firm Orrick, Herrington & Sutcliffe LLP.
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By **James M. Spears**, a partner, and **Jeff Pearlman**, and associate, respectively, in the Washington, D.C. office of the law firm Ropes & Gray.
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By **Gabriel L. Imperato**, a former Deputy Chief Counsel in the U.S. Department of Health and Human Services and current Chairman of the Criminal and Civil Health Fraud Group of the Florida law firm of Broad and Cassel.
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By **Honorable Harris W. Fawell**, former U.S. Representative for the Thirteenth District of Illinois and currently a Counsel with the Naperville, Illinois law firm James, Gustafson & Thompson, and **Sean Sullivan**, Chief Executive Officer of the Health Care Information Institute and former CEO of the National Business Coalition on Health.
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By **W. Bradley Tully** and **William A. Larkin**, attorneys with the Los Angeles law firm Hooper, Lundy & Bookman, Inc.
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By **Stuart M. Gerson**, head of the national litigation practice of the law firm Epstein Becker & Green, P.C.
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By **Rando W.H. Wick**, an attorney in Seattle with the law firm Johnson, Graffe, Keay, & Moniz.
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By **Joseph E. Schmitz**, Inspector General at the U.S. Department of Defense and formerly an attorney in the Washington, D.C. law firm Patton Boggs.
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By **David B. Rivkin, Jr.**, a partner in the Washington, D.C. law firm Baker & Hostetler.
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By **William J. Kilberg**, a senior partner and **Mark Snyderman**, an associate in the Washington, D.C. office of the law firm Gibson, Dunn & Crutcher.
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By **John N. Drobak**, a Professor of Economics and a Fellow of the Center in Political Economy at Washington University in St. Louis.
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I. INSURANCE REGULATION

Self-Evaluative Privilege Would Benefit Insurers And Their Customers
By **Peter A. Bisbecos**, Legislative and Regulatory Counsel of the National Association of Mutual Insurance Companies.
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By **Peter A. Bisbecos,** Director, Legislative and Regulatory Affairs, of the National Association of Insurance Companies.
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By **Craig Berrington**, Senior Vice President and General Counsel of the American Insurance Association.
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By **Wayne White**, President and Chairman of Home Mutual Fire Insurance Company, Conway Arkansas, and Vice Chairman of the Board of Directors of the National Association of Mutual Insurance Companies.
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By **Peter Bisbecos**, Legislative and Regulatory Counsel of the National Association of Mutual Insurance Companies.
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By **Thomas D. Hughes**, Senior Vice President & General Counsel, and Assistant Secretary, to the Greater New York Insurance Companies in New York.
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By **Peter Bisbecos**, Legislative and Regulatory Counsel of the National Association of Mutual Insurance Companies, **Victoria E. Fimea**, Senior Counsel, Litigation, of the American Council of Life Insurers, **David F. Snyder**, Assistant General Counsel of the American Insurance Association, and **Kenneth A. Stoller**, Counsel of the American Insurance Association.
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By **Peter Bisbecos**, Legislative and Regulatory Counsel of the National Association of Mutual Insurance Companies.
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By **Warren W. Heck**, Chairman and Chief Executive Officer of Greater New York Mutual Insurance Company (GNY Insurance Companies) and its wholly owned stock subsidiaries, Insurance Company of Greater New York, and Strathmore Insurance Company.
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By **The Honorable Mike Fisher**, former Attorney General of the Commonwealth of Pennsylvania.
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By **Lawrence H. Mirel**, Commissioner of the District of Columbia Department of Insurance and Securities Regulation.
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By **Pamela J. Allen**, former Vice President - Federal Affairs, and David Reddick, Ph.D., Market Regulation Manager, both of the National Association of Mutual Insurance Companies (NAMIC).
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By **Mark F. Horning**, a partner at the Washington, D.C. law firm Steptoe & Johnson, LLP, and **Shannen W. Coffin**, a partner in the Washington, D.C. office of the law firm Steptoe & Johnson, LLP.
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By **Dennis Jay**, Executive Director of the Coalition Against Insurance Fraud.
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By **Kirk M. Herath**, an attorney, who is Chief Privacy and Public Policy Officer for Nationwide Insurance Enterprise.
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By **Nancy L. Perkins**, Special Counsel to the Washington, D.C. law firm Arnold & Porter.
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By **D. Joseph Olson**, General Counsel of Amerisure Companies in Farmington Hills, Michigan and former State of Michigan Insurance Commissioner, 1995-1997.
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By **Congressman Joe Knollenberg**, a Junior Member from Michigan's 11th District who serves on the House of Representatives VA-HUD Subcommittee on Appropriations.
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By **Thomas M. Crisham** and **Mary Patricia Benz**, partners in the Chicago firm of Quinlan & Crisham, Lts., specializing in insurance, reinsurance, and other complex cases.
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By **Ronald E. Mallen**, a partner with the San Francisco law firm of Long & Levit.
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By **Michael P. Duncan** and **Robyn B. Simon**, Assistant Counsel to the National Association of Independent Insurers.
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Courts Should Strike Down HUD's Attempts To Regulate Property Insurance
By **Richard M. Esenberg**, a partner with the Milwaukee law firm of Foley & Lardner, specializing in civil rights and governmental affairs litigation.
LEGAL BACKGROUNDER, December 15, 1995, 4 pages

Time To Scrutinize HUD Funding Of Activist Groups
By **Daniel J. Popeo**, WLF's Chairman and General Counsel.
LEGAL BACKGROUNDER, July 21, 1995, 4 pages

Regulating Property Insurance Is Beyond HUD's Jurisdiction
By **Congressman John A. Boehner** (R-OH), who represents Ohio's Eighth District.
LEGAL OPINION LETTER, June 30, 1995, 2 pages

No-Fault Insurance: Let The Market Decide
By **Peter J. Spiro**, a law professor at Hofstra University and a former clerk to Associate Justice David Souter.
LEGAL OPINION LETTER, June 5, 1992, 2 pages

J. PROTECTING DUE PROCESS RIGHTS IN REGULATION

Epidemiologic Evidence In Public And Legal Policy: Reality Or Metaphor
By **Gio Batta Gori**, ScD, MPH, director of the Health Policy Center of Bethesda, Maryland and a former deputy director at the U.S. National Cancer Institute.
WORKING PAPER, June 2004, 33 pages

Administrative Reform Needed To Ensure Quality Of Federal Agency Data
By **Gerald H. Yamada**, a partner at the law firm of O'Connor & Hannan, Washington, D.C. He was EPA's Principal Deputy General Counsel for 13 years and Acting EPA General Counsel over several extended periods.
LEGAL OPINION LETTER, October 1, 2004, 2 pages

Comments Due On Flawed Federal Rules And "Guidances"
By **Richard G. Stoll**, who practices environmental and administrative law with the D.C. office of Foley & Lardner.
COUNSEL'S ADVISORY, May 10, 2002, 1 page

Participate In OMB's Regulatory Reform Efforts
By **Jim J. Tozzi**, a member of the Board of Advisors of the Center for Regulatory Effectiveness and a senior career official at the inception of OMB's Office of Information and Regulatory Affairs.
COUNSEL'S ADVISORY, May 10, 2002, 1 page

Federal Agency Policies Imperil Privacy Of Business Information
By **Gerald H. Yamada**, a partner with the law firm O'Connor & Hannan in Washington, D.C.
LEGAL OPINION LETTER, April 5, 2002, 2 pages

President Expands Oversight Of Federal Agency Rulemaking
By **Ernest Gellhorn**, a Professor of Law at George Mason University, **Wendy L. Gramm**, Director of the Regulatory Studies Program, Mercatus Center, at George Mason University, and **Susan E. Dudley**, a Senior Research Fellow with the Mercatus Center.
LEGAL BACKGROUNDER, November 16, 2001, 4 pages

Science And Reason Must Guide Rulemaking In New Administration
By **Alan Charles Raul**, a partner in the Washington, D.C. office of the law firm Sidley Austin Brown & Wood who served as General Counsel of the Office of Management and Budget and the U.S. Department of Agriculture, as well as Associate White House Counsel in the first Bush Administration and the Reagan Administration.
LEGAL OPINION LETTER, January 12, 2001, 2 page

High Court Ruling Sends Message To Ambitious Federal Regulators
By **Andrew S. Gold**, an associate in the Government Division at the Washington, D.C. office of Venable LLP.
LEGAL OPINION LETTER, July 14, 2000, 2 pages

Courts Should Not Defer To Agencies' Interpretation Of Their Own Rules
By **James N. Christman, David S. Harlow, and Craig S. Harrison**, attorneys in the Washington, D.C. and Richmond offices of the law firm Hunton & Williams.
LEGAL BACKGROUNDER, May 12, 2000, 4 pages

Nondelegation Doctrine's Revival Could Limit Regulatory Activism
By **Daniel E. Troy**, Chief Counsel of the Food & Drug Administration and formerly a partner with the Washington, D.C. law firm Wiley, Rein & Fielding.
LEGAL BACKGROUNDER, July 23, 1999, 4 pages

Regulatory Inspection Procedure Guidelines
By **W. Hugh O'Riordan**, a partner with the Boise, Idaho law firm of Givens Pursley & Huntley and a member of WLF's Legal Policy Advisory Board.
LEGAL BACKGROUNDER, June 3, 1994, 4 pages

K. SECURITIES REGULATION

Lawyers, Other Corporate Advisers Face Exposure To Securities Claims
By **Steven S. Scholes**, a partner in the Trial Department of the law firm McDermott, Will & Emery, resident in its Chicago office, and co-chair of the firm's Securities Litigation Practice Group, as well as its SEC Defense Group.
LEGAL BACKGROUNDER, January 30, 2004, 4 pages

Corporate Governance Reforms Shouldn't Weaken Directors' Role
By **Timothy Hoeffner**, a partner, and **Katayun Jaffari** is an associate, with the law firm Saul Ewing LLP.
LEGAL BACKGROUNDER, October 29, 2004, 4 pages

SEC Complaint Urges Jurisdiction Over Plaintiffs' Lawyers
By **Paul D. Kamenar**, Senior Executive Counsel of the Washington Legal Foundation.
COUNSEL'S ADVISORY, February 14, 2003, 1 page

Proposal Asks SEC To Require Disclosure Of Plaintiffs' Lawyers' Contacts With Analysts
By **Victor E. Schwartz**, a partner in the Washington, D.C. office of the law firm Shook, Hardy & Bacon LLP and Chairman of the firm's Public Policy Group, and **Peter D. Bernstein**, an associate in the firm's Business Litigation Group.
COUNSEL'S ADVISORY, April 11, 2003, 1 page

Protect Investors From Plaintiffs' Lawyers' Stock Manipulation
By **Victor E. Schwartz**, a partner in the Washington, D.C. office of the law firm Shook, Hardy & Bacon LLP and **Peter D. Bernstein**, an associate in the Business Litigation Group of Shook, Hardy & Bacon, LLP in Washington, D.C.
LEGAL BACKGROUNDER, June 27, 2003, 4 pages

The Sarbanes-Oxley Act: Turning Lawyers Into Corporate Whistleblowers?
By **Richard A. Kirby**, a partner in the Washington, D.C. office of the law firm of Preston Gates Ellis & Rouvelas Meeds LLP and **Dan Marino**, also a partner at the firm.
WORKING PAPER, August 2003, 12 pages

Sarbanes-Oxley's Impact On State Corporate Governance
By **David A. Kotler**, a partner with the law firm Dechert LLP, and **Rick Swedloff**, an associate with the firm.
LEGAL OPINION LETTER, July 25, 2003, 2 pages

SEC Proxy Reform Initiative Could Have Significant Impact On Corporate Governance
By **Frank G. Zarb, Jr.**, a partner at the Washington, D.C. law firm Morgan, Lewis & Bockius LLP.
LEGAL BACKGROUNDER, July 18, 2003, 4 pages

SEC Enforcement: A Better "Wells Process"
By **Mitchell E. Herr**, a partner with the law firm Holland & Knight LLP.
WORKING PAPER, October, 2003, 20 pages

Analyst Conflicts, Efficient Markets And "Failure To Supervise" Liability
By **Peter L. Welsh**, an attorney with the law firm of Ropes & Gray in the areas of government enforcement, securities litigation, and corporate governance litigation.
LEGAL BACKGROUNDER, October 3, 2003, 4 pages

New SEC Disclosure Proposals Require Public Companies' Attention
By **Linda L. Griggs**, a partner, **Scott D. Museles**, of counsel, and **Ross H. Parr**, an associate, respectively, in the Washington, D.C. office of the law firm Morgan, Lewis & Bockius LLP.
LEGAL OPINION LETTER, July 26, 2002, 2 pages

The Sarbanes-Oxley Act Of 2002: Will It Prevent Future "Enrons?"
By **Robert A. McTamaney**, a partner in the New York City law firm Carter, Ledyard & Milburn, where he chairs the Corporate Department.
LEGAL BACKGROUNDER, August 9, 2002, 4 pages

SEC Expands Foreign Corruption Law Beyond Congressional Intent
By **Claudius O. Sokenu**, a securities litigator in the New York office of the law firm Mayer, Brown, Rowe & Maw, and a former senior attorney with the Securities and Exchange Commission, Division of Enforcement.
LEGAL BACKGROUNDER, July 26, 2002, 4 pages

Public Financial Disclosure In The Post-Enron Era
By **Linda L. Griggs**, **George G. Yearsich**, and **David A. Sirignano**, partners in the Washington, D.C. office of the law firm Morgan, Lewis & Bockius.
LEGAL BACKGROUNDER, March 22, 2002, 4 pages

Aftermath Of Enron May Test Limits On Professionals' Liability
By **Larry E. Ribstein**, a professor at the University of Illinois College of Law.
LEGAL OPINION LETTER, March 22, 2002, 2 pages

Enron Provides Lessons On Audits For Accountants And Public Companies
By **David Priebe**, Special Counsel at the law firm Gray Cary Ware & Freidenrich LLP, Palo Alto, California, and **Henry C. Montgomery**, the Chairman of Montgomery Financial Services Corporation, San Mateo, California.
LEGAL BACKGROUNDER, March 8, 2002, 4 pages

SEC Self-Policing Policy Presents Benefits And Pitfalls
By **Richard A. Spehr**, a litigation partner in the New York office of the law firm Mayer, Brown & Platt, and **Claudius O. Sokenu**, a litigation associate with Mayer, Brown & Platt, and a former senior attorney with the U.S. Securities and Exchange Commission, Division of Enforcement.
LEGAL BACKGROUNDER, January 25, 2002, 4 pages

SEC "Fair Disclosure" Rule Is Constitutionally Suspect
By **Larry E. Ribstein**, a professor at the University of Illinois College of Law.
LEGAL OPINION LETTER, October 6, 2000, 2 pages

SEC "Fair Disclosure" Proposal Can Chill Market Communications
By **Daniel L. Goelzer**, formerly partner in the Washington, D.C. office of the law firm Baker & McKenzie and General Counsel of the SEC.
LEGAL OPINION LETTER, March 17, 2000, 2 pages

SEC "Tombstone Ad" Restrictions Constitutionally Suspect
By **Larry Akiyama**, a student in the Washington Legal Foundation's Economic Freedom Law Clinic at George Mason University School of Law.
LEGAL BACKGROUNDER, January 21, 2000, 4 pages

Comment On Proposed SEC Rule On Proxy Statements
By **Joseph P. Galda**, an attorney with the Buffalo, New York law firm Hodgson Russ, LLP.
COUNSEL'S ADVISORY, November 7, 1997, 1 page

SEC And FDA Conflict Reduces Quality Of Medical Product Information
By **David M. Hoffmeister**, of counsel to the Palo Alto law firm Wilson Sonsini Goodrich & Rosati, and California attorney **Richard A. Shupack**.
LEGAL BACKGROUNDER, January 5, 1996, 4 pages

Business Community Has Opportunity To Influence Developments On SEC Proxy Rules
By **James R. Doty**, Senior Partner in the Washington, D.C. office of Baker & Botts, L.L.P.
COUNSEL'S ADVISORY, May 19, 1993, 1 page

Environmental Expenses: Disclosure Requirements For Public Corporations
By **Vicki R. Patton-Hulce**, a corporate attorney who worked with EPA for over six years.
LEGAL BACKGROUNDER, February 19, 1993, 4 pages

New Rules On The Time Period For Filing Fraud Claims Under Rule 10b-5 Of The Federal Securities Laws
By **Andrew N. Vollmer** and **James Lee Buck, II**, attorneys with Wilmer, Cutler & Pickering, Washington, D.C.
LEGAL BACKGROUNDER, February 14, 1992, 4 pages

L. WORKPLACE REGULATION

Passage Of House Bill Advances Important OSHA Reforms
By **Arthur G. Sapper,** partner in the OSHA Practice Group of McDermott, Will & Emery LLP. He is a former adjunct professor of OSHA law, and the former Deputy General Counsel of the Occupational Safety and Health Review Commission.
LEGAL BACKGROUNDER, October 1, 2004, 4 pages

Managing Ergonomic Concerns Under OSHA's New Guidelines
By **Jerome K. Bowman**, formerly a partner in the Environmental Health & Safety Group of Ross & Hardies in Chicago.
LEGAL BACKGROUNDER, May 24, 2002, 4 pages

California High Court Muddles Standard For Workplace Tort Suits
By **Lynn A. Bersch**, a partner with the law firm Crosby, Heafey, Roach & May PC in San Francisco.
LEGAL BACKGROUNDER, April 26, 2002, 4 pages

OSHA Should Be Consultant, Not Regulator, On Ergonomics
By **Thomas J. Slavin**, Manager, Safety and Health, for International Truck and Engine Corporation, and **William B. Bunn III**, Vice President, Health, Safety and Productivity, and Medical Director, of International Truck and Engine Corporation.
LEGAL BACKGROUNDER, August 10, 2001, 4 pages

Assessing OSHA's New Ergonomics Standard
By **Jerome K. Bowman**, formerly a partner in the Environmental Health & Safety Group of Ross & Hardies in Chicago.
WORKING PAPER, December 2000, 38 pages

California Court Expands Employers' Liability Under State OSHA Law
By **Jeffrey M. Tanenbaum**, senior shareholder and co-chair of the occupational safety and health practice group with the San Francisco law office of Littler Mendelson, a Professional Corporation.
LEGAL BACKGROUNDER, September 22, 2000, 4 pages

OSHA's Ergonomics Standard Is Flawed Beyond Repair
By **Willis J. Goldsmith**, a partner, and **Jacqueline M. Holmes**, an associate, both in the Washington, D.C. office of the law firm Jones, Day, Reavis & Pogue.
LEGAL BACKGROUNDER, June 23, 2000, 4 pages

Vigorous Debate Expected Over Washington Ergonomics Proposal
By **Bruce Michael Cross**, a partner with the Seattle law firm Perkins Coie LLP.
LEGAL BACKGROUNDER, March 31, 2000, 4 pages

Beware The Stresses And Strains Of OSHA's Ergonomics Proposal
By **Jerome K. Bowman**, formerly a partner in the Environmental Health & Safety Group of Ross & Hardies in Chicago.
LEGAL BACKGROUNDER, December 17, 1999, 4 pages

Is The OSHA Review Commission Treading On State Sovereignty?
By **Velma Montoya, Ph.D.**, a California-based economist specializing in research on regulatory and educational policies.
LEGAL OPINION LETTER, August 20, 1999, 2 pages

Court Rejects Agency's Alteration Of Equal Access To Justice Act
By **Kent W. Seifried**, a partner with the Covington, Kentucky law firm of Poston, Seifried & Schloemer.
LEGAL OPINION LETTER, July 23, 1999, 2 pages

OSHA Ergonomics Proposal Is Fatally Flawed
By **Representative Cass Ballenger**, who has represented the Tenth District of North Carolina since 1986.
LEGAL BACKGROUNDER, June 25, 1999, 4 pages

Court Restricts Agencies' Ability To Informally Compel "Cooperation"
By **Eugene Scalia**, Solicitor to the Department of Labor and formerly a partner with the Washington, D.C. office of the law firm Gibson, Dunn & Crutcher LLP.
LEGAL OPINION LETTER, June 11, 1999, 2 pages

New OSHA Rule Will Impose Mandates Without Due Process
By **Jerome K. Bowman**, formerly a partner in the Environmental Health & Safety Group of Ross & Hardies in Chicago.
LEGAL BACKGROUNDER, April 30, 1999, 4 pages

Local Citizen Inspection Law: Taking "Right-to-Know" Too Far?
By **Steve Barnett**, an Associate with the law firm Connell, Foley & Geiser, LLP, Roseland, New Jersey.
LEGAL BACKGROUNDER, April 30, 1999, 4 pages

Influential Court Queries OSHA On Meaning Of "Repeat Violation"
By **Robert P. Davis**, a partner in the Washington, D.C. office of the law firm Mayer, Brown & Platt.
LEGAL OPINION LETTER, December 4, 1998, 2 pages

OSHA Workplace Violence Guidance Creates New Liability Concerns
By **Peter A. Susser**, a partner in the Washington, D.C. office of the national employment law firm Littler Mendelsohn, P.C.
LEGAL BACKGROUNDER, November 13, 1998, 4 pages

Court Blocks OSHA Attempt To Significantly Expand Its Authority
By **Charles M. Chadd**, an attorney and legal publisher in Chicago, and **Jerome K. Bowman**, formerly a partner in the Environmental Health & Safety Group of Ross & Hardies in Chicago.
LEGAL OPINION LETTER, September 18, 1998, 2 pages

Judge's Ruling Exposes Junk Science Fueling OSHA's Actions On Ergonomics
By **Willis J. Goldsmith**, a partner, and **Jacqueline M. Holmes**, an associate, with the Washington, D.C. office of the law firm Jones, Day, Reavis & Pogue.
LEGAL OPINION LETTER, April 17, 1998, 2 pages

OSHA's New Enforcement Initiative: Cooperation Or Coercion?
By **The Honorable W. Scott Railton**, Chairman of the OSHA Review Commission and formerly a partner with the McLean, Virginia office of Reed Smith.
LEGAL OPINION LETTER, February 20, 1998, 2 pages

Mandatory Safety Programs: OSHA's Ultimate Regulation?
By **Robert C. Gombar, P.C.** and **Arthur G. Sapper**, partners in the Washington, D.C. office of the law firm McDermott, Will & Emery, and **Melissa A. Bailey**, an attorney with the Washington, D.C. law firm Arent Fox Kitner Plotkin & Kahn.
LEGAL BACKGROUNDER, February 20, 1998, 4 pages

Hostile Work Environment Claims Implicate Free Speech Rights
By **William V. Whelan** and **Richard M. Freeman**, partners in the San Diego office of Sheppard, Mullin, Richter & Hampton LLP.
LEGAL OPINION LETTER, December 19, 1997, 2 pages

New OSHA Hazard Abatement Rule Brings Burdens And Opportunities
By **George R. Salem**, a partner, and **Robert G. Lian, Jr.**, an associate, in the Washington office of the law firm Akin, Gump, Strauss, Hauer & Feld, L.L.P.
LEGAL OPINION LETTER, October 10, 1997, 2 pages

OSHA Authority Over Contractors Expanded
By **Donald W. Jones**, managing partner of Hulston, Jones, Gammon & Marsh, Springfield, Missouri.
COUNSEL'S ADVISORY, August 22, 1997, 1 page

Worker's Compensation Reforms Cut New York Businesses' Costs And Increase Worker Safety
By **Governor George E. Pataki**, State of New York.
LEGAL BACKGROUNDER, March 7, 1997, 4 pages

OSHA Ignores Sound Science In Ergonomics Efforts
By **Willis J. Goldsmith**, a partner, and **Jacqueline M. Holmes**, an associate, with the Washington, D.C. office of the law firm Jones, Day, Reavis & Pogue.
LEGAL BACKGROUNDER, May 30, 1997, 4 pages

Will California Set The Standard For Ergonomics Regulations?
By **Jeffrey M. Tanenbaum**, a shareholder and chair of the Occupational Safety and Health Group of the San Francisco office of Littler Mendelson.
LEGAL BACKGROUDER, May 30, 1997, 4 pages

New OSHA Abatement Programs May Reduce Employers' Rights
By **Mark N. Savit**, a partner, and **Adele L. Abrams**, an associate, with Patton Boggs L.L.P.'s Washington, D.C. office.
LEGAL BACKGROUNDER, November 1, 1996, 4 pages

Court Holds Repeat OSHA Prosecutions Unconstitutional
By **Arthur G. Sapper**, a partner in the Washington, D.C. office of the law firm McDermott, Will & Emery.
COUNSEL'S ADVISORY, October 18, 1996, 1 page

Comment On OSHA Workplace Violence Guidelines
By **Peter A. Susser**, a partner with the Washington, D.C. office of Littler Mendelson P.C.
COUNSEL'S ADVISORY, September 6, 1996, 1 page

Expanding The "Maine 200" Program: Is OSHA Pulling A Bait And Switch?
By **Richard D. Wayne**, a partner with the Boston law firm Hinkley, Allen & Snyder.
LEGAL OPINION LETTER, June 7, 1996, 2 pages

OSHA Issues Proposal On Recordkeeping Requirements
By **Frederick D. Braid**, a partner in the New York office of the law firm Holland & Knight.
COUNSEL'S ADVISORY, April 12, 1996, 1 page

Administrative Court's Decisions Erode OSHA Penalty Policy
By **Arthur G. Sapper**, a partner in the Washington, D.C. office of the law firm McDermott, Will & Emery.
LEGAL BACKGROUNDER, February 2, 1996, 4 pages

FOIA Requests: A Valuable Weapon In Battling Defiant OSHA
By **Donald W. Jones** and **Jason N. Shaffer**, an associate attorney with the Springfield, Missouri law firm Hulston, Jones, Gammon & Marsh
LEGAL OPINION LETTER, January 19, 1996, 2 pages

Repeat OSHA Prosecutions Violate The Fifth Amendment
By **Arthur G. Sapper** and **Laura Rolander**, then a law clerk with the Washington, D.C. office of the law firm McDermott, Will & Emery.
LEGAL OPINION LETTER, November 10, 1995, 2 pages

OSHA's New Litigation Strategy: How Employers Should React
By **Charles M. Chadd**, an attorney and legal publisher in Chicago, and **Jerome K. Bowman**, formerly a partner in the Environmental Health & Safety Group of Ross & Hardies in Chicago.
LEGAL BACKGROUNDER, September 29, 1995, 4 pages

Bigger OSHA Penalties Ineffective At Reducing Workplace Injuries
By **Mark M. Moran**, a consultant with Moran Associates specializing in OSHA matters.
LEGAL BACKGROUNDER, February 3, 1995, 4 pages

Should OSHA Hold Employers Responsible For Violence In The Workplace?
By **Frederick D. Braid**, a partner in the New York office of the law firm Holland & Knight.
LEGAL BACKGROUNDER, November 18, 1994, 4 pages

OSHA's New Interpretation Of "Imminent Danger" Poses Significant Threat To Business
By **Willis J. Goldsmith** and **Michael F. Dolan**, partners with the law firm of Jones, Day, Reavis & Pogue, in Washington, D.C. and Chicago.
LEGAL OPINION LETTER, October 21, 1994, 2 pages

OSHA's Proposed Indoor Air Quality Standard: An $8.1 Billion Burden On Economic Growth And Job Creation
By **F. Edwin Froelich**, a partner with the Washington, D.C. law firm Wilcox, Carroll & Froelich PLLC, and **Traci J. Stegemann, J.D.**, an attorney with the Washington, D.C. law firm Shaw Pittman.
LEGAL BACKGROUNDER, August 26, 1994, 4 pages

Sixth Circuit Provides Employers With Legal Basis To Challenge OSHA Inspections
By **Lawrence P. Halprin**, a partner in the Washington, D.C. office of the law firm of Keller and Heckman.
LEGAL BACKGROUNDER, August 26, 1994, 4 pages

OSHA's Proposed Indoor Air Quality Standard Adds Many Burdens And Requires Response
By **Charles M. Chadd**, an attorney and legal publisher in Chicago.
COUNSEL'S ADVISORY, July 1, 1994, 1 page

Can OSHA Constitutionally Bring Criminal Charges Against Businesses Based On Evidence Obtained Under An Administrative Inspection Warrant?
By **Lawrence P. Halprin**
LEGAL BACKGROUNDER, April 22, 1994, 4 pages

How Much Judicial Deference To OSHA? — The Dangers Of Unchecked Administrative Power
By **Arthur G. Sapper** and **Robert C. Gombar**, a partner in the Washington, D.C. office of the law firm McDermott, Will & Emery.
LEGAL BACKGROUNDER, March 11, 1994, 4 pages

Will OSHA Reform Undercut Goal Of A Safer Workplace?
By **Baruch A. Fellner**, a partner in the Washington, D.C. office of the law firm of Gibson, Dunn & Crutcher.
LEGAL BACKGROUNDER, February 11, 1994, 4 pages

State And Federal Regulation Of Workplace Health & Safety: A Delicate Balance
By **Peter A. Susser**, a partner with the Washington, D.C. office of Littler Mendelson P.C.
LEGAL BACKGROUNDER, January 28, 1994, 4 pages

OSHA'S Use Of General Duty Clause Raises Questions Of Fairness And Legislative Intent
By **Nina G. Stillman**, a partner, and **Karen L. Taylor**, an associate, in the Chicago office of the law firm Vedder, Price, Kaufman & Kammholz.
LEGAL BACKGROUNDER, January 28, 1994, 4 pages

OSHA's Egregious Policy For General Duty Citations Is Overturned
By **The Honorable W. Scott Railton**, Chairman of the OSHA Review Commission and formerly a partner with the McLean, Virginia office of Reed Smith.
COUNSEL'S ADVISORY, January 21, 1994, 1 page

How To Survive An OSHA Inspection In Today's Regulatory Climate
By the late **Robert D. Moran**, who was an Attorney at Law, President of Moran Associates in Washington, D.C., and former first Chairman of the U.S. Occupational Safety and Health Review Commission.
CONTEMPORARY LEGAL NOTE, October 1993, 29 pages

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Will Businesses Lose Their Day In Court To Challenge OSHA Citations?
By **The Honorable W. Scott Railton**, Chairman of the OSHA Review Commission and formerly a partner with the McLean, Virginia office of Reed Smith.
LEGAL BACKGROUNDER, August 20, 1993, 4 pages

Serious Questions Raised By OSHA Reform Proposal Need To Be Answered
By **Michael J. Connolly** and **Clifford J. Scharman**, shareholders with the Detroit law firm Riley Roumell & Connolly, P.C.
LEGAL BACKGROUNDER, May 14, 1993, 4 pages

Sorting Out ADA's Conflict With OSHA
By **F. Edwin Froelich** and **Elizabeth A. Cullen**, an attorney with the Washington, D.C. law firm of Shaw Pittman.
LEGAL OPINION LETTER, August 28, 1992, 2 pages

The Occupational Safety And Health Act: A Case For Expanded Preemption
By **Lynn L. Bergeson**, a partner with the Washington, D.C. law firm Bergeson & Campbell.
LEGAL BACKGROUNDER, June 5, 1992, 4 pages

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January 17, 2005

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 the principles of freedom and justice.

WLF engaged in the following activities during calendar year 2004.

COURT PROCEEDINGS

NATIONAL SECURITY -- MILITARY TRIBUNALS. ***Hamdan v. Rumsfeld.*** On December 8, 2004, WLF filed a brief in the U.S. Court of Appeals for the District of Columbia Circuit, urging the court to uphold the Bush Administration's plan to convene military tribunals to conduct trials of al Qaeda leaders accused of war crimes. WLF argued that Congress has explicitly endorsed the creation of such tribunals; and that even if Congress had not done so, the Constitution authorizes the President, as Commander in Chief of American military forces, to order military trials for enemy combatants. The Bush Administration in November 2001 issued an order authorizing the establishment of military commissions to hear war crimes charges brought against those captured during the war against al Qaeda. The pending federal court challenge to that order was filed by Salim Ahmed Hamdan, a citizen of Yemen who was captured during fighting in Afghanistan and is being detained at Guantanamo Bay, Cuba. Hamdan, who admits that he served as a driver and close aide to Osama bin Laden for several years, is one of a handful of al Qaeda operatives against whom war crimes charges have been filed. WLF filed its brief on behalf of itself and the Allied Educational Foundation. WLF also filed a brief in the case in September 2004, when it was before the district court. That court ruled in favor of Hamdan in November, and the military appealed that ruling to the D.C. Circuit.

Status: Awaiting oral argument on March 8, 2005.

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IMMIGRATION -- PUBLIC WELFARE. ***Friendly House v. Napolitano.*** On December 22, 2004, the U.S. District Court for the District of Arizona upheld Proposition 200, an initiative adopted in November by Arizona voters and designed to deter illegal aliens from collecting welfare benefits. The decision was a victory for WLF, which argued in a brief filed on December 14, 2004, that Arizona voters were well within their rights in adopting such measures. In denying a motion for a preliminary injunction against the new law, the court agreed with WLF that Proposition 200 does not in any way conflict with federal immigration law; indeed, the court noted, Congress has passed several laws that encourage states to ensure that illegal aliens do not collect welfare payments. The court also agreed with WLF that Proposition 200 does not violate the constitutional rights of either state employees or welfare applicants; the rights of illegal aliens are not violated because they are barred from collecting welfare, while Proposition 200 does nothing to prevent aliens who are here legally from obtaining benefits, the court ruled. WLF filed its brief on behalf of itself and Protect Arizona NOW, the organization that sponsored Proposition 200 and arranged to have it placed on the November 2004 ballot.

Status: Victory. Monitor for appeal.

TERRORISM -- SOVEREIGN IMMUNITY. ***Ungar v. Palestine Liberation Organization.*** On November 24, 2004, WLF filed a brief in the U.S. Court of Appeals for the First Circuit in Boston, urging the court to require the 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. WLF argued 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. WLF's brief took no position on whether the PLO and the PA are, in fact, responsible for the terrorist killings. The case arose in the aftermath of the murder 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 filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Awaiting oral argument on January 3, 2005.

PROPERTY RIGHTS -- CONTRACT CLAUSE. ***RUI One Corp. v. City of Berkeley.*** On December 1, 2004, WLF filed a brief in the U.S. Supreme Court, urging the Court to prevent governments from adopting laws that impose increased costs on their lessees, above and beyond the costs imposed by the lease agreement. WLF urged the Court to review, and ultimately overturn, 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. 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.

Status: Awaiting decision.

OVERCRIMINALIZATION -- U.S. SENTENCING GUIDELINES. ***United States v. Fanfan; United States v. Booker.*** On September 25, 2004, WLF filed a brief with the United States Supreme Court urging it to affirm a pair of lower court rulings that held that the U.S. Sentencing Guidelines are unconstitutional under the Sixth Amendment's guarantee to a person's right to trial. If the Court agrees with WLF, as many legal observers believe it will, Congress will likely revamp the controversial guidelines which have mandated draconian sentences even for minor regulatory offenses. In the last few months, several federal courts have declared that the Supreme Court's June 2004 ruling in *Blakely v. Washington,* which addressed the constitutionality of the State of Washington's sentencing guidelines, also applies to the federal guidelines. In *Blakely*, the Supreme Court ruled in a 5-4 decision written by Justice Scalia, that factors used by the judge to enhance a prison sentence must be found beyond a reasonable doubt by the jury under the Sixth Amendment. WLF's brief, filed on behalf of itself and the Allied Educational Foundation, was drafted with the *pro bono* assistance of Donald B. Verrilli, Jr. and Elaine J. Goldenberg of the Washington, D.C. office of Jenner & Block LLP.

Status: Oral argument held on October 4, 2004; awaiting decision.

PROPERTY RIGHTS -- TAKINGS CLAUSE. ***San Remo Hotel v. City and County of San Francisco.*** On December 10, 2004, the U.S. Supreme Court agreed to review an appeals court decision that essentially bars assertion of Fifth Amendment claims in the federal courts and relegates such claims to the state courts. The decision to review the case was a victory for WLF, which on November 12 filed a brief urging the Court to review (and ultimately overturn) the lower court decision. The appeals court refused to hear the claim of a hotel owner who claimed that San Francisco improperly seized more than $500,000 of his property. 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. WLF filed its brief on behalf of the Chamber of Commerce of the United States, the National Taxpayers Union, the Allied Educational Foundation, the American Association of Small Property Owners, the Property Rights Foundation of America, the South Carolina Landowners Association, the Small Property Owners Association, the Small Property Owners of San Francisco Institute, and the United Lot Owners of Cambria. Now that the Supreme Court has agreed to hear the case, WLF in January will file a new brief urging the Court to reverse the appeals court.

Status: Victory; review granted. Next WLF brief due January 24, 2005.

CLASS ACTIONS -- EMPLOYMENT DISCRIMINATION. ***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" 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 oral argument.

NATIONAL SECURITY -- ENVIRONMENTAL REGULATION. ***National Audubon Society v. Dep't of the Navy.*** On October 27, 2004, WLF filed a brief in the U.S. Court of Appeals for the Fourth Circuit in Richmond, urging it to permit the Navy to go forward with plans to build a new North Carolina airfield. The airfield, desperately needed for pilots being trained to land planes on aircraft carriers, has been blocked by a U.S. district judge in North Carolina who has raised questions about whether the Navy prepared an adequate environmental impact statement (EIS) before going ahead with the project. WLF argued that the district judge acted improperly in second-guessing the Navy's determination that building the base is vital for national security. WLF argued that the Constitution requires courts to defer to military determinations by those Executive Branch officials who have expertise in the area. WLF also argued that if the courts believe that the Navy's EIS was inadequate, the proper remedy is to order the Navy to revise its EIS, not to block all work on a project that will take years to complete. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Awaiting oral argument on February 1, 2005.

FIRST AMENDMENT -- COMPELLED SPEECH. ***Veneman v. Livestock Marketing Ass'n.*** On October 15, 2004, WLF filed a brief in the U.S. Supreme Court, urging it to bar the federal government from forcing beef producers to provide financial support for advertising with which they disagree. 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. *Veneman* is 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. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Oral argument held December 8, 2004. Awaiting decision.

BUSINESS CIVIL LIBERTIES -- OVERCRIMINALIZATION. ***Arthur Anderson LLP v. United States.*** On December 7, 2004, WLF filed a brief with the U.S. Supreme Court urging it to review and reverse a court of appeals decision that would criminalize legitimate business housekeeping activities without prosecutors having to show any criminal intent. In *Arthur Anderson 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. Anderson supervisors had simply reminded company employees to follow the company's legitimate document retention policy *prior* to the initiation of an investigation of Anderson 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.

Status: Review granted; argument to be held in April 2005.

GLOBAL WARMING -- EPA RULEMAKING AUTHORITY. ***Massachusetts v. EPA***. On November 1, 2004, WLF filed a brief in the United States Court of Appeals for the District of Columbia Circuit urging it to reject an effort by several states and environmental groups to require that the Environment Protection Agency (EPA) regulate carbon dioxide as a pollutant under the Clean Air Act. If the court rules in favor of the petitioners, the EPA would be 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, 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.

Status: Case pending.

COPYRIGHT LAW -- FILE-SHARING SOFTWARE. ***Metro-Goldwyn-Mayer Studios v. Grokster***. On December 10, 2004, the U.S. Supreme Court agreed to review a decision by the U.S. Court of Appeals for the Ninth Circuit that held that a company whose file-sharing software allows others to illegally copy and disseminate copyrighted music and films on the Internet does not itself violate the copyright law. 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. WLF had filed a brief on November 8, 2004 urging the Court to grant review. WLF's brief was drafted with the *pro bono* assistance of Herbert Fenster, a partner in both the Washington, D.C. and Denver offices of McKenna Long & Aldridge LLP.

Status: Review granted; argument to be held in March 2005.

CIVIL JUSTICE – PUNITIVE DAMAGES. ***Johnson v. Ford Motor Co.*** On December 9, 2004, WLF filed a brief in the Supreme Court of California opposing a $10 million punitive damages award in a consumer fraud case where the economic damages amounted to less than $18,000. 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. and won the punitive damages award. The state Court of Appeals reduced the punitive award to three times the compensatory damages award, or $53,435. WLF's brief in the state's Supreme Court argued that the trial court's punitive damages award violated the Due Process Clause of the Fourteenth Amendment. WLF argued that the punitive damage award in this case disregarded past U.S. Supreme Court rulings in that it was not reasonably proportional to the maximum civil penalty set by the California legislature (namely, twice the actual damages) and in that it was based partly on the defendant's overall wealth. Susan Liebeler of Malibu, California represented WLF as local counsel in the case on a *pro bono* basis.

Status: Awaiting oral argument.

CIVIL JUSTICE – PUNITIVE DAMAGES. ***Simon v. San Paolo U.S. Bank Holding Co.*** On October 13, 2004, WLF filed a brief asking the Supreme Court of California to reverse 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. 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 his out-of-pocket losses were only $5,000, but nonetheless awarded the heavy punitive damages. The case has twice been remanded by the U.S. Supreme Court for further consideration in light of the High Court's decisions restricting punitive damages. WLF's brief argued that the punitive damages award in this case violated due process in that it was not proportional to the plaintiff's actual losses under California law and was not proportional to the gravity of the defendant's conduct. Susan Liebeler of Malibu, California represented WLF as local counsel in the case on a *pro bono* basis.

Status: Awaiting oral argument.

CIVIL JUSTICE – FEDERAL PREEMPTION OF STATE LAW ACTIONS. ***Bates v. Dow AgroSciences LLC.*** On November 24, 2004, WLF filed a brief asking the U.S. Supreme Court to declare that if an herbicide label complies with the federal regulatory system governing the labeling of pesticides and herbicides, the label cannot be the basis of a state law tort action. The lawsuit, brought under Texas law, is based on allegations that an herbicide caused crop damage because its label failed to warn against use on high-pH soil. The district court and the U.S. Court of Appeals for the Fifth Circuit accepted the defendant's argument that the preemption language of the relevant federal statute – the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – renders those claims invalid. In its brief, WLF argued that private lawsuits, such as this one, are inconsistent with Congress's intent in enacting FIFRA. The brief noted that if plaintiffs' lawyers were given leeway to bring labeling actions under state law, then enforcement would be limited only by the ability of those lawyers to recruit claimants, not by the congressionally-mandated policy considerations such as protection of agriculture.

Status: Awaiting oral argument.

NATIONAL SECURITY -- DETENTION OF ENEMY COMBATANT. ***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 a greater opportunity to put on his side of the case than he was initially afforded by the federal appeals court. WLF filed its brief on behalf of itself, the Allied Educational Foundation, the Jewish Institute for National Security Affairs, and three Members of Congress: U.S. Representatives Joe Barton, Walter Jones, and Lamar Smith. William T. DeVinney and Thomas Loran, lawyers with Pillsbury Winthrop LLP, provided *pro bono* assistance in preparing the brief.

Status: Partial victory.

ANTITERRORISM -- DETENTION OF ALIEN ENEMY COMBATANTS. ***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 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. WLF filed its brief on behalf of itself, the Allied Educational Foundation, and the Jewish Institute for National Security Affairs. WLF also filed a brief in the case when it was before the lower courts.

Status: Loss.

NATIONAL SECURITY -- DETENTION OF ENEMY COMBATANT. ***Rumsfeld v. Padilla.*** On June 28, 2004, the U.S. Supreme Court dismissed a challenge to 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 in support of Padilla's detention. The Court agreed with WLF that Padilla's petition should be dismissed because he filed the petition in the

wrong court: he filed in New York instead of the State in which he is being detained (South Carolina). WLF also argued that the government is entitled to detain Padilla without trial just as it is entitled to detain any enemy soldier captured in time of war. WLF argued that the government's right to detain Padilla is not diminished simply because he is a U.S. citizen and was captured in Chicago rather than on some overseas battlefield. WLF argued that Congress has explicitly authorized detention of al Qaeda operatives, regardless of their citizenship. WLF filed its brief on behalf of itself, the Allied Educational Foundation, and two Members of Congress: Walter Jones (N.C.) and Lamar Smith (Tex.). WLF has pledged to continue its involvement in the case in connection with Padilla's new petition filed in South Carolina.

Status: Victory.

FIRST AMENDMENT -- COMMERCIAL SPEECH. ***People of the State of 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 some youth would see its ads is not sufficient to sanction non-misleading speech, WLF argued.

Status: Review denied.

CRIMINALIZING BUSINESS ACTIVITIES -- ENVIRONMENTAL CRIMES. ***Blandford v. United States***. In early June, WLF's clients began serving their draconian 97-month federal prison sentence for importing frozen lobster tails from Honduras in plastic bags instead of cardboad boxes, allegedly in violation of an Honduran regulation. On February 25, 2004, the Supreme Court denied review in this important case of overcriminalization of business activities. WLF filed a petition for writ of certiorari last October 2003 on behalf of three seafood importers and dealers seeking review of a divided court of appeals decision that upheld their convictions and sentences of 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 federal Lacey Act for importing lobster tails in violation of foreign regulations. The Honduran seafood exporter was also convicted and sentenced to eight years in prison, and has already served two years of that time. A separate petition to the Supreme Court was filed on his behalf by Miguel Estrada of Gibson Dunn & Crutcher, LLP. Because the seafood was shipped in clear plastic bags instead of opaque boxes, they were also charged with "smuggling," even though the shipments regularly went through Customs inspections and testing by the FDA. Furthermore, because the seafood importers paid the exporter for the seafood they purchased in a normal commercial transaction, they were charged with money laundering. However, the Honduran regulations that served as the predicate for the charges were later declared to be null and void, repealed, and otherwise of no legal effect by Honduran courts. The Honduran

government, represented by former Solicitor General Seth Waxman, took the extraordinary step of filing a brief in the Supreme Court supporting WLF's position. WLF attorneys were assisted with *pro bono* support by Barry M. Hartman and Dylan B. Carp of Kirkpatrick & Lockhart, LLP.

Status: Loss. Defendants serving sentence; habeas petitions to be filed in February.

OVERSEAS CONDUCT -- LAW ENFORCEMENT. ***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. WLF filed its brief on behalf of itself, the National Fraternal Order of Police, and the Allied Educational Foundation. WLF's brief was prepared with the *pro bono* assistance of Donald Ayer and Christian Vergonis of the Jones Day law firm. WLF was also successful in convincing the Court to review the case in a brief filed in the fall of 2003.

Status: Victory.

ASBESTOS -- DISQUALIFICATION OF JUDGES. ***In re Kensington International Ltd.*** On May 17, 2004, the U.S. Court of Appeals for the Third Circuit disqualified a judge from overseeing three contentious bankruptcies (filed by Owens Corning, W.R. Grace & Co., and USG Corp. in the face of massive numbers of asbestos-liability claims) because he hired advisors with impermissible conflicts of interest. The decision was a victory for WLF, which filed three separate briefs urging that Judge Alfred Wolin be removed from the case. His highly-compensated advisors are plaintiffs' attorneys who represent asbestos claimants in other bankruptcy proceedings; the appeals court agreed with WLF that the close relationship between the judge and his advisors created an appearance of partiality that required the judge's disqualification. WLF filed its briefs with the assistance of Roderick R. McKelvie, a Washington, D.C. lawyer who recently retired as a federal judge in Delaware.

Status: Victory.

PRICE CONTROLS -- MEDICAID. ***Pharmaceutical Research and Mfrs. of America v. Thompson.*** 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 had 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.

Status: Loss.

ANTITRUST -- MONOPOLIZATION. ***3M Company v. LePage's Inc.*** On June 30, 2004, the U.S. Supreme Court 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. In a brief filed last year urging the Court to grant review, 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 involves 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, LePage's Inc., whose share of the tape market is about 10%. WLF argued that the lower-court decision, unless reversed on appeal, will chill pro-consumer price cuts by companies that seek to avoid potential antitrust liability. WLF filed its brief on behalf of itself and the National Association of Manufacturers.

Status: Certiorari denied.

CLASS ACTIONS -- IMPROPER CERTIFICATION. ***Ysbrand v. DaimlerChrysler Corp.*** On November 6, 2003, the Oklahoma Supreme Court, by a 5-4 vote, declined WLF's request that it reconsider a decision certifying a nationwide class action lawsuit. WLF argued that plaintiffs' lawyers often bring such 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 sets of laws often apply to class members from different states. 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.

Status: Rehearing denied. Petition for Supreme Court review denied on June 28, 2004.

LEGAL REFORM -- PUNITIVE DAMAGES. ***Rhyne v. Kmart Corp.*** On April 10, 2004, WLF scored a major victory when the North Carolina Supreme Court upheld the legality of caps on the award of punitive damages. On July 18, 2003, WLF had filed a brief in the case urging the court to uphold a divided court of appeals ruling that sustained the constitutionality of a North Carolina tort reform statute. 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. WLF's brief urged the court to affirm a favorable ruling last year by the lower court overturning a $23 million punitive damages award imposed on Kmart Corporation in a case where damages were less than $20,000. The court held that legislation limiting such awards was not unconstitutional. On April 5, 2001, WLF had filed its initial brief with the North Carolina Court of Appeals, urging the court to reverse the original trial court decision. Represented on appeal by an officer of the Association of Trial Lawyers of America, the plaintiffs have used this case to challenge the validity of North Carolina's statutory punitive damages cap under state constitutional law. In its briefs, WLF argued that Kmart's federal constitutional claim that the $23 million punitive damage award violates its due process rights finds convincing support in the U.S. Supreme Court's case law. WLF filed its briefs on behalf of itself and the Allied Educational Foundation.

Status: Victory.

FIRST AMENDMENT -- COMPELLED SPEECH. ***Gerawan Farming, Inc. v. Kawamura.*** On June 3, 2004, the California Supreme Court issued a decision that sets tough 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 will 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.

Status: Partial victory; case remanded for trial.

NATIONAL SECURITY -- CONFIDENTIALITY OF DETAINEES' IDENTITIES. ***Center for National Security Studies v. Dep't of Justice.*** On January 12, 2004, the Supreme Court denied review of this important case, thereby leaving intact WLF's victory. 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 the aliens detained in the United States following the September 11, 2001 terrorist attack on America. In a 2-1 decision, the court agreed with WLF that releasing the information could interfere with law enforcement efforts, and that the government was not otherwise required by law to disclose the information. WLF filed briefs in the case in both the district court and court of appeals on behalf of itself and its client, the Jewish Institute for National Security Affairs (JINSA). In this case, the activists, led by the ACLU, filed

a Freedom of Information Act (FOIA) request with DOJ to obtain the names of all aliens who were arrested or detained in connection with the DOJ's investigation of the terrorist attack, as well as the names of any of their attorneys. The activists claim that the detainees were being mistreated. The plaintiffs in this lawsuit include the ACLU, the Center for Constitutional Rights, People for the American Way, National Association of Criminal Defense Lawyers, Amnesty International, the Multiracial Activist, and some 15 other groups.

Status: Victory. Petition for Supreme Court review denied.

BORDER SECURITY -- VEHICLE SEARCHES. ***U.S. v. Flores-Montano.*** On 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 involves 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. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Victory.

ENVIRONMENTAL LAW -- FEDERAL SUPERFUND LIABILITY. ***United States v. Alcan Aluminum Corporation.*** On January 14, 2004, the Supreme Court denied review in this important Superfund case. On December 15, 2003, WLF had filed a brief in the U.S. Supreme Court in support of a petition for review filed by Alcan Aluminum seeking review and reversal of an adverse decision by the U.S. Court of Appeals for the Second Circuit. On January 7, 2003, the court of appeals upheld a district court ruling in this important Superfund case. On May 31, 2001, WLF had filed a brief with the court urging it to reverse a district court ruling against Alcan Aluminum Corporation (Alcan) for approximately $13 million in cleanup costs of two EPA Superfund sites in upstate New York. Alcan's allegedly "hazardous substance" was essentially nothing more than water. WLF argued that if the decision is not reversed, then practically everything in the universe could be considered a "hazardous substance" under the Superfund law, including breakfast cereal, vitamins, and garden soil. Businesses, restaurants, municipalities, and even ordinary citizens could face crippling liability for properly disposing of harmless waste materials. WLF's brief was filed on behalf of itself and a leading group of federal, state, and local officials, trade associations, and policy organizations. WLF's clients include U.S. Senator Larry E. Craig, Chairman of the Subcommittee on Forests and Public Land Management of the Senate Energy and Natural Resources Committee; U.S. Representative Michael G. Oxley, Chairman of the House Financial Services Committee; and U.S.

Representatives John E. Peterson and John M. McHugh. WLF also represents New York State Senator James W. Wright, New York State Assemblywoman Frances T. Sullivan, and Mayor John J. Gosek, Mayor of the City of Oswego, New York. WLF is also representing business, civic, and policy organizations, including the Chamber of Commerce of the United States, the National Association of Manufacturers, the National Restaurant Association, the National Food Processors Association, the Manufacturers Association of Central New York, the New York State Conference of Mayors and Municipal Officials, the Business Council of New York State, Inc., Operation Oswego County, Inc., and the Allied Educational Foundation.

Status: Loss. Supreme Court review denied.

ENDANGERED SPECIES ACT -- COMMERCE CLAUSE. ***Rancho Viejo, LLC v. Norton***. On March 2, 2004, the United States Supreme Court declined to review and reverse a court of appeals decision that would effectively remove any limits on Congress to regulate development under the Commerce Clause of the Constitution. 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 endangered species which is located only in California and only ranges about one mile from the streams in which it breeds. In its brief, filed on January 28, 2004, on behalf of itself and the Allied Educational Foundation, WLF had argued that the court of appeals decision would effectively undermine the Supreme Court's jurisprudence on the Commerce Clause.

Status: Loss. Supreme Court review denied.

SECURITIES LAW -- STATE CONTROL OF CORPORATE INVESTING. ***Alliant Energy Corp. v. Bridge.*** On January 12, 2004, the U.S. Supreme Court issued an order declining to hear a challenge to a Wisconsin law that regulates the investments and stock sales of non-Wisconsin companies. The decision was a setback for WLF, which in November 2003 filed a brief urging that review be granted. WLF argued that the law violates the Commerce Clause of the U.S. Constitution by regulating the out-of-state activities of out-of-state corporations. The lower court, the U.S. Court of Appeals for the Seventh Circuit, upheld the restrictions. In its brief, WLF argued that state laws that directly control extraterritorial commerce – commerce occurring wholly outside the state's borders – are *per se* invalid under the Commerce Clause. WLF's brief also pointed to the need for a free flow of investment capital in the public utility industry in view of the infrastructure investment required to modernize the nation's electrical grid. Finally, the brief pointed out the international implications of laws such as Wisconsin's, which affect international investment in the U.S. utility industry; the brief argued that regulation of such investment is properly carried out at the federal level, where national policy can speak with a single voice. WLF's brief was drafted on a *pro bono* basis by Donald B. Verrilli, Jr., a partner in the Washington, D.C. office of Jenner & Block, and Iris Bennett, an associate at the firm.

Status: Loss.

CRIMINAL LAW -- CRIME VICTIMS RIGHTS. ***Lynn v. Reinstein.*** On January 14, 2004, the Supreme Court denied review in this important victim rights case. On September 24, 2003, WLF filed a brief with the Court urging it to hear the case to resolve a conflict among lower courts: whether the constitution *per se* bars a crime victim from recommending an appropriate punishment in a capital case, whether the recommendation is death or life imprisonment. In *Lynn v. Reinstein*, Duane Lynn's wife and another victim were shot and killed at a homeowners association meeting in Arizona. Invoking his rights under Arizona's Victims' Bill of Rights, Mr. Lynn asked the trial court that he be allowed to give an opinion as to the sentence that should be imposed on the defendant. In its decision, the Arizona Supreme Court held that "the Eighth Amendment prohibits a victim from making a sentencing recommendation to the jury in a capital case." WLF's clients include U.S. Senator Jon Kyl and Congressman John Shadegg of Arizona, the National Organization of Victim Assistance, Parents of Murdered Children, and the Allied Educational Foundation. WLF's brief was drafted with the *pro bono* assistance of Richard Willard, formerly Assistant Attorney General in the Reagan Administration.

Status: Loss. Petition for Supreme Court review denied.

ANTITRUST LAW -- IMMUNITY OF U.S. POSTAL SERVICE. ***United States Postal Service v. Flamingo Industries.*** On February 25, 2004, the United States Supreme Court unanimously held that federal antitrust laws are not applicable to the U.S. Postal Service (USPS) for those commercial activities which are not part of its statutory monopoly for certain mail delivery services. The Court ruled that even though Congress revoked sovereign immunity of the USPS, it was not a "person" subject to the antitrust laws. On September 15, 2003, WLF had filed a brief with the U.S. Supreme Court urging it to uphold a lower court ruling which held that federal antitrust laws are applicable to the U.S. Postal Service (USPS) for those commercial activities which are not part of its statutory monopoly for certain mail delivery services. In *U.S. Postal Service v. Flamingo Industries,* the U.S. Court of Appeals for the Ninth Circuit ruled that the Postal Service was not immune from being sued for antitrust violations with respect to certain conduct that is not directly connected to its statutory mission of delivering the mail. In its brief, filed on behalf of itself, the Allied Educational Foundation, and Americans for Tax Reform, 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 held liable as any other private competitor, except for the narrow area of certain mail delivery services. Accordingly, the court should analyze the specific conduct that is the subject of the antitrust complaint to see if it falls within USPS's statutory mission. WLF's brief was drafted with the *pro bono* assistance of Alan Charles Raul and Derek Brown of the Washington, D.C. law firm of Sidley Austin Brown & Wood LLP.

Status: Loss.

ANTITRUST -- ESSENTIAL FACILITIES DOCTRINE. ***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 company customer that Verizon, the owner of all telephone lines in New York City, was failing to maintain its lines properly. The decision was a victory for WLF, which in May of 2003 had filed a brief urging reversal. The Court agreed with WLF that the far-reaching antitrust theories

upheld by the appeals court in the case -- the "essential facilities" doctrine and the "monopoly leveraging" doctrine -- are based on misinterpretations of prior antitrust cases. WLF's brief was drafted on a *pro bono* basis by Steven G. Bradbury and Kannon Shanmugam of the Washington, D.C. law firm of Kirkland & Ellis.

Status: Victory.

CLASS ACTIONS -- EXCESSIVE ATTORNEY'S FEES. ***In re: Magazine Antitrust Litigation***. On February 10, 2004, WLF scored a victory when the federal district court denied an award of attorneys' fees in this class action case because no substantive benefit was provided to the class members. On May 5, 2003, WLF had filed its objections on behalf of itself and several consumers to the proposed award of $1.1 million in attorney's 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. 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. That guideline had the effect of limiting discounts to subscriptions of magazines such as *TV Guide* and *Sports Illustrated* to no more than 50 percent off the list price. The Complaint sought declaratory, injunctive, and treble damages for violations of the Sherman Act.

Status: Victory.

PATENTS -- PHARMACEUTICALS. ***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. WLF filed its brief with the *pro bono* assistance of Philip A. Lacovara, Donald M. Falk, Michael O. Warnecke, Joseph A. Mahoney, and Thomas R. Striebel of the law firm of Mayer Brown Rowe and Maw.

Status: Victory.

LEGAL REFORM -- ASBESTOS LITIGATION. ***Crown Cork & Seal Co. v. Ieropoli.*** On February 24, 2004, the Pennsylvania Supreme Court, in a 4-3 decision, struck down as unconstitutional a Pennsylvania statute that limits the liability of certain manufacturers that have been unfairly drawn into asbestos tort litigation. The statute limits the liability of Pennsylvania corporations that are being sued for damages based on their having acquired other corporations that previously manufactured products that contained asbestos. WLF argued that the statute is constitutional and promotes the public interest by limiting liability of such companies. WLF had filed an earlier brief on August 9, 2002, urging the court to hear the case on the merits.

Status: Loss.

ALIEN FELONS -- DEPORTATIONS TO SOMALIA. ***Jama v. Immigration and Naturalization Service.*** On July 22, 2004, WLF filed a brief in the U.S. Supreme Court, urging it to permit the U.S. government to deport alien felons to Somalia. WLF urged the Court to reject a lower court decision that bars deporting *anyone* to Somalia because that country lacks a functioning central government. WLF argued 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 has 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. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Oral argument held on October 12, 2004. Awaiting decision.

EXECUTIVE AUTHORITY -- APPOINTMENT OF JUDGES. ***Stephens v. Evans.*** On October 14, 2004, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta 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 Pryor 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 Pryor'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 also argued that the constitutionality of such recess appointments raises a political question that is not justiciable by the courts. President Bush nominated Pryor for a seat on the Eleventh Circuit on April 9, 2003. Although the nomination was approved by the Senate Judiciary Committee and has the support of a majority of the Senate, Democratic Senators to date have successfully filibustered the nomination. On February 20, 2004, while the Senate was in an 11-day recess, President Bush gave Pryor a temporary "recess" appointment to the court, an appointment that will last through the end of 2005. WLF has pledged to continue its support of Judge Pryor -- a former member of WLF's Board of Legal Advisors -- if the plaintiffs convince the U.S. Supreme Court to hear their claims.

Status: Victory. Petition for Supreme Court review pending.

OVERCRIMINALIZATION -- U.S. SENTENCING GUIDELINES. ***Thurston v. United States***. On July 17, 2004, WLF filed a brief in the U.S. Supreme Court urging the Court to review and reverse a court of appeals decision that sharply limited the trial court from departing downward under the Sentencing Guidelines in a case where one business defendant received probation in a plea bargain, but a less culpable executive would have to serve five years for exercising his constitutional right to stand trial for the same offense. If the High Court reviews and reverses the decision, it would make it easier for trial courts to depart from the excessive sentences dictated by the U.S. Sentencing Guidelines. In its brief filed on behalf of itself and the Allied Educational Foundation, WLF 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.

Status: Certiorari pending.

LEGAL REFORM -- SECURITIES CLASS ACTIONS. ***Dura Pharmaceuticals v. Broudo.*** On September 12, 2004, WLF filed a brief in the U.S. Supreme Court urging it to reverse a ruling from the U.S. Court of Appeals for the Ninth Circuit that allows a more relaxed pleading standard for attorneys filing securities class action cases against publicly-held companies. Unless reversed by the Supreme Court, the court of appeals decision would invite windfall damage awards and would be particularly harmful to smaller companies such as those in the life sciences industry. WLF argued that Congress enacted the Private Securities Litigation Reform Act (PSLRA) in 1995 to prevent class action attorneys from filing such abusive securities fraud cases against a company simply because the price of the stock went down. The PSLRA requires counsel to show that the loss from the drop in stock price was due directly to the alleged misrepresentation by the company rather than simply to claim that the plaintiffs purchased the stock during the time of the alleged misrepresentation. WLF's brief was drafted with the *pro bono* assistance of Michael L. Kichline, David A. Kotler, and John J. Sullivan of Dechert LLP from both the Philadelphia, Pennsylvania and Princeton, New Jersey offices.

Status: Oral argument to be held January 12, 2005.

LEGAL REFORM -- PUNITIVE DAMAGES. ***Lowry's Reports Inc. v. Legg Mason, Inc.*** On July 13, 2004, WLF filed a brief in the U.S. Court of Appeals for the Fourth Circuit seeking to overturn a massive jury award of approximately $20 million in punitive fines levied 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 district court failed to conduct meaningful judicial review of the fines to comport with constitutional and procedural standards. If left intact, the award could set a dangerous precedent that could be used against any business that may run afoul of numerous other statutes, such as environmental laws, which provide for statutory penalties that can amount

to millions of dollars regardless of how minor the violation may have been. WLF's brief was drafted with the *pro bono* assistance of Sean E. Andrussier of Womble Carlyle Sandridge & Rice, PLLC, in Raleigh, North Carolina.

Status: Awaiting oral argument.

COMMERCE CLAUSE -- ENDANGERED SPECIES. ***GDF Realty Investments v. Norton*** On September 6, 2004, WLF filed a brief on behalf of itself and the Allied Educational Foundation in the United States Supreme Court urging it to review and reverse a court of appeals decision that would give 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. 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. The developer even offered to donate portions of the land to a nonprofit conservation group, but was rebuffed by government officials. WLF's brief was drafted with the *pro bono* assistance of Mark A. Perry and Amir Cameron Tayrani of the Washington, D.C. office of Gibson, Dunn & Crutcher, LLP.

Status: Certiorari pending.

CLASS ACTIONS — LACK OF COMMON ISSUES. ***Engle v. Liggett Group, Inc.*** On July 23, 2004, WLF filed a brief in the Florida Supreme Court opposing a state-wide plaintiff class in a product liability personal-injury suit filed against all the major cigarette companies. In this case wherein the trial court entered a $145 billion judgment against the defendants, WLF's brief (filed on behalf of itself and the National Association of Manufacturers) argues that class certification is inappropriate where, as here, individualized issues predominate over issues common to the class. WLF also urged the court to reject the plaintiffs' argument that the court should rely on "public policy" to certify class actions that otherwise would fail to meet the requirements of Florida law for class certification. Rebecca O'Dell Townsend of the Tampa law firm of Haas, Dutton, Blackburn, Lewis & Longley, P.L., represented WLF as local counsel in the case on a *pro bono* basis.

Status: Awaiting decision.

EXPERT TESTIMONY — PROFESSIONAL PEER REVIEW. ***Fullerton v. Florida Medical Association.*** On September 9, 2004, WLF filed a brief in circuit court in Florida, urging the court the dismissal of a libel suit filed by a doctor who had been accused by his peers of professional misconduct. The plaintiff regularly serves as an expert witness for plaintiffs in medical malpractice cases. Three other doctors filed a complaint against him with the Florida Medical Association (FMA), accusing him of misconduct in connection with testimony he gave in a 2003 case; they alleged that his testimony was medically indefensible and was tailored to advance the legal interests of the individual for whom he testified. The plaintiff responded by filing a libel suit against the three doctors and the FMA, claiming that their accusations were false. In its brief, WLF argued that the federal Health Care Quality Improvement Act provides immunity to those

who report allegations of misconduct to medical review boards. Rebecca O'Dell Townsend of the Tampa law firm of Haas, Dutton, Blackburn, Lewis & Longley, P.L., represented WLF as local counsel in the case on a *pro bono* basis.

Status: Awaiting decision.

PATENTS -- PUBLIC USE BAR. ***SmithKline Beecham Corp. v. Apotex Corp.*** On June 15, 2004, WLF filed a brief in the U.S. Court of Appeals for the Federal Circuit, urging it to rehear *en banc* a case in which a three-judge panel invalidated a significant pharmaceutical patent on a minor technicality. WLF argued that if allowed to stand, the initial decision will undermine confidence in the patent system as an effective means of protecting intellectual property rights. The court invalidated the patent because the drug company had begun a clinical trial of its drug's effectiveness slightly more than a year before filing its patent application; the court held that that trial amounted to "public use" of the drug -- even though it was never offered for sale to anyone until seven years *after* the company applied for the patent.

Status: Awaiting decision.

ILLEGAL ALIENS -- DETAINING CONVICTED FELONS. ***Clark v. Martinez.*** On May 7, 2004, WLF filed a brief in the U.S. Supreme Court urging it to overturn lower-court decisions that could result in the release from detention of more than 1,100 illegal aliens convicted of violent crimes. WLF 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 involve 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. WLF filed its brief on behalf of U.S. Representatives John Doolittle, Lamar Smith, and Dave Weldon; the Allied Educational Foundation; Friends of Immigration Law Enforcement; and the National Border Control Council.

Status: Oral argument held on October 13, 2004. Awaiting decision.

ANTITRUST LIABILITY -- PATENT SETTLEMENTS. ***Schering-Plough Corp. and Upsher-Smith Laboratories v. FTC.*** On June 9, 2004, WLF filed a brief in the U.S. Court of Appeals for the Eleventh Circuit, urging it to overturn an FTC decision that condemned a patent settlement agreement as an antitrust violation. The agreement settled a contentious dispute involving generic drug companies who wished to manufacture a drug for which Schering-Plough Corp. claimed to have a patent. The FTC held that the settlement unreasonably restrained trade by inducing the generic companies to delay their entry into the market. WLF argued that patents always entail some restraints on commerce, but that those restraints are warranted in light of the large benefits derived from the patent system. WLF argued that parties ought to be encouraged to

settle patent disputes, but by increasing the possibility that settlements will be held to violate antitrust laws, the FTC is unnecessarily discouraging settlements.

Status: Awaiting decision.

ANTITERRORISM -- LAWSUIT AGAINST IRAQ. ***Acree v. Iraq***. On August 18, 2004, the United States Court of Appeals for the District of Columbia Circuit declined to reconsider its earlier ruling of June 10, 2004 that reversed a lower court ruling awarding monetary damages in favor of American servicemen who were unlawfully tortured by Saddam Hussein's regime as Prisoners of War (POWs) in the 1991 Gulf War. The Court ruled that while the district court had jurisdiction in the case, there was no cause of action. On February 11, 2004, WLF filed a brief on behalf of several Members of Congress in the United States Court of Appeals for the District of Columbia Circuit urging it to uphold the district court's ruling against Iraq. In *Acree v. Iraq*, Colonel Clifford Acree and 16 other American servicemen filed suit against the Republic of Iraq in early 2002 seeking damages against Iraq, Saddam Hussein, and the Iraqi Intelligence Service 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 default judgment and awarded damages in their favor when the Iraqi government failed to contest the charges. In its brief filed on behalf of U.S. Senators Harry Reid, George Allen, and Patty Murray, and Representatives John Conyers, Howard Berman, and Gregory Meeks, WLF argued that even if the Justice Department could intervene in the case at this late date, the court of appeals should reject the argument that the trial court lacked jurisdiction to enter the judgment in favor of the ex-POWs. In particular, WLF argued that emergency appropriations by Congress to help rebuild Iraq cannot be construed to retroactively oust the district court of jurisdiction to issue the judgment in favor of the ex-POWs.

Status: Supreme Court review pending; WLF to file brief February 18, 2005.

TORT REFORM -- ASBESTOS LITIGATION. ***3M Company v. Johnson.*** On February 6, 2004, WLF filed a brief in the Mississippi Supreme Court, urging it to overturn a record $150 million asbestos product liability judgment awarded to six men, none of whom were injured. WLF argued that the award was a textbook example of the tort system run amok, with damages being freely awarded even in the absence of credible evidence of exposure to asbestos or negligence on the part of the defendants. In addition, there was no proof that any negligence caused the plaintiffs' alleged injuries, nor proof that the plaintiffs suffered any damages. WLF was particularly critical of the trial court's decision to consolidate numerous claims against numerous defendants into a single trial. WLF argued that the consolidation deprived defendants of their rights to have their defenses adjudged on an individual basis.

Status: Oral argument held December 15, 2004. Awaiting decision.

CLASS ACTIONS -- COMMONALITY OF CLAIMS. ***Aspinall v. Philip Morris, Inc.*** 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. Evan Slavitt, a partner in the Boston law firm of Bodoff & Slavitt, represented WLF as local counsel in the case on a *pro bono* basis.

Status: Loss.

FDA REFORM -- ACCESS TO LIFESAVING MEDICINES. ***Abigail Alliance for Better Access to Investigational Drugs v. McClellan***. On December 6, 2004, WLF responded to the FDA's motion for summary affirmance in this constitutional case. The FDA's motion seeks summary affirmance of WLF's appeal before the U.S. Court of Appeals for the D.C. Circuit. WLF has appealed the dismissal of its lawsuit asking the court to strike down FDA regulations that prohibit terminally ill patients with no approved treatment options from obtaining new drugs while the drugs are undergoing clinical trials. WLF filed the lawsuit on July 28, 2003, in federal district court against the Food and Drug Administration (FDA) on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a nonprofit group with numerous members and supporters who are suffering from terminal illness or who have lost family members to terminal illness. The lawsuit challenges FDA restrictions that prevent the terminally ill from obtaining new medicines that have shown safety and efficacy during clinical trials. Under FDA regulations, the vast majority of patients with life-threatening illnesses do not gain entry into clinical trials or compassionate use programs, and thus do not have access to promising new medications during the years of clinical testing and review required by the FDA. The drugs remain unavailable to patients even though the patients have no alternative to the drugs other than to wait for their own death. While expressing sympathy for WLF's claims, the district court said that there are no existing court decisions that recognize the constitutional right asserted by WLF: the right of individuals with no approved treatment options to buy investigational drugs (that is, drugs undergoing clinical trials) without undue governmental interference.

Status: Awaiting oral argument.

BORDER SECURITY -- ILLEGAL IMMIGRANTS. ***Ambros-Marcial v. U.S.*** On November 4, 2003, WLF filed a brief in federal district court in Arizona, urging the court not to permit immigrants rights groups to undermine border security measures by suing the federal government for failing to establish water stations in the Arizona desert. WLF argued 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 arises in connection with a lawsuit for damages filed by relatives of Mexicans who died in the desert. WLF argued

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. WLF filed its brief on behalf of itself, the Allied Educational Foundation, and Friends of Immigration Law Enforcement.

Status: Awaiting decision.

LEGAL REFORM -- PUNITIVE DAMAGES. ***City of Hope Medical Center v. Genentech, Inc.*** On October 21, 2004, the California Court of Appeal in Los Angeles upheld a trial court ruling that imposed an unprecedented $200 million punitive damages award against a biotech company that was involved in a contract dispute over royalties owed to a developer of synthesized DNA material. The $200 million award was in addition to the $300 million compensatory damages award, bringing the total to $500 millioin. WLF argued in its brief submitted on January 6, 2004, that if the decision were left intact, all businesses involved in typical contract disputes are at risk for 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.

Status: Loss; petition for review pending in California Supreme Court.

CLASS ACTION -- EXCESSIVE ATTORNEYS' FEES. ***Azizian v. Federated Dept. Stores, Inc.*** On December 21, 2004, WLF submitted a proposed order for the trial court to consider in the final hearing of this major class action case in which WLF had filed several pleadings during the year. On March 26, 2004, WLF filed preliminary objections on behalf of a group of 33 objectors to a proposed settlement in a nationwide class action case that would award attorneys' fees of up to $24 million to class action attorneys, but offer only a chance for consumers to get a "free" item of cosmetics allegedly valued between $18-$25 if they purchased so-called "high end" cosmetics or fragrances over the last 10 years. In *Azizian v. Federated Department Stores*, a nationwide class action was filed five years ago in California against a group of department stores for antitrust violations with respect to the sale of cosmetics manufactured by companies such as Estee Lauder and Chanel. In its preliminary objections filed on behalf of 33 class members in the U.S. District Court for the Northern District of California, WLF argued that the official notice about the proposed settlement was neither sufficient nor timely in reaching class members; notices were buried in fine print in the March 2004 issues of certain magazines and recent newspapers. WLF also argued that the settlement, which provides that unspecified "free" products would be given away, was vague, did not afford consumer choice of products, and would lead to long lines at stores. On June 1, 2004, WLF had filed an extensive 25-page supplemental objection to this class action settlement and participated in a five-hour hearing held in San Francisco, California before Special Master Charles Renfrew who had been appointed by the district court to hear all other objections that were filed. Of the dozen or so objectors, WLF and the 11 State Attorneys General were given preference in presenting their objections. On September 10, 2004, WLF filed its response to the Special Master reports approving the settlement contesting a proposed recommendation to award $24 million in attorneys' fees in this case.

Status: Final hearing scheduled for January 11, 2005.

LEGAL REFORM -- COMPARATIVE NEGLIGENCE. ***Brodsky v. Grinell Haulers, Inc.*** On August 12, 2004, WLF scored a victory when the New Jersey Supreme Court agreed with WLF's brief filed on February 19, 2004, and 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. In such a case, a jury is likely to impermissibly shift liability to a solvent defendant company in order to compensate the plaintiffs for their injuries. In *Brodsky v. Grinell Haulers, Inc.*, the plaintiff's car was struck and forced off the road when a company-owned truck negligently veered too close to the vehicle. The driver of the car got out of his car safely, but was then hit by a careless speeding motorist and suffered injuries. Before the trial began, however, the driver of the speeding car declared bankruptcy. New Jersey tort reform law provides that a defendant can be held jointly and severally liable for *all* the damages but only if the jury finds that the defendant was responsible for at least 60 percent of the accident. If the jury finds that particular defendant was responsible for less than 60 percent, then damages are apportioned based on the percentage of fault among the responsible parties. WLF's brief was filed with the *pro bono* assistance of Edward J. Fanning, Jr., and David R. Kott of McCarter & English, LLP of New Jersey. Joining with WLF on the brief was the New Jersey Business & Industry Association and the New Jersey Defense Association.

Status: Victory.

LEGAL REFORM -- EXCESSIVE ATTORNEYS' FEES. ***Graham v. DaimlerChrysler Corp.*** On November 30, 2004, in a sharply divided 4-3 decision, the California Supreme Court recently 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 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 towing capacity of the vehicle. Because the company began to correct the misprint in the manual well before the suit was filed and even offered to repurchase any vehicle sold before the misprint was corrected, 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. WLF argued in its brief that this judge-made catalyst theory has been rejected by the U.S. Supreme Court and should also be rejected by California courts. WLF's brief was filed with the *pro bono* assistance of Mark S. Pulliam, Jennifer F. Ziegaus, Daniel P. Brunton, attorneys with the San Diego office of Latham & Watkins.

Status: Case remanded for further review.

BUSINESS CIVIL LIBERTIES -- EPA MISCONDUCT. ***Riverdale Mills Corp. v. United States***. On November 1, 2004, the U.S. District Court in Massachusetts ruled against Riverdale Mills Corporation and ruled that the EPA was not liable for malicious prosecution under the Federal Tort Claims Act but excoriated the EPA for the unprofessional manner in which they conducted its investigation. On December 22, 2004, the U.S. Court of Appeals for the First Circuit ruled that the 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 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. The EPA defendants were also sued individually for violating RMC's and Knott's constitutional rights under the Fourth and Fifth Amendments by conducting unlawful searches and seizures, and by selectively enforcing EPA regulations against RMC and Knott because of their public criticism of EPA. RMC, located in Northbridge, Massachusetts, is an environmental award-winning, energy-efficient facility that manufactures galvanized and plastic-coated welded steel wire mesh used for lobster traps, aquaculture, erosion control, and other commercial purposes. In the 38-page complaint, WLF recounts EPA's malicious, vexatious, and selective criminal investigation and felony indictment against RMC and Knott for allegedly violating an EPA regulation by discharging rinsewater with a pH of less than 5.0 from RMC's plant into the public sewer on October 21, 1997 and November 7, 1997. After the 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, the EPA was forced to turn over the original logs of its investigators, which revealed that a lawful pH reading of 7 was altered to look like a 4, and that other 7s were altered to look like 2s. The government dropped all criminal charges just before trial.

Status: Loss. Motion to amend adverse district court ruling pending.

ANTITRUST -- PATENT SETTLEMENTS. ***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 was a setback for WLF, which filed a brief 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. In a separate order issued the same day, the Supreme Court declined to review a decision from the federal appeals court in Atlanta that reached the opposite result: the Atlanta court ruled (in a case in which WLF actively participated) that patent settlement agreements are *never* subject to *per se* condemnation under the antitrust laws. The Supreme Court's decision not to hear the two cases leaves intact a conflict between lower court decisions, a conflict that the High Court sooner or later will have to address.

Status: Review denied.

FIRST AMENDMENT -- COMPELLED SPEECH. ***R.J. Reynolds Tobacco Co. v. Shewry.*** On October 26, 2004, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit in San

Francisco, urging the court to uphold the First Amendment rights of individuals and corporations not to be compelled to speak against their will. WLF argued that the First Amendment prohibits a State from forcing a company to pay for advertisements that vilify the company. The case arises in connection with an advertising campaign being conducted by the State of California. California spends $25 million per year in a 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. The campaign is funded entirely by the tobacco industry. In September 2004, a three-judge Ninth Circuit panel voted 2-1 to uphold the California scheme, holding that a state may use tax revenues virtually any way it sees fit -- even if the state raises the taxes from a single source and uses the revenues for the sole purpose of vilifying the taxpayer. WLF's brief asked the court to grant a rehearing in the case.

Status: Awaiting decision.

CLASS ACTIONS -- PHARMACEUTICALS. ***Stetser v. TAP Pharmaceutical Products.*** On July 6, 2004, the North Carolina Court of Appeals issued a decision that imposed strict limits on certification of nationwide class action lawsuits. The decision was a victory for WLF, which had filed a brief urging that the certification of a nationwide class action be overturned in this case. WLF argued that plaintiffs' lawyers often bring such 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 sets of laws often apply to class members from different states. The trial judge in this case tried to avoid those 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 also appeared to agree with WLF that each class member's claim must be governed by the law of his home state since class members come from all 50 states.

Status: Victory.

CLASS ACTIONS -- EXCESSIVE ATTORNEYS' FEES. ***Price v. Philip Morris, Inc.*** On December 10, 2003, WLF filed a brief asking the Illinois Supreme Court to reverse an excessive attorneys' fee award in a class action. In the case, a Madison County, Illinois judge hit the tobacco company, Philip Morris, with $7.1 billion in damages based on claims that the company had fraudulently implied that its low-tar cigarettes are safer than ordinary cigarettes. The judge held that the plaintiffs' attorneys who brought the suit were entitled to slightly more than $1.77 billion of that amount. In its brief, WLF argued that meaningful appellate review of this award from the plaintiffs' damages fund is vital in light of the fact that the plaintiff class had no separate representation with respect to the award and no opportunity to contest it. WLF noted that the fee award amounts to an hourly rate for the attorneys of nearly $32,000 per hour. WLF further noted that the fee award is greater than the entire 2003 budget for all United States

Attorneys' offices combined. In addition, WLF argued that the trial court erred by ordering that any unclaimed funds from the damages award must go to a specified list of institutions to advance various social causes. WLF argued that any fluid class recovery in the case must be fashioned to benefit the plaintiff class, not unrelated segments of the population or the population at large. WLF filed the brief on behalf of itself and the Illinois Civil Justice League. Matthew J. Iverson, a partner in the Chicago office of the law firm Litchfield Cavo, represented WLF as local counsel in the case on a *pro bono* basis.

Status: Awaiting decision.

CLASS ACTIONS -- PHARMACEUTICALS. ***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. WLF argued that personal injury product liability suits are virtually never appropriate for class action treatment because the claims of each class members 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. WLF also filed a brief in the case in the fall of 2003, successfully urging the court to agree to review the case.

Status: Victory.

NATIONAL SECURITY -- SUITS AGAINST TERRORIST NATIONS. ***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 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. WLF filed its brief in conjunction with the Jewish Institute for National Security Affairs. Joel J. Sprayregen and Jared M. Wayne, attorneys in Chicago, assisted in the preparation of WLF's brief.

Status: Awaiting oral argument.

CLASS ACTIONS -- MEDICAL MONITORING. ***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 agreed with WLF that a case may be maintained as a class action only if the class is "cohesive," *i.e.*, where common issues of fact and law "predominate" over issues unique to individual class members. The court ruled that, in the absence of a showing of cohesiveness, certification was even less appropriate when sought, as here, under Rule 23(b)(2) (class actions seeking injunctive relief) than under Rule 23(b)(3), the more commonly invoked class action rule.

Status: Victory.

ANTITRUST -- PATENT SETTLEMENTS. ***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. WLF prepared its brief with the *pro bono* assistance of Stephen Paul Mahinka, Scott A. Stempel, Penelope M. Lister, and John F. Terzaken III of the Washington, D.C. office of Morgan, Lewis & Bockius LLP.

Status: Victory. Petition for Supreme Court denied October 12, 2004.

PRODUCT LIABILITY -- CLASS ACTIONS. ***In re Simon II Litigation.*** On November 20, 2003, oral argument was held in this important class action case. On June 4, 2003, WLF had filed a brief in the U.S. Court of Appeals for the Second Circuit in New York, urging the court to overturn a district court decision that certified a nationwide class action on behalf of smokers seeking punitive damages against the cigarette industry. WLF argued that the suit would be wholly unmanageable if it proceeds as a class action on behalf of millions of individuals, each of whose claims depend on a unique set of facts. WLF argued that certification of the class violates federal court rules as well as the constitutional rights of both absent class members and the defendants. WLF filed its brief on behalf of itself and the National Association of Manufacturers.

Status: Awaiting decision.

PRODUCT LIABILITY -- CLASS ACTIONS. ***U.S. ex rel. Gilligan v. Medtronic, Inc.*** On November 26, 2003, WLF filed a brief in the U.S. Court of Appeals for the Sixth Circuit in Cincinnati, urging the court not to permit individual litigants to file suits designed to second-

guess decisions by the Food and Drug Administration (FDA) authorizing the sale of drugs or medical devices. 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. WLF argued that federal law prohibits damage suits based on claims that the manufacturer obtained FDA approval for its product by defrauding the FDA. WLF argued that the FDA should be the sole judge of whether it has been defrauded. WLF argued that plaintiffs should not be permitted to evade this preemption rule by (as here) recasting their suits as claims arising under the federal False Claims Act, which permits *qui tam* suits by private individuals who allege that the federal government has been defrauded. WLF achieved a preliminary victory in this case in September when, in response to a previous brief filed by WLF, the appeals court agreed to review a trial court determination that the case should be allowed to go forward.

Status: Oral argument held November 4, 2004. Awaiting decision.

CLASS ACTIONS -- IMPROPER CERTIFICATION. ***Peterson v. BASF Corp.*** On February 18, 2004, the Minnesota Supreme Court declined an opportunity to impose limits on the 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 setback for WLF, which filed a brief urging the court to impose such limitations. 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. Nationwide class actions tend to be totally unmanageable because class members will often have widely varying damages claims, and different sets of laws often apply to class members from different states. This case involves claims by farmers who objected to the manner in which BASF Corp. marketed its herbicides. The trial judge tried to avoid the manageability problems by decreeing that all claims would be judged under New Jersey law. WLF argued that that procedure is unconstitutional because most class members have no contact whatsoever with New Jersey. Because it disposed of the case on procedural grounds, the Minnesota Supreme Court was not required to address those issues.

Status: Appeal dismissed. U.S. Supreme Court review pending.

ALIEN TORT STATUTE -- CORPORATE LIABILITY. ***Doe v. Unocal Corporation***. On April 16, 2003, WLF filed a brief with the full United States Court of Appeals for the Ninth Circuit sitting *en banc* seeking to overturn a lower court ruling and an original panel decision of the court of appeals that greatly expanded the reach of the Alien Tort Statute (ATS). 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." When the law was enacted in 1789, it was intended to govern relations between nation states; however, human rights activists are now invoking the law to hold U.S. corporations operating abroad, like Unocal, liable for human rights abuses allegedly suffered by aliens at the hands of the foreign country's military forces in the course of protecting a company's facilities from being damaged or vandalized. In this case, the aliens claim that injuries they suffered at the hands of the Myanmar military for protecting an oil pipeline project should be attributed to Unocal Corporation under a theory of secondary liability. WLF argued that contrary to Ninth Circuit precedent, the ATS does not create a cause of action; rather, the

ATS is merely a jurisdictional statute that does not create any substantive federal rights. WLF's brief was drafted with the *pro bono* assistance of Donald Ayer and Christian Vergonis of the Washington, D.C. office of Jones Day. Supplemental briefs were filed by the parties over the last few months following the Supreme Court's recent decision in *Sosa v. Alvarez-Machain.*

Status: Case settled December 2004.

LEGAL REFORM -- CLASS ACTIONS. ***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) 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 violates the antitrust laws because all non-OEM parts are categorically inferior to OEM parts. The appeals court threw out plaintiffs' claims as lying outside the scope of the antitrust laws without addressing the propriety of certifying such a massive class action.

Status: Victory.

LEGAL REFORMS -- CLASS ACTIONS. ***State Farm Mut. Automobile Ins. Co. v. Lopez.*** On December 3, 2004, the Texas Supreme Court overturned a lower-court decision that certified a class action consisting of several million automobile insurance policy holders. The decision was a victory for WLF, which filed a brief urging that the class be decertified, and could go a long way toward clamping down on the excessive number of class action lawsuits being certified by state trial courts. 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. The court held that the trial court abused its discretion by certifying a class without first preparing a "trial plan" that explained how the court intended to bring the case to trial. The Texas Supreme Court explained that such trial plans are needed to allow reviewing courts to meaningfully evaluate whether certification of the class conforms with all the prerequisites for a class action -- including a showing that common issues of fact predominate over issues unique to individual class members and that the named plaintiffs can adequately represent all class members. The court also held that before certifying a class, a trial court should resolve all choice-of-law issues and determine whether the case should be permitted to go forward under the applicable state's laws. The Texas Supreme Court indicated that the trial

court's "certify now and worry later" approach had resulted in its failing to address the serious questions raised by the defendant under each of the issues enumerated above.

Status: Victory.

LEGAL REFORM -- CLASS ACTIONS. ***Avery v. State Farm Mut. Automobile Ins. Co.*** Oral argument was held in May 2003 in this important class action case. On November 6, 2002, WLF filed a brief in the Illinois Supreme Court, urging the court to overturn a massive $1.2 billion judgment against auto insurer State Farm, the largest judgment ever rendered in Illinois. The court's October 2, 2002 decision to review the case was a victory for WLF, which has been involved in this case for several years, because it believed that State Farm did 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 case involves 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 favor use of generic parts as a way of holding down repair costs. WLF's three briefs in the case -- filed not only in the Illinois Supreme Court but also in the trial court and the U.S. Supreme Court -- argued that the case should not have been certified as a nationwide class action when, as here, notice cannot be provided to the millions of class members; individual class members have little in common; and the laws of all 50 states should be applied to the various claims.

Status: Awaiting decision.

REGULATORY PROCEEDINGS

FEDERAL DEPOSIT INSURANCE CORPORATION

Definition of "Small Bank" under Community Reinvestment Act. On October 20, 2004, WLF and WLF's Economic Freedom Law Clinic at George Mason University School of Law filed formal comments in general support of the Federal Deposit Insurance Corporation's (FDIC) proposed changes to 12 CFR Part 345 that would increase the asset size limit of banks eligible for the streamlined small-bank Community Reinvestment Act (CRA) examination. FDIC's proposed changes would do three things: 1) change the definition of "small bank" to raise the asset size threshold to $1 billion regardless of holding company affiliation; 2) add a community development activity criterion to the streamlined evaluation method for small banks with assets greater than $250 million and up to $1 billion; and 3) expand the definition of "community development" to encompass a broader range of activities in rural areas.

DEPARTMENT OF INTERIOR
FISH & WILDLIFE SERVICE

Application of Environmental Rules to Combat Training Exercises. On August 2, 2004, WLF filed comments with the Fish & Wildlife Service regarding a proposed rule that gives the

Department of Defense the authority to determine that a proposed or an ongoing military activity is likely to result in a significant adverse effect on the sustainability of a population of a migratory bird species of concern. WLF supports the DoD's discretionary determination of significant adverse effects, which is defined as "an effect that could result in a population no longer being maintained at a 'biologically viable level for the long term.'" However, WLF does not support the proposed rules on suspension and withdrawal of the DoD's take authorizations because they are in conflict with the intent of the 2003 Authorization Act, and otherwise infringe on the President's Commander-in-Chief powers.

UNITED STATES SENTENCING COMMISSION

Criteria for Effective Compliance Programs. On May 1, 2004, WLF scored a partial victory when the Sentencing Commission deleted a proposed measure that was opposed by WLF. On March 15, 2004, WLF had filed comments with the United States Sentencing 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. WLF vigorously opposed the proposed revision as being unnecessary and burdensome, forcing companies to expend resources on monitoring even trivial regulatory infractions rather than serious criminal activity, and the Commission relented by deleting that provision. On May 19, 2002, WLF had also filed comments with the Advisory Group when it was first established 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 targeted for review.

DEPARTMENT OF JUSTICE
CRIMINAL DIVISION

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 argued that its investigations and prosecutions are consistent with free speech rights. WLF's response to the Justice Department will be published in early 2005 in a leading industry trade journal.

Decriminalization of Regulatory Offenses. The Justice Department still has under advisement WLF's critique and proposal sent last year to 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 request filed in 2001 on behalf of itself and Business Civil Liberties, Inc. (BCL), that the Department of Justice (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. Unfortunately, U.S. Attorneys have increasingly initiated criminal investigations and prosecutions arbitrarily for minor regulatory offenses when administrative and civil remedies would clearly be more appropriate. Criminal prosecutions in such cases against individuals often have draconian consequences because of the application of the U.S. Sentencing Guidelines that result in the imposition of substantial prison sentences for even minor or trivial infractions for first offenders.

Principles of Federal Prosecution. Pending before DOJ is WLF request filed in 2001 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.

ENVIRONMENTAL PROTECTION AGENCY

Petition to Close 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 as well. Following the attack on America on September 11, 2001, the EPA has 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. Not only is the EPA considering putting this information back on its website, the EPA continues to this day to make this sensitive information readily available for inspection by anyone with a driver's license, whether forged or not, who visits any EPA reading room located in each State and the District of Columbia. EPA is implementing some of WLF's suggestions.

Petition Governing EPA Inspections. On May 14, 2001, WLF filed a formal petition for rulemaking with the Environmental Protection Agency (EPA) that would require the EPA to provide regulated companies and businesses with a "Statement of Rights of Owners and Operators" before any EPA agents can enter and inspect the premises for possible violations of the myriad environmental laws and regulations administered by the EPA. For a further description of this petition, see the "Business Civil Liberties Project" section. The petition is pending before the EPA.

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 investigating all of the environmental justice complaints that have been filed with the EPA and will continue to oppose the EPA's environmental justice program. A draft policy was released in early 2001, and EPA's Administrator issued a policy statement on the topic in August 2001. EPA is conducting further review of the proposed guidance, and has recently issued a "toolkit" for businesses to help them evaluate environmental justice issues.

Petition to Adopt Guidelines Governing the Publication of Environmental Data Via the Internet. On May 15, 2001, WLF petitioned the EPA to adopt certain guidelines for publicizing environmental information via the Internet. First, WLF recommended that the EPA prohibit the release of data unless expressly authorized for publication by statute. Second, WLF recommended that the EPA clearly state on its website when particular activities are authorized by law, regulation, or permit. Third, WLF recommended that the EPA explain the nature of each environmental violation and its impact (or non-impact) on the local community. Fourth, WLF urged the EPA to include sites favorable to free enterprise alongside those that advocate environmental litigation. And fifth, WLF asked the EPA to prohibit the release of trade secrets and confidential business information. EPA is considering WLF's suggestions.

FEDERAL ENERGY REGULATORY COMMISSION

Prohibiting Public Access to Critical Information. On November 21, 2002, WLF, along with its Economic Freedom Law Clinic at George Mason University School of Law (Clinic), filed comments with FERC regarding the appropriate treatment of previously public documents in the aftermath of the September 11, 2001 terrorist attacks on the United States of America. WLF and the Clinic argued that it was in the public interest for FERC to use all available legal means, including invoking appropriate exemptions under the Freedom of Information Act, to restrict access to sensitive information. In particular, FERC should not disclose critical energy infrastructure information (CEII), the public release of which may assist would-be terrorists in

carrying out future terrorist acts. WLF and the Clinic filed similar comments on March 25, 2002 in an earlier related proceeding.

FEDERAL TRADE COMMISSION

False asbestos claims. On December 15, 2004, the FTC advised WLF that it will not take action against deceptive practices in asbestos cases. On July 7, 2004, WLF had petitioned the FTC to investigate attorney-sponsored mass screening programs that improperly generate large numbers of claims for asbestos injury on behalf of claimants who have not been injured. WLF's petition pointed to evidence from judicial proceedings and the news media indicating that asbestos claims have been improperly generated in large numbers in violation of federal law, with the intention and effect of deceiving courts and defrauding defendant businesses on a national scale.

Product placement. On March 26, 2004, WLF filed comments with the Federal Trade Commission and the Federal Communications Commission in opposition to a proposed rule on product placement from Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert had petitioned the FTC and the FCC in September, 2003, to adopt new regulations that would mandate an on-screen warning for all instances of product placement on television. WLF's comments in opposition to Commercial Alert noted that television product placement dates to the medium's earliest days. WLF also 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. WLF further argued that the proposed regulations would violate freedom of speech, as defined in U.S. Supreme Court cases.

HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICAID AND MEDICARE SERVICES

Proposals on Medicare Reimbursement. On September 13, 2004, WLF filed comments with HHS regarding that agency's proposal to modify the process of reimbursement for so-called "Part B" -covered drugs. WLF submitted a WLF Legal Opinion Letter dated June 18, 2004 authored by Glenn Lammi cautioning the Centers for Medicaid and Medicare Services that modifications to reimbursement rates and processes should ensure access to quality care and not delay market based pricing.

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.

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
CENTERS FOR MEDICARE AND MEDICAID SERVICES

Risks of medical device reuse. On September 10, 2004, WLF filed a Freedom of Information Act request with the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) seeking copies of all studies, reports, or memoranda within the past five years regarding the health risks of re-using medical devices. WLF intends to use the results of this request to educate policymakers and the public of CMS policies that are effectively compelling patients to re-use medical devices that the FDA has approved only for one-time use based on hygienic concerns.

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
FOOD AND DRUG ADMINISTRATION

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 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 claims by FDA staff.

WLF wrote to the new acting FDA commissioner on April 16, 2004, to urge prompt action on the issue.

FDA Request for Comments on First Amendment Issues. 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. On September 13, 2002, WLF filed initial comments with the Food and Drug Administration (FDA), urging the agency to modify its regulatory activities so that they no longer violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. WLF argued that recent court decisions, including WLF's victory in *Washington Legal Foundation v. Friedman,* make clear that FDA is subject to First Amendment constraints and that much of its regulatory activity does not conform to those constraints. WLF made its submission to FDA in response to FDA's May 16, 2002 request for comments on First Amendment issues.

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.

Proposal That Prescription Allergy Medications Be Switched to OTC Status. On May 11, 2001, WLF filed comments with the U.S. Food and Drug Administration, 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 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. While Claritan was recently approved for OTC status, the FDA is still considering the status of Allegra and Zyrtec.

NATIONAL INSTITUTES OF HEALTH

Abrogation of Patent Rights via "March-In" Petition. On September 17, 2004, the National Institutes of Health (NIH) sided with WLF in rejecting the petition of an activist group called Essential Inventions, which was seeking to abrogate the exclusive patent rights held by Pfizer in the medicine Xalatan. The "march-in" petition invoked the Bayh-Dole Act of 1980, which governs patents based in part on federally-funded research. WLF had filed comments opposing the petition on August 9, 2004, arguing that the Bayh-Dole Act does not authorize NIH to abrogate patent rights on the basis set forth by Essential Inventions – namely, that Pfizer had allegedly set excessive prices for the drug. WLF argued that the Bayh-Dole Act is not a price control statute.

NUCLEAR REGULATORY COMMISSION

Deleting Sensitive Materials from Government Websites. On December 31, 2001, WLF filed a petition with the Nuclear Regulatory Commission (NRC), urging the NRC to review its policies regarding posting sensitive information on its Internet site. The NRC's responsibilities include the regulation of all nuclear power plants in this country. Until September 11, 2001, the NRC provided detailed information about the location and operation of regulated facilities on its website. Since then, the NRC has removed some of the more sensitive information from its website. WLF urged the NRC not to re-post any of that information and to ensure that the information is no longer available in the NRC's public reading rooms. WLF argued that there is simply too great a danger that terrorist groups could attempt to use that information for nefarious purposes.

POSTAL RATE COMMISSION

Petition to Regulate Commercial Activities of U.S. Postal Service. On January 30, 2003, WLF and WLF's Economic Freedom Law Clinic at George Mason University School of Law, filed formal comments in support of a petition filed with the Postal Rate Commission (PRC) by Consumer Action and PRC's Office of Consumer Advocate to institute a proceeding to determine (1) whether the Commission has jurisdiction over fourteen specified services offered to the public without a prior request by the Postal Service for a recommended decision under 39 U.S.C.

§§ 3621, 3622, and 3623 of the Postal Reorganization Act ("PRA"), and (2) to establish rules that would require a full accounting by the Postal Service of the costs and revenues of non-jurisdictional domestic services so as to ensure that they are not being cross-subsidized by jurisdictional domestic services. Currently, the Postal Service engages in a variety of commercial activities in addition to selling postage, such as offering online payments services, phone cards, and other merchandise and services. On November 12, 2004, the PRC agreed with WLF's arguments and proposed a definition of "postal services" to limit the abusive practice.

SECURITIES AND EXCHANGE COMMISSION

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: 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, California, 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 before U.S. District Court Judge Marilyn Hall Patel. Judge Patel has raised troubling questions about the genesis of the case and the role of two of the lead plaintiffs and their attorneys. 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, Judge Patel was clearly troubled by the arrangement. "[It] disturbs me that the people who are going to drive the litigation are in fact people who are betting on the stock going down," Judge Patel told an attorney from Milberg Weiss. She was also troubled by the fact that Cardinal did not disclose its short positions in the stock and the role of Milberg Weiss in the litigation. On March 26, 2004, Milberg Weiss filed a response to Judge Patel's concerns, denying any wrongdoing. However, Terayon argued that Milberg's response raises more questions than it answers, and is conducting

discovery of Milberg Weiss. WLF is preparing a complaint similar to the one it filed with the SEC to be filed in July with New York Attorney General Eliot Spitzer.

Proposed Revisions to the "Wells Process." On November 24, 2003, WLF petitioned the SEC to revise its so-called "Wells Process" which provides a party under SEC investigation a formal opportunity to present its side of the case before the SEC decides to file formal charges against that party for violating the securities laws. WLF urged the SEC to adopt the recommendations made by Mitchell E. Herr in a Working Paper published by WLF's Legal Studies Division in October 2003.

SEC Freedom of Information Requests. On August 20, 2003, WLF filed a Freedom of Information Act (FOIA) request with the SEC seeking all enforcement documents relating to complaints filed with the SEC regarding short-selling and plaintiffs' attorneys, including documents generated in the course of investigating WLF's January 21, 2003 complaint.

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 its 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. The hedge funds short the stock and reap profits when the suit is filed due to the subsequent drop in the price of the stock. WLF subsequently submitted supplemental comments that included WLF's congressional testimony presented on May 22, 2003, on the same issue. In late September 2003, the SEC staff issued its report to the Commission, and proposed regulations will be issued later this year.

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 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.

In re: 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.

OFFICE OF THE COMPTROLLER OF THE CURRENCY, U.S. DEPARTMENT OF THE TREASURY

National Bank Preemption. On October 6, 2003, WLF filed comments with the Office of the Comptroller of the Currency (OCC) urging the agency to adopt an amended version of its proposal increasing the nationwide uniformity of legal requirements for OCC-regulated banks. OCC's proposal, issued on August 5, 2003, would clarify the applicability of state law to the activities of national banks. The proposal would preempt any state law that obstructs a national bank's authority to lend or take deposits, making clear that OCC has exclusive power to regulate those activities. WLF argued in its comments that the increased consolidation in the banking industry and the rapid growth of interstate banking – in response to technological improvements, increased mobility of consumers, and state and federal legal reforms – have created a greater need for national rules to govern banking products and operations. For banks operating in numerous states, WLF argued, a patchwork of inconsistent state legal requirements creates inordinate compliance burdens and undue obstacles to the provision of new banking products and services on a national level. WLF urged OCC to amend one provision of the proposal, however, concerning predatory real estate lending. The proposal would prohibit a national bank from making a loan secured by real estate where the loan is "based predominantly on the value of the borrower's collateral, without regard to the borrower's repayment ability." WLF's comments stated that the proposed rule does not take account of proper lending practices under which collateral is typically a crucial element of the decision to grant credit.

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

Commercial Free Speech. On October 21, 2003, WLF filed comments in opposition to proposed regulations that would impose excessive and unjustified restrictions on statements in 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. WLF noted that the U.S. 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.

NEW YORK ATTORNEY GENERAL'S OFFICE

In re: Complaint on Short-Selling and Class Actions. On July 1, 2004, WLF filed a complaint with the New York Attorney General's Bureau of Investor Protection and Securities requesting that New York Attorney General Eliot Spitzer investigate whether or not any New York 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. A similar complaint has been filed with the SEC.

ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION

Restrictions on Continuing Medical Education (CME). 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. WLF further argued that without the participation of top doctors, CME would no longer be the important source of new medical information that it is today. In October 2004, ACCME revised their guidelines.

NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS AND AMERICAN LAW INSTITUTE

Uniform Commercial Code. The American Bar Association's House of Delegates voted at its mid-year meeting in February, 2004, to approve proposed revisions to Articles 2 and 2A of the Uniform Commercial Code. WLF had submitted comments to the ABA, and earlier to the National Conference of Commissioners on Uniform State Laws (NCCUSL) and the American Law Institute (ALI), arguing against approval of the changes. WLF argued that the revisions -- if enacted by state legislatures -- would create excessive uncertainty in business transactions. The revisions also introduce new forms of tort-like liability that are properly within the province of tort law. WLF additionally submitted copies of its LEGAL BACKGROUNDER "Revised UCC Articles Erect New Hurdles For E-Commerce" by Holly K. Towle and a working draft of the WLF LEGAL BACKGROUNDER "Changes to UCC Section 2 Will Provide New Litigation Opportunities for Lawyers" by Jeff C. Dodd.

MICHIGAN SUPREME COURT: ASBESTOS LITIGATION REFORM

Inactive Docket Proposal. On August 25, 2003, WLF joined with over a dozen leading industry and trade organizations in urging the Michigan Supreme Court to adopt an administrative procedure 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. In its filing, WLF requested that the Michigan Supreme Court grant a petition filed recently 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.

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.

JUDICIAL INQUIRY BOARD OF ILLINOIS

Judicial Misconduct. On September 14, 2004, the Judicial Inquiry Board of Illinois informed WLF that it would not bring ethics charges based on WLF's misconduct complaint against Nicholas G. Byron of the Madison County, Illinois Circuit Court. WLF had filed its complaint on April 23, 2004, based on reported comments by Judge Byron from the bench in which he indicated that he intended to ban the national law firm of King & Spalding from all Madison County cases. The statements appeared to be in retaliation for a speech delivered two days earlier by former United States Attorney General Griffin Bell of that firm, in which Mr. Bell criticized the handling of asbestos cases in Madison County. WLF's complaint argued that any such action would violate the Illinois Code of Judicial Conduct.

AMERICAN BAR ASSOCIATION

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 not only torture, but vaguely defined "degrading" or "cruel" treatment of any terrorist suspect who is in the physical control of United States government authorities. Read broadly, the ABA resolution could prohibit interrogators from using effective and well-recognized techniques such as shouting at prisoners, or waking them up to ask them questions about terrorist activities, because that might constitute sleep deprivation. While not unanimous, the overwhelming majority of the 539 members of the House of Delegates rejected arguments presented that day by WLF that the ABA's extreme position was wrong both as a matter of law and sound public policy. 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.

SPECIAL PROJECTS

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 WLF 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 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 litgation 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 two 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; (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; (4) filed comments with the SEC on hedge fund regulation; (5) filed formal objections and briefs in four class action cases. In addition, WLF published several op-eds and Legal Studies publications on the topic; and (6) met with the General Counsel of the SEC on October 5, 2004 to discuss WLF's initiatives pending with the SEC. 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.

WLF Economic Freedom Law Clinic at George Mason University School of Law

George Mason University School of Law in Arlington, Virginia and the Washington Legal Foundation proudly inaugurated the *Washington Legal Foundation Economic Freedom Law Clinic at George Mason University School of Law* beginning with the 1999-2000 academic year. Students enrolled in WLF's Clinic are exposed to a wide variety of public interest law and

public policy issues advanced through litigation, regulatory, and advocacy strategies primarily from a pro-free enterprise, limited government, and economic freedom perspective. The Clinic thus meets a critical need to provide law students with an opportunity to participate in the kind of public interest legal activities that are sorely lacking in the clinical program at most law schools today.

Students in both the day and evening divisions have the opportunity to participate in "hands-on" legal activities in conjunction with WLF. Taught by WLF's Senior Executive Counsel Paul Kamenar, the Clinic's curriculum includes substantive topics from a broad range of constitutional, statutory, and administrative law issues, such as the Takings Clause and property rights; Commerce Clause jurisdiction; Due Process Clause; First Amendment and commercial free speech; regulation of business; administrative law and procedure; environmental law and regulation; product liability law, punitive damages, class action cases, and other civil justice and criminal law topics. Students also attend and critique Supreme Court arguments in WLF-supported and other cases, as well as congressional and agency hearings.

Projects of WLF's Clinic during 2004 included:

* Drafting Freedom of Information Act requests with the EPA and other agencies seeking release of documents regarding abusive investigative practices against businesses;

* Researching lawsuits filed by activist groups which threaten our national security;

* Researching immigration policies and procedures with respect to illegal aliens that may pose a threat to national security; and

* Researching pending class action lawsuits for opportunities to file objections to excessive attorney's fees.

Students in the Clinic have also drafted WLF LEGAL BACKGROUNDERS, some of which have been published in professional trade publications. Some of the recent topics include:

* The lawfulness of rulings by the International Court of Justice regarding the compliance by the United States to treaties when enforcing criminal laws.

* Making notices of class action lawsuits more effective.

* The ACLU's challenge to the Homeland Security Department's "no fly list."

* The legality of the military's power to detect and capture suspected terrorists on U.S. soil under the Posse Comitatus Act.

* Reining in EPA's enforcement authority under CERCLA.

* Limiting attorneys' fees in class action cases

* Property rights at risk under the Public Trust Doctrine

* Copyright law and internet file sharing services

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 that 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 Fredrick 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 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 December 22, 2003, WLF filed a motion in the U.S. Court of Appeals for the D.C. Circuit in *Massachusetts v. EPA,* seeking permission to file a brief in this case where Massachusetts, other states, and environmental groups are suing EPA for failing to regulate carbon dioxide; the motion was granted. Massachusetts and their allied states filed their opening briefs on June 26, 2004, and WLF filed its brief on November 1, 2004.

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 throughout 2004 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 discussed.

Titles and summaries of the op-eds published during 2004 include:

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)

Freedom. Justice. Free Enterprise.
(Since 1977, WLF has fought for economic and individual rights through litigation and educational campaigns)

"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)

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

Fueling National Insecurity.
(Energy development in America has been unnecessarily limited by activists and overly restrictive regulations)

A Pause for Foresight.
(Activist courts have provided suspected terrorists with civil liberties that could endanger all Americans)

Government's Lawsuit Addiction.
(Department of Justice's lawsuit against tobacco companies is misguided and a waste of valuable resources)

National Security and Energy
(American dependence on foreign oil is the result of activists' efforts to prohibit domestic exploration and production)

Disenfranchised by Lawyers

(Trial lawyers and overzealous state attorneys general impose ideological agenda by litigation rather than by democratic legislation)

Media Briefings & Educational Programs

Reaching out to journalists in the national media is critical to communicating the 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 Board Chairman Dick Thornburgh. WLF's "Media Nosh" press conferences focus on a different, timely legal policy topic each week. 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.

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 the electronic and print media such as *USA Today*, *National Law Journal*, the *Wall Street Journal*, the *New York Times*, the *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.

WLF media briefings during 2004 included the following:

Supreme Court Briefing

Previewing the 2004 U.S. Supreme Court Term, September 15, 2004
- **Donald B. Verrilli, Jr.**, Jenner & Block
- **Gregory G. Garre**, Hogan & Hartson LLP

Review of 2003 Supreme Court Term, June 30, 2004
- **The Honorable Dick Thornburgh**, Kirkpatrick & Lockhart (Moderator)
- **The Honorable Kenneth W. Starr**, Pepperdine University, School of Law
- **Andrew J. Pincus**, Mayer, Brown, Rowe & Maw LLP
- **Richard Klingler**, Sidley Austin Brown & Wood LLP

Assessing the High Court At Mid-Term, February 11, 2004
- **Michael A. Carvin**, Jones Day
- **Jeffrey A. Lamken**, Baker Botts L.L.P.
- **Andrew J. Pincus**, Mayer, Brown, Rowe & Maw LLP

Media Briefings

***Veneman v. Livestock Marketing*: Compelled Commercial Speech Pays Another Visit to the Supreme Court**, December 2, 2004

- **Philip C. Olsson**, Olsson, Frank and Weeda, P.C.
- **Gregory G. Garre**, Hogan & Hartson L.L.P.
- **Thomas C. Goldstein**, Goldstein & Howe, P.C.

On the '05 Agenda: Priorities for State and Federal Financial Services Regulators, November 18, 2004

- **Bert Ely**, Ely & Company, Inc.
- **Charles M. Horn**, Mayer, Brown, Rowe & Maw LLP
- **Timothy R. McTaggart**, Willkie Farr & Gallagher LLP

Federal Sentencing In Flux: The Impact of *Blakely* on White Collar Criminal Enforcement, August 4, 2004

- **Roscoe C. Howard, Jr.**, Shepperd, Mullin, Richter & Hampton LLP
- **Ronald H. Weich**, Zuckerman Spaeder LLP
- **David C. Frederick**, Kellogg, Huber, Hansen, Todd & Evans, P.L.L.C.

Courts, Commerce & Regulation: How The Judiciary Can Help (And Hinder) Free Enterprise in America, June 22, 2004

- **The Honorable Randall T. Shepard**, Supreme Court of Indiana
- **Lawrence H. Mirel**, District of Columbia Department of Insurance, Banking & Securities
- **Peter A. Bisbecos**, National Association of Mutual Insurance Companies

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

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

Antitrust on the World Stage: Microsoft, Mario Monti, and Future of Harmonizing Competition Policy, April 28, 2004

- **Charles F. (Rick) Rule**, Fried, Frank, Harris, Shriver & Jacobson
- **William J. Kolasky**, Wilmer Cutler Pickering LLP
- **Albert A. Foer**, American Antitrust Institute

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

"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

Environmental Justice Project

During 2004, WLF continued to monitor developments by the Environmental Protection Agency to implement EPA's Environmental Justice program to thwart economic development in certain urban areas. The EPA and activist groups have alleged that the siting of facilities in communities where there is a large minority population constitutes discrimination under Title VI of the Civil Rights Act because those facilities allegedly affect those communities disproportionately. WLF has made legal and policy arguments against these activists in the courts, before the Environmental Protection Agency (EPA), and in the public arena arguing that the facilities meet all the strict federal and state pollution requirements and that there is no showing of any intentional discrimination.

WLF filed extensive comments with the EPA opposing its Title VI Interim Guidance on policy and legal grounds. WLF also filed petitions with the EPA to intervene in all pending Title VI administrative complaint proceedings, requesting that all pending complaints be dismissed. Because of WLF's effectiveness, activist groups filed a complaint against WLF with the EPA alleging that WLF's opposition to their Environmental Justice complaints constitutes illegal harassment. WLF also monitored the EPA's Environmental Justice advisory committees and submitted its views to them. WLF, along with WLF's Economic Freedom Law Clinic at George Mason University School of Law, has investigated funding grants made by EPA to activist groups and universities to promote EPA's Environmental Justice agenda. WLF's Legal Studies Division has published several publications on Environmental Justice and sponsored a media briefing on the issue as well. WLF attorneys have also appeared before corporate trade groups to present WLF's views and work in this important area of the law.

WLF is also coordinating its efforts with the National Association of Manufacturers' Business Network for Environmental Justice (BNEJ), and reviewing EPA's recently issued Environmental Justice "Toolkit" for businesses.

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. WLF inaugurated Phase Five of SCALES in 2001 to require attorneys to submit to Bar authorities court rulings that reduced their attorneys' fees for possible disciplinary action for charging excessive fees.

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 counter-claims 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 has filed petitions with all 50 states as well as the District of Columbia and Puerto Rico, thereby completing this phase of WLF's 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.

PHASE THREE: JUDICIAL CAMPAIGN CONTRIBUTIONS. WLF continues to work on this third phase of WLF's SCALES project, 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 contributions rules in that state. In addition to California, WLF filed similar petitions in Alabama and in 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. Accordingly, WLF inaugurated Phase Four of its SCALES Project during 1997 with the filing of petitions to make the disciplinary process more public in California, Alabama, Florida, Texas, Illinois, Ohio, Missouri, Georgia, Colorado, Maryland, and Pennsylvania. During 1998, WLF filed additional petitions in Washington, Mississippi, South Carolina, New York, New Jersey, Michigan, Minnesota, Virginia, and Louisiana. In June 1998, Pennsylvania authorities responded favorably to WLF's petition and is seeking WLF's assistance as they examine their disciplinary process. Virginia has also expressed a strong interest in WLF's petition. With the filing in Montana in December 2001, WLF completed filing petitions in all 50 states and the District of Columbia. WLF will continue to monitor these states for any proposed revisions to their attorney disciplinary program.

PHASE FIVE: EXCESSIVE ATTORNEYS' FEES. On June 15, 2001, WLF launched a new phase of its SCALES Project by petitioning the Florida Bar to require attorneys to file with Bar authorities a copy of any court decision reducing a fee award or application as being excessive or improper, so that appropriate disciplinary proceedings against those attorneys may be instituted. WLF plans to file similar excessive fee petitions over the coming months in all the other states. All state Bars prohibit attorneys from charging or collecting unreasonable or excessive fees. Disciplinary actions have been taken against attorneys when a client files a complaint with Bar authorities alleging that the attorney has charged an excessive fee. However, in many cases, a court will reduce a fee award where the attorney is required to submit his or her fee request for court approval. In those cases, a Bar complaint is usually not filed, although it has been judicially determined that the fee was excessive. Such findings are made where a court determines that the fee application contains inflated or false claims, or where the amount awarded is excessive based on the amount of work performed, such as in class action cases. WLF's petition would require attorneys to file those adverse decisions with the Bar so that the Bar can decide whether disciplinary proceedings are appropriate. WLF also filed petitions with the State Bars of Alabama and Texas.

Business Civil Liberties Project

WLF continued throughout 2004 to fight for business civil liberties via litigation, administrative proceedings, and publications. In late 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 (FOIA) requests recently filed with the Environmental Protection Agency (EPA) and five other regulatory agencies, WLF is demanding 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 other office. WLF is also asking the agencies to disclose their training manuals which will disclose enforcement policies. WLF's probe into agency misconduct was spurred by a number of instances where enforcement agents had harassed and threatened business owners, their employees, and others in the course of investigating suspected violations of agency regulations. In addition to the EPA, WLF's investigation is directed at the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), the Department of Interior's Office of Surface Mining and Bureau of Land Management (BLM), and the U.S. Forest Service of the Department of Agriculture. WLF is looking at other regulatory agencies as well for future FOIA demands. The FOIA requests were drafted by students enrolled in WLF's Economic Freedom Law Clinic at George Mason University School of Law. WLF and the Clinic plan to file suit against the agencies if they fail to release the requested documents.

WLF will use the information to support reform of agency enforcement policy that would require agencies to inform companies what rights they have when the agency conducts an inspection of their business. Such rights include the right to have counsel, right to remain silent, right to videotape or record the search, and the right to obtain split samples of any evidence obtained by the EPA.

WLF also met with Thomas Sansonetti, Assistant Attorney General of the Environment and Natural Resources Division of the Justice Department, to discuss DOJ's environmental criminal enforcement policy. Attending the meeting at the Justice Department with WLF was George Terwilliger III, former Deputy Attorney General. WLF also met with DOJ officials on April 28, 2003, to discuss the issue, and submitted comments to U.S. Attorney Timothy Burgess of Alaska who chairs a subcommittee of the Attorney General's Advisory Committee of U.S. Attorneys. WLF is continuing to research and develop initiatives that would enhance business civil liberties and deter prosecutorial abuses.

In February 2003, WLF was the only public interest legal group that opposed recently issued Department of Justice prosecutorial guidelines that would unfairly intrude on the attorney-client privilege between counsel and corporations. WLF was also the only public interest organization that filed comments in March 2004 critical of the U.S. Sentencing Commission's proposed guidelines which will make it harder for companies to comply with the myriad laws and regulations. WLF was also the only pro-free enterprise public interest organization to file briefs in the U.S. Sentencing Guidelines cases before the U.S. Supreme Court.

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.

On November 5, 2003, WLF petitioned Judge Anthony Scirica (Chief Judge of the U.S. Court of Appeals for the Third Circuit), asking him to cancel a November 10 asbestos-related presentation scheduled in connection with the Third Circuit's annual Judicial Conference. WLF objected that the panelists making the presentation (entitled, "Mass Tort Litigation and Bankruptcy") consisted of several of the nation's leading asbestos tort-claim litigators, all of whom have major appeals pending before the Third Circuit. The Third Circuit admonished all the panelists not to discuss issues that may come before the court.

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

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 2004, 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, CONVERSATIONS WITH, and MONOGRAPHS in 2004.

COUNSEL'S ADVISORIES

CMS Advises On Reimbursement For Off-Label Use of Drugs
By **David Price**, Senior Vice President for Legal Affairs of the Washington Legal Foundation.

FBI Arrests Drug Injury Claimants For Filing False Claims
By **David Price**, Senior Vice President for Legal Affairs of the Washington Legal Foundation.

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.

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.

NIH Invites Public Comment On Petition Seeking Drug Price Controls
By **David Price**, Senior Vice President for Legal Affairs of the Washington Legal Foundation.

Investigations Of Drug Promotion Threaten First Amendment Rights
By **Richard A. Samp,** Chief Counsel to the Washington Legal Foundation.

Petitions Seek Investigations Of Asbestos Plaintiff Recruitment
By **David Price**, Senior Vice President for Legal Affairs of the Washington Legal Foundation.

Appeals Court Opens Door To Suits On Medicare Agency Decisions
By **David Price**, Senior Vice President, Legal Affairs, of the Washington Legal Foundation.

New State Law Permits Private Bounty Hunter Suits Against California Employers
By **Jeffrey M. Tanenbaum**, a partner in the San Francisco office of the law firm Nixon Peabody, LLP.

Complaint Urges SEC & DOJ Investigation Of Short-selling In Class Action
By **Paul Kamenar**, Senior Executive Counsel of the Washington Legal Foundation.

LEGAL OPINION LETTERS

State Driver's License Policies For Illegal Immigrants Should Survive Legal Attacks
By **Barnaby W. Zall**, an attorney in private practice in Rockville, Maryland.

West Virginia Supreme Court Sets High Bar For Plaintiffs In Medical Monitoring Cases
By **Sean Wajert**, who is a partner at Dechert LLP and the chair of its Mass Torts & Product Liability practice

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.

High Court Should Review Ruling On Securities Fraud "Safe Harbor"
By **Joseph De Simone**, a partner, and **Matthew D. Ingber** and **Evan A. Creutz**, associates, in the New York office of the law firm Mayer, Brown, Rowe & Maw LLP.

SEC Enforcement Action Reflects Approach On Market "Gatekeepers"
By **James H. Nixon III** and **J. Chase Cole**, partners in the Nashville, Tennessee law firm Waller Lansden Dortch & Davis, where they are members of the Securities Practice Group.

Federal Court Upholds Oil And Gas Exploration On Leased Public Lands
By **L. Poe Leggette**, a partner, and **Bret A. Sumner**, a senior associate, in the Washington, D.C. office of the law firm Fulbright & Jaworski L.L.P.

"Piggyback" Class Action Suits Don't Merit Exorbitant Fees
By **Paul D. Kamenar**, Senior Executive Counsel of the Washington Legal Foundation.

Federal Appeals Court Rules Alcohol Ad Ban Unconstitutional
By **Eric S. Sarner**, a Counsel in the New York office of Skadden, Arps, Slate, Meagher & Flom LLP, where he focuses on products liability, First Amendment and regulatory matters.

Administrative Reform Needed To Ensure Quality Of Federal Agency Data
By **Gerald H. Yamada**, a partner at the law firm of O'Connor & Hannan, Washington, D.C. He was EPA's Principal Deputy General Counsel for 13 years and Acting EPA General Counsel over several extended periods.

Stopping Frivolous Litigation And Protecting Small Businesses
By **Congressman Lamar Smith**, who has represented the residents of the 21st Congressional District of Texas since 1987.

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.

Medicare Drug Reimbursement Reform Presents Challenges And Opportunities
By **Glenn Lammi,** Chief Counsel of the Washington Legal Foundation's Legal Studies Division.

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.

Federal Drug Law Preempts California's Proposition 65
By **Gene Livingston,** a Principal in the San Francisco Law Firm Livingston & Mattesich. **Dan Fuchs** is a senior associate with the firm.

New Federal Law Provides Additional "Sticks & Carrots" To Antitrust Prosecutors
By **Stanley Gorinson** and **Connie Robinson**, partners in the Washington, D.C. office of the law firm Kilpatrick Stockton LLP.

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.

President's Authority Clear On Recess Appointments Of Judges
By **H. Christopher Bartolomucci**, a partner in the Washington, D.C. office of Hogan & Hartson L.L.P. who, from 2001 to 2003, served as Associate Counsel to President George W. Bush.

Mississippi Joins The Ranks Of Tort Reform Success Stories
By **David W. Clark**, a partner in the Jackson, Mississippi office of the law firm Bradley Arant Rose & White LLP.

Court Limits Activists' Ability To Dispute ESA Listing Decisions
By **Sandra Snodgrass**, an associate in the Denver office of the law firm Holland & Hart LLP where she is a member of the firm's environmental compliance group.

Public Agency Or Private Entity? The Janus Face Of The Postal Service
By **Paul Kamenar**, Senior Executive Counsel to the Washington Legal Foundation.

Judge's Theory Unlikely To Support "Global Warming" Lawsuits
By **David Pettit**, a partner in the Los Angeles law firm Caldwell, Leslie, Newcombe & Pettit.

What Is The Law Today? Better Check The EPA's Website
By **Robert J. Martineau, Jr. and Edward M. Callaway**, members in the Nashville, Tennessee law firm of Waller Lansden Dortch & Davis, PLLC.

Key Federal Court Rules On Securities Fraud Pleading Standard
By **Clifford Thau**, a partner, and **Gregory Zimmer**, an associate in the New York office of the law firm Vinson & Elkins L.L.P.

State Suit On Federal Banking Rules Imperils Consumers' Access To Loans
By **James M. Rockett**, a partner in the law firm of Bingham McCutchen LLP where he co - heads the Financial, Corporate and Regulatory practice.

Coming To Terms With America's Criminal Alien Crisis
By **U.S. Representative Charlie Norwood**, who represents the State of Georgia's Ninth Congressional District.

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.

State High Court Rejects Daubert But Embraces Scientific Gatekeeping
By **Ninette Byelich**, an associate in the Philadelphia office of the law firm Schnader Harrison Segal & Lewis LLP.

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.

Courts Wield Harsh Penalties For Abusing The Discovery Process
By **Evelyn Alfonso**, an associate in the Newark, New Jersey law firm Podvey, Sachs, Meanor, Catenacci, Hildner & Cocoziello, P.C.

Appeals Court Sets OSHA Straight On "Willful" Violations Of Law
By **Arthur G. Sapper,** a partner with the OSHA Practice Group at McDermott, Will & Emery.

Proper Management, Not Courts Can Best Control Litigation Costs
By **Lawrence A. Salibra II**, Senior Counsel of Alcan Aluminum Corporation.

LEGAL BACKGROUNDERS

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.

Federal "E-Discovery" Rules Proposal Requires Scrutiny And Comment
By **Alfred W. Cortese, Jr.,** of Cortese PLLC, Washington, D.C. Mr. Cortese 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.

Drug Price Regulation By Lawsuit Hazardous to American's Health
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.

Empower Shareholders, Not Courts and Lawyers, To Deter Corporate Wrongdoing
By **Patrick M. Garry,** a visiting professor at the South Dakota School of Law.

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.

Sarbanes-Oxley's Retroactive Impact On Fraud Suits Remains Uncertain
By **Jeffrey B. Grill,** a partner, and **Damon D. Colbert,** an associate, in the Washington, D.C. office of the law firm Shaw Pittman LLP.

The Community Reinvestment Act: Will Current Debate Determine Its Future?
By **Bruce O. Jolly** and **John B. Beaty,** partners in the Washington, D.C. office of the law firm Venable LLP, where they practice in the Banking and Financial Services area.

The Attorney-Client Privilege: A Casualty Of Post-Enron Enforcement
By **John M. Callagy,** a partner with, and Chairman of, the New York law firm Kelley Drye & Warren LLP.

Corporate Governance Reforms Shouldn't Weaken Directors' Role
By **Timothy Hoeffner,** a partner, and **Katayun Jaffari,** an associate, with the law firm Saul Ewing LLP.

High Court Should Resolve Dispute Over Key Patent Law Requirement
By **Christopher J. Renk,** managing partner of the law firm of Banner & Witcoff, Ltd. and an adjunct professor at the Georgetown University Law Center where he teaches Patent Trial Practice, and Michael L. Krashin, a 2004 summer associate at the firm.

Lawsuits Targeting Alcohol Ads Tread On Free Speech Rights
By **John J. Walsh,** Senior Counsel to the New York City law firm Carter Ledyard & Milburn LLP.

Criminal Antitrust Enforcement: A Global Challenge
By **Steven M. Kowal,** a partner in the Chicago office of the law firm Bell, Boyd & Lloyd LLP where he heads the firm's White Collar Criminal Defense Group and is a member of the antitrust department.

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.

Passage Of House Bill Advances Important OSHA Reforms
By **Arthur G. Sapper,** partner in the OSHA Practice Group of McDermott, Will & Emery LLP. He is a former adjunct professor of OSHA law, and the former Deputy General Counsel of the Occupational Safety and Health Review Commission.

Cooperation In SEC Enforcement: The Carrot Becomes The Stick
By **Russell G. Ryan,** partner in the Washington, D.C. office of King & Spalding LLP and a former Assistant Director of Enforcement at the Securities and Exchange Commission.

Is Sarbanes-Oxley Vulnerable To Constitutional Challenge?
By **Steven M. Salky** and **Adam L. Rosman** who are, respectively, partner and Counsel at Zuckerman Spaeder LLP in Washington, D.C.

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 the firm.

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 and Hampton 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.

Broudo V. Dura Pharmaceuticals: High Court Wades Into Murky Waters Of Securities Fraud Litigation
By **Lyle Roberts,** a partner in the Reston, Virginia office of Wilson Sonsini Goodrich & Rosati. **Paul Chalmers** is a special counsel, and **Gerard Stegmaier** is an associate at the firm.

Heavyweight Litigation: Will Public Nuisance Theories Tackle The Food Industry?
By **Charles H. Moellenberg, Jr.,** a partner in the international law firm Jones Day in its Pittsburgh office.

Florida High Court Should Reject "Regulation Through Litigation"
By **Glenn Lammi,** Chief Counsel of the Washington Legal Foundation's Legal Studies Division.

High Stakes Communications: Wishful Thinking vs. Real World Effectiveness
By **Eric Dezenhall,** the President of Dezenhall Resources, Ltd., and author of four books, including the non-fiction study, *Nail 'em!: Confronting High Profile Attacks on Celebrities and Businesses* and the new damage control novel, *Shakedown Beach.*

New Ohio Asbestos Reform Law Protects Victims And State Economy
By **Kurtis A. Tunnell,** a partner with the law firm of Bricker & Eckler LLP and the Chair of the firm's Government Relations Practice Group; **Anne Marie Sferra Vorys,** also a partner with the firm; and **Miranda C. Motter,** an associate with the firm practicing in government relations.

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.

"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.

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.

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, and former National Legal Director of the ACLU.

Is Criminal Enforcement Needed To Combat Alleged Corporate Conflicts Of Interest?
By **Kim Baker,** a member of the Seattle office of the law firm Williams, Kastner & Gibbs, PLLC.

Regulation And The Role Of The Courts: Drawing A Line In A Sandstorm
By **Peter A. Bisbecos,** Director, Legislative and Regulatory Affairs, of the National Association of Insurance Companies.

Activists' Product Placement Proposal Threatens Commercial Free Speech
By **Douglas J. Wood,** a partner at Reed Smith, LLP, a top 25 international law firm, and head of Reed Smith Hall Dickler, the firm's advertising and marketing practice.

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.

Avoiding And Settling State Attorney General Lawsuits
By **Don Stenberg,** who served as Nebraska's Attorney General from 1991 to 2003 and is presently Of Counsel to the Omaha, Nebraska law firm of Erickson & Sederstrom.

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.

Losing More Than Weight: Unscientific "War" On Obesity Will Trim Personal Freedoms
By **John C. Luik,** an independent public policy researcher whose work focuses on the use of science in policy and the question of government intervention to change "risky" behaviors. He is a former Senior Associate of the Conference Board of Canada's Niagara Institute, and is the co-author with Mike Waterson of the 1996 text ADVERTISING AND MARKETS.

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.

Federal Court Raises Uncertainty For ESA "No Surprises" Policy
By **David J. Hayes,** a partner and Chair of the Environment, Land and resources Department at the law firm of Latham & Watkins, LLP, located in Washington, D.C., and **Janice M. Schneider**, a senior associate with the firm.

Will Federal Court Ruling Torpedo the "Submarine Patent"?
By **George L. Graff,** a litigation partner specializing in intellectual property law at the law firm Paul, Hastings, Janofsky & Walker LLP in New York and **Adam E. Kraidin,** a senior corporate associate specializing in intellectual property law at the firm.

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.

Study On Class Actions Attorney Fees Fails To Undermine Case For Reform
By **Victor E. Schwartz** and **Kimberly D. Sandner**, attorneys with the law firm Shook, Hardy & Bacon L.L.P. in Washington, D.C.; and **Sherman Joyce**, President of the American Tort Reform Association.

Innovation At A Crossroads: Microsoft, Mario Monti & 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.

A Progress Report On Rule 23(f): Five Years Of Immediate Class Certification Appeals

By **Brian Anderson**, a partner in the Washington, D.C. office of O'Melveny & Myers LLP specializing in class actions and other complex litigation and **Patrick McLain**, who is presently a law clerk to The Honorable Jane A. Restani of the U.S. Court of International Trade.

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.

Does Reprocessing Of Medical Devices Tread On Trademark Rights?
By **James Dabney Miller**, a partner with the law firm King & Spalding LLP.

"Informal" EPA Waste Regulation Treads On Due Process Protections
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Self-Evaluative Privilege Would Benefit Insurers And Their Customers
By **Peter A. Bisbecos**, Legislative and Regulatory Counsel of the National Association of Mutual Insurance Companies.

Lawyers, Other Corporate Advisers Face Exposure To Securities Claims
By **Steven S. Scholes**, a partner in the Trial Department of the law firm McDermott, Will & Emery, resident in its Chicago office, and co-chair of the firm's Securities Litigation Practice Group, as well as its SEC Defense Group.

Engineering Legal Risk Management Into Agricultural Biotechnology
By **Thomas P. Redick**, a member of the law firm Gallop, Johnson & Neuman, L.C. in St. Louis.

The Seven Myths Of Highly Effective Plaintiffs' Lawyers
By **Steven B. Hantler**, Assistant General Counsel, DaimlerChrysler Corporation.

WORKING PAPERS

The "Race To The Top" In State Corporate Law: The Delaware Model
By **Rolin P. Bissell,** a partner in the Corporate Counseling and Litigation Section of the Wilmington, Delaware law firm of Young Conaway Stargatt & Taylor LLP.

The European Commission's Decision In The *Microsoft* Case: An Economic Perspective
By **Peter Passell,** a senior fellow at the Milken Institute.

Epidemiologic Evidence In Public And Legal Policy: Reality Or Metaphor
By **Gio Batta Gori, ScD, MPH,** the director of the Health Policy Center of Bethesda, Maryland and a former deputy director at the U.S. National Cancer Institute.

How We Lost Our Way: The Road To Civil Justice Reform

By **James M. Wootton**, a partner with the law firm Mayer, Brown, Rowe & Maw, LLP in its Washington, D.C. office. Foreword by **Thomas A. Gottschalk**, Executive Vice President & General Counsel of General Motors Corporation.

Information Security Vulnerabilities: Should We Litigate Or Mitigate?
By **Jeffrey D. Neuburger**, a partner in the New York office of the law firm Raysman Millstein Felder & Steiner LLP and the Chair of the firm's Information Technology Practice Group, and **Maureen E. Garde**, an associate at the firm and member of that practice group.

Dispelling The Myth: Advertising Bans And Alcohol Consumption
By **John C. Luik**, a private social sciences and public policy researcher who has taught philosophy and management studies at a number of universities, and was Senior Associate of the Conference Board of Canada's Niagra Institute.

CONTEMPORARY LEGAL NOTES

Understanding and Complying With The "CAN-SPAM" Act
By **Kristen J. Mathews**, an associate in the New York office of the law firm Brown Raysman Millstein Felder & Steiner LLP.

New EU Rules On "GMO" Food And Feed: Details And Analysis
By **Mark Mansour**, a partner with the law firm of Morgan Lewis, LLP and **Sara Key**, an associate with the firm.

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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.

CONVERSATIONS WITH

***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.

PUBLIC APPEARANCES

Highlights of public appearances made by WLF attorneys during 2004 include:

* January 23, WLF Chief Counsel Richard 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.

* January 26, Samp was interviewed on CBS Radio regarding *Sosa v. Alvarez-Machain*, a Supreme Court case that addresses whether individuals may sue in federal court for alleged violations of international law.

* February 24, Samp was interviewed on CBS Radio regarding *U.S. v. Flores-Montano*, a Supreme Court case that addresses constitutional limitations on the federal government's power to inspect vehicles entering the country.

* February 26, WLF Senior Executive Counsel Paul 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. Other speakers included Steve Hantler, Assistant General Counsel of DaimlerChrysler, James Copland, Director of the Center for Legal Policy of the Manhattan Institute, and John Stossel, co-anchor of ABC's 20/20 show.

* February 27, Kamenar was a featured panelist on capital punishment debating a representative of the ACLU before a group of 300 high school students sponsored by the National Youth Leadership Forum on Law.

* 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.

* March 19, Kamenar discussed the role of the Supreme Court and important cases pending before the Court with a group of college students from Marquette University.

* March 24, Kamenar was a featured panelist debating capital punishment with a representative from the ACLU and the American Bar Association before a group of law students at George Washington University Law School in an event sponsored by the school's American Constitution Society and the National Lawyers Guild.

* March 29, Samp spoke on recent developments in the Supreme Court before a group of 400 high school students visiting Washington sponsored by the Close-Up Foundation.

* March 31, Samp was a panelist at a forum sponsored by the Environmental Law Institute in Washington, DC. Samp addressed the government's obligation to reimburse property owners when it seizes their property in pursuit of environmental goals.

* April 12, Samp was interviewed on ABC-Radio regarding national security cases pending in the U.S. Supreme Court.

* April 13, Kamenar spoke before the Close-Up Foundation at the Jewish Center in Washington, D.C., on the role of the judiciary.

* April 26, Samp addressed a group of high school students visiting Washington under the auspices of Panim el Panim (a Jewish youth group) on the death penalty.

* April 29, WLF Chairman and General Counsel Daniel Popeo, spoke at Cazenovia College in Cazenovia, New York, on "Public Advocacy and Nonprofit Organizations."

* April 29, WLF co-sponsored a briefing in Boston with Kirkpatrick & Lockhart LLP on "Homeland Security-Venture Capital Investment and Business Opportunitites."

* 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' detention of enemy combatants.

* 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 25, WLF Chief Counsel, Legal Studies Division, Glenn Lammi discussed energy policy and the war on terrorism on the Pat Whitely Show, WRKO, Boston.

* May 26, Popeo addressed the Washington University's Widenbaum Center Breakfast Meeting in St. Louis, Missouri. Popeo's speech, "Is Litigation Good for America," was presented before business leaders, media, professors, and students.

* June 10, 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 seeking earlier availability of investigational drugs for the terminally ill.

* July 15, Kamenar, Samp, and Price met with a group of African-American pre-law students from various colleges and universities at WLF's offices to discuss public interest law and the legal profession. The students were part of the internship program sponsored by the Institute for Responsible Citizenship. One of the students had interned at WLF's offices during the summer.

* September 13, 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.

* September 20, Samp was interviewed on KNX-Radio (the CBS affiliate in Los Angeles) regarding the federal government's racketeering lawsuit against the tobacco industry.

* On October 19, Samp was interviewed on KPCC-Radio in Los Angeles regarding claims that the USA Patriot Act unnecessarily infringes on civil liberties.

* On October 29, 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.

* On November 9, Samp was interviewed on Voice of America regarding, *Hamdan v. Rumsfeld,* a federal court decision that halted Bush Administration efforts to try alleged war criminals before military tribunals.

* On December 7, Samp was interviewed on the "Straight Talk with Mychal Massie" radio show regarding Justice Clarence Thomas.

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REPORT

to the

WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

WLF ACTIVITIES
IN SUPPORT OF
PATIENTS' RIGHTS AND
IMPROVED HEALTH CARE

February 28, 2005

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FEBRUARY 28, 2005

REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

WLF ACTIVITIES IN SUPPORT OF 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 28 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 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 achieved 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 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.

A. Protecting the First Amendment

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.

Fullerton v. Florida Medical Association. On September 9, 2004, WLF filed a brief supporting the Florida Medical Association and a group of physicians who are defendants in a civil action for defamation based on professional peer review of another physician's courtroom testimony. WLF's brief asked the trial court in the case, the Circuit Court of the Second Judicial Circuit in Florida, to rule that participants in peer review of medical testimony are immunized from liability for money damages under a federal statute, the Health Care Quality Improvement Act of 1986. Improper expert testimony in civil litigation is a longstanding concern of the business community. WLF believes vigorous peer review, and the possibility of sanctions by medical associations against wrongdoers, may bring about higher ethics in such testimony.

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.

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 in the coming year.

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 matters 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 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. The result of that change is that television advertising of prescription drugs has increased substantially over the past eight years, and consumers have received significantly more information about these products.

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 in 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 a 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 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

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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 filed 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. McClellan. On August 30, 2004, the U.S. District Court for the District of Columbia dismissed this WLF lawsuit, in

which WLF asked the court to strike down FDA regulations that prohibit terminally ill patients with no approved treatment options from obtaining new drugs while the drugs are undergoing clinical trials. WLF has asked the U.S. Court of Appeals for the District of Columbia Circuit to reverse the decision. WLF brought the lawsuit on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a nonprofit group with numerous members who are suffering from a terminal illness or who have lost family members to a terminal illness. Filed in the U.S. District Court for the District of Columbia on July 28, 2003, the lawsuit challenges FDA restrictions that prevent the terminally ill from obtaining new medicines that have shown safety and efficacy during clinical trials. Under FDA regulations, the vast majority of patients with life-threatening illnesses do not gain entry into clinical trials, and thus do not have access to promising new medications during the years of clinical testing and review required by the FDA. The drugs remain unavailable to patients even though there is evidence of the drugs' safety and efficacy, and even though the patients have no alternative to the drugs other than to wait for their own death. In the lawsuit, WLF and the Abigail Alliance contend that these regulations violate the constitutional rights of terminally ill patients who have no other treatment options.

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 human-tissue 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.

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.

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.

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 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.

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 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.

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 is 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 is invalid because it conflicts with Michigan law and violates separation-of-powers principles of the Michigan Constitution. WLF also argued that the program will result in substandard care for the State's poorest citizens, because it will result in their being denied access to essential drugs that the State has deemed too expensive. WLF argued that the price control statute is 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 contends 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. FDA is expected to rule in the near future.

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.

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 have from time-to-time 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 from 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 is demanding 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 is also asking 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.

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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.

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. 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 January 19, 2005, WLF filed a brief in the U.S. Supreme Court, urging it to review (and ultimately overturn) 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 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 out-of-state corporations should be permitted to move suits to federal court without regard to the presence of fraudulently joined in-state defendants.

United States v. Lane Labs-USA, Inc. On January 31, 2005, WLF filed a brief in the U.S. Court of Appeals for the Third Circuit, urging the court to prevent FDA from attempting to exercise enforcement powers that Congress has never delegated to it. WLF argued that FDA has no power to seek restitution from manufacturers alleged to have violated the Federal Food, Drug, and Cosmetics Act. The district court agreed with FDA that the defendant had been improperly promoting health benefits of its dietary supplements. But instead of simply imposing a fine and ordering the manufacturer to cease violations, the district court granted FDA's request that the manufacturer be ordered to repay all sales proceeds for the past five years, totalling $109 million. WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that restitution is not among them.

City of Hope Medical Center v. Genentech, Inc. On February 3, 2005, at the urging of WLF, the California Supreme Court agreed to review 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 in its brief that if the decision were left intact, all businesses involved in typical contract disputes are at risk of 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 will file a brief on the merits later in 2005.

Dura Pharmaceuticals v. Broudo. On September 12, 2004, WLF filed a brief in the U.S. Supreme Court urging it to reverse an appeals court ruling that allows a more relaxed pleading standard for attorneys filing securities class action cases against publicly-held companies. The Supreme Court heard arguments on January 12, 2005. Unless reversed by the Court, the court of appeals decision would invite windfall damage awards and would be particularly harmful to smaller companies such as those in the life sciences industry. WLF argued that Congress enacted the Private Securities Litigation Reform Act (PSLRA) in 1995 to prevent class action attorneys from filing such abusive securities fraud cases against a company simply because the price of the stock went down. WLF argued that the PSLRA requires counsel to show that any loss from the drop in stock price was due directly to the alleged misrepresentation by the company rather than simply to claim that the plaintiffs purchased the stock during the time of the alleged misrepresentation.

Baxter International Inc. v. Asher. On February 4, 2005, WLF filed a brief in the U.S. Supreme Court, urging it 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 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, including the healthcare company whose statements are at issue in this case. WLF argued that Congress intended to provide broad protection for forward-looking statements in order to encourage companies to provide such information.

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 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

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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.

U.S. ex rel. Gilligan v. Medtronic, Inc. On November 26, 2003, WLF filed a brief in the U.S. Court of Appeals for the Sixth Circuit in Cincinnati, urging the court not to permit individual litigants to file suits designed to second-guess decisions of the Food and Drug Administration (FDA) authorizing the sale of drugs or medical devices. 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. WLF argued that federal law prohibits damage suits based on claims that a manufacturer obtained FDA approval for its product by defrauding the FDA. WLF argued that the FDA should be the sole judge of whether it has been defrauded. WLF argued that plaintiffs should not be permitted to evade this preemption rule by (as here) recasting their suits as claims arising under the federal False Claims Act, which permits *qui tam* suits by private individuals who allege that the federal government has been defrauded. WLF achieved a preliminary victory in this case in September 2003 when, in response to a previous brief filed by WLF, the appeals court agreed to review a trial court determination that the case should be allowed to go forward. The appeals court heard oral arguments in the case in November 2004, and is expected to issue a decision in 2005.

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 FDA-approved 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

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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.

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.

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SmithKline Beecham Corp. v. Apotex Corp. On June 15, 2004, WLF filed a brief in the U.S. Court of Appeals for the Federal Circuit, urging it to rehear *en banc* a case in which a three-judge panel invalidated a significant pharmaceutical patent based on nothing more than a minor technicality. WLF argued that if allowed to stand, the initial decision will undermine confidence in the patent system as an effective means of protecting intellectual property rights. The court invalidated the patent because the drug company had begun a clinical trial of its drug's effectiveness slightly more than a year before filing its patent application; the court held that that trial amounted to "public use" of the drug -- even though it was never offered for sale to anyone until seven years *after* the patent was applied for. The court had not acted on the petition as of February 2005, suggesting that the court is giving serious consideration to granting a rehearing.

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.

Proposed 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

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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.

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.

Schering-Plough Corp. and Upsher-Smith Laboratories v. FTC. On January 14, 2005, the U.S. Court of Appeals for the Eleventh Circuit heard oral arguments in this case involving antitrust claims based on a patent settlement agreement. On June 9, 2004, WLF had filed a brief urging the appeals court to overturn an FTC decision that condemned a patent settlement agreement as an antitrust violation. The settlement agreement settled a lawsuit between Schering-Plough Corp. and generic drug companies that intended to introduce a drug for which Schering-Plough claimed to have patent rights. The FTC held that the settlement unreasonably restrained trade by inducing the generic companies to delay their entry into the market. WLF argued that patents always entail some restraints on commerce but that those restraints are warranted in light of the large benefits derived from the patent system. WLF argued that parties should be encouraged to settle patent disputes, but that by raising the possibility that settlements will be held to violate antitrust laws, the FTC is unnecessarily deterring settlements and discouraging investment in new medicines.

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, 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 health-related issues have included the following:

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

Priorities for the New FDA Commissioner, October 3, 2001
- **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. 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. Healthcare policy and FDA regulation has been the focus of a number of "In All Fairness" columns:

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•***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.)

•***Bad Medicine for Consumers***, June 21, 2000 (Price controls should not be placed on drugs because the free market, not a new bureaucracy, is most suited to determining how much drugs ought to cost and because price controls stifle innovation.)

•***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 Web site, www.wlf.org.

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.

C. 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 the Medical Device Manufacturers Association. What follows are highlights of the numerous public appearances that WLF attorneys have made in the past nine years, to address health-related issues:

January 27, 2005, WLF Chief Counsel Richard 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?"

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.

May 13, 2003, WLF Chairman and General Counsel Daniel J. 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.

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-to-consumer 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

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FDA regarding the suppression of medical literature discussing off-label uses of FDA-approved drugs and devices.

June 27, 1995, WLF Executive Legal Director Paul 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 six 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:

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

Drug Price Regulation By Lawsuit Hazardous To American's Health
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

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.

CONFIDENTIAL
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

FDA Lacks Authority To Impose Civil Monetary Fines
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
By **Daniel A. Kracov**, a partner with the Washington, D.C. law firm Patton Boggs LLP, and **David J. Bloch**, a partner in the Washington, D.C. office of the law firm Reed Smith.
LEGAL BACKGROUNDER, October 4, 1996, 4 pages

Era Of Big Government Continues With Scrutiny Of Menus
By **Elizabeth Toni Guarino**, an attorney with the Washington, D.C. law firm Vorys, Sater, Seymour and Pease LLP.
LEGAL BACKGROUNDER, September 6, 1996, 4 pages

Comment On Potential Revisions To FDA Regulations
By **Alan R. Bennett**, a partner in the Washington, D.C. office of the law firm Ropes & Gray.
COUNSEL'S ADVISORY, August 23, 1996, 1 page

FDA Prevents Doctors And Consumers From Receiving Health Care Information
By **William G. Castagnoli**, former Chairman of Medicus Communications, and **Harry A. Sweeney, Jr.**, President of Dorland Sweeney Jones, agencies specializing in pharmaceutical advertising and health care communications.
LEGAL BACKGROUNDER, December 15, 1995, 4 pages

The Pedicle Screw And FDA: Another Example Of Politicized Science
By **Neil Kahanovitz, M.D.**, a practicing orthopedic surgeon and founder and President of Center for Patient Advocacy.
COUNSEL'S ADVISORY, October 18, 1995, 1 page

FDA Suppression Of Advertising To Consumers Violates The First Amendment
By **William C. MacLeod**, a partner with the Washington, D.C. law firm of Collier Shannon Scott.
LEGAL BACKGROUNDER, September 15, 1995, 4 pages

FDA Inhibits Free Flow Of Information On Medical Products
By **Alan R. Bennett**, a partner in the Washington, D.C. office of the law firm Ropes & Gray, and **Mark E. Boulding**, General Counsel and Vice President, Regulatory Affairs for Medscape.
LEGAL BACKGROUNDER, September 1, 1995, 4 pages

FDA Criminal Enforcement: Punish Intent — Not Relationships
By **John F. Lemker**, a partner with the Chicago law firm Bell, Boyd & Lloyd.
LEGAL BACKGROUNDER, June 30, 1995, 4 pages

FDA Financial Disclosure Proposal Should Be Withdrawn
By **Jeffrey N. Gibbs**, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL BACKGROUNDER, April 14, 1995, 4 pages

FDA Reform Will Improve Nation's Health Care And Competitiveness
By **Alan H. Magazine**, former President of the Health Industry Manufacturers Association.
LEGAL BACKGROUNDER, March 3, 1995, 4 pages

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Oversight Of FDA Should Focus On Agency's Abuse Of Power And Misuse Of Science
By **James R. Phelps**, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL BACKGROUNDER, March 3, 1995, 4 pages

FDA Direct-To-Consumer Advertising Regulation Raises Constitutional And Policy Concerns
By **James M. Johnstone**, a Washington, D.C. lawyer.
LEGAL BACKGROUNDER, January 20, 1995, 4 pages

Weigh In Against FDA Suppression
By **Richard A. Samp**, Washington Legal Foundation Chief Counsel.
COUNSEL'S ADVISORY, December 16, 1994, 1 page

FDA's Legally Suspect Actions Invite Challenge
By **Glenn G. Lammi**, Chief Counsel of WLF's Legal Studies Division.
LEGAL BACKGROUNDER, November 28, 1994, 4 pages

FDA Paralysis Raises Health Care Costs
By **Alan M. Slobodin**, Senior Counsel to the House Energy & Commerce Committee, and **Roman P. Storzer**, a former WLF Fellow.
LEGAL BACKGROUNDER, November 14, 1994, 4 pages

The Real Problem With Health Care In America: While FDA Fiddles, Medical Approvals Lag And Americans Die
By **Alan M. Slobodin**, Senior Counsel to the House Energy & Commerce Committee.
LEGAL BACKGROUNDER, October 28, 1994, 4 pages

What The FDA Doesn't Want You To Know Could Kill You
By **Richard A. Samp**, Chief Counsel to the Washington Legal Foundation.
LEGAL BACKGROUNDER, October 7, 1994, 4 pages

Let's Stop Playing Culinary Roulette And Get On With Irradiating Food
By **Paul B. Jacoby**, a Washington, D.C. attorney, and **James Baller**, a partner with the Washington, D.C. law firm of Baller Hammett, P.C.
LEGAL OPINION LETTER, May 20, 1994, 2 pages

Regulate To Eliminate: The Real Goal Of The Neo-Prohibitionist Movement
By **Dr. James T. Bennett**, a Professor of Economics at George Mason University.
LEGAL BACKGROUNDER, February 28, 1994, 4 pages

The Delaney Clause Should Not Block A More Balanced Food Safety Policy
By **Richard A. Merrill**, Dean of the University of Virginia School of Law and Special Counsel to the Washington, D.C. law firm of Covington & Burling.
LEGAL BACKGROUNDER, March 19, 1993, 4 pages

FDA Should Stay Bound By Its Advisory Opinions
By **Jeffrey N. Gibbs**, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL OPINION LETTER, March 5, 1993, 2 pages

FDA Criminal Enforcement: How To Prevent And Defend Against Liability
By **Steven M. Kowal**, a partner with the Chicago law firm Bell, Boyd & Lloyd. Foreword by **C. Manly Molpus**, President and CEO, Grocery Manufacturers of America, Inc.

MONOGRAPH, January 1993, 72 pages

Zero-Risk Standards For Pesticides In Foods Should Be Reversed
By **Paul B. Jacoby, Frederick A. Provorny**, Washington, D.C. attorneys, and **Sarah J. Ross**, an attorney with the Washington, D.C. firm of Shaw Pittman.
LEGAL OPINION LETTER, September 25, 1992, 2 pages

Public Health Advances Impeded As Anti-Science Activists Thwart Food Safety Program
By **Robert G. Hibbert**, a partner with the law firm of McDermott, Will & Emery, Washington, D.C.
LEGAL BACKGROUNDER, August 14, 1992, 4 pages

FDA's Enforcement Agenda — What's Next?
By **Stuart M. Pape**, a partner in the Washington, D.C. law firm of Patton Boggs specializing in food and drug law.
LEGAL BACKGROUNDER, June 5, 1992, 4 pages

Pesticide Tolerances And Food Safety: Two Hot Topics In Congress And The Courtroom In 1992
By **Paul B. Jacoby, Frederick A. Provorny**, Washington, D.C. attorneys, and **Sarah J. Ross**, an attorney with the Washington, D.C. firm of Shaw Pittman.
LEGAL OPINION LETTER, April 10, 1992, 2 pages

There They Go Again: Activists Use Junk Science To Block Food Irradiation Technology
By **Glenn G. Lammi**, Chief Counsel to WLF's Legal Studies Division.
LEGAL OPINION LETTER, February 21, 1992, 2 pages

Proposed FDA Advertising And Promotion Guidelines Would Inhibit Free Exchange Of Ideas
By **Melinda L. Sidak**, an attorney with the Washington, D.C. office of Covington & Burling.
LEGAL BACKGROUNDER, February 21, 1992, 4 pages

FDA Food Agenda Overlooks The Basics
By **Gary Jay Kushner**, a partner in the Washington, D.C. office of Hogan & Hartson.
LEGAL BACKGROUNDER, February 21, 1992, 4 pages

Targeting Of Brand Names By FDA And USDA Raises First And Fifth Amendment Issues
By **Hugh Latimer**, a partner in the Washington, D.C. office of Wiley, Rein & Fielding.
LEGAL BACKGROUNDER, January 24, 1992, 4 pages

MSG "Junk Science": A Folly That Does Not Warrant FDA Regulation
By **Glenn G. Lammi**
LEGAL BACKGROUNDER, January 10, 1992, 4 pages

Proposed Legislation To Enhance FDA Enforcement Powers Raises Constitutional Concerns By **Edward Dunkelberger**, formerly a partner in the Washington, D.C. office of Covington & Burling.
LEGAL BACKGROUNDER, September 6, 1991, 4 pages

FORM 990, PART I - OTHER INCREASES IN FUND BALANCES

DESCRIPTION	AMOUNT
NET UNREALIZED GAINS ON INVESTMENTS	144,492.
TOTAL	144,492.

FORM 990, PART II - OTHER EXPENSES

DESCRIPTION	TOTAL	PROGRAM SERVICES	MANAGEMENT AND GENERAL	FUNDRAISING
INSURANCE	38,677.		38,677.	
OTHER PROFESSIONAL FEES	6,375.			6,375.
MISCELLANEOUS	6,877.	6,877.		
REPAIRS AND MAINTENANCE	66,230.	43,023.	15,248.	7,959.
TOTALS	118,159.	49,900.	53,925.	14,334.

FORM 990, PART III - ORGANIZATION'S PRIMARY EXEMPT PURPOSE
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THE FOUNDATION SERVES THE PUBLIC INTEREST THROUGH LITIGATION AND REPRESENTATION, LEGAL PUBLIC POLICY ANALYSIS, INTERN PROGRAMS, RESEARCH AND BRIEFS, MONOGRAPHS, AND EDUCATIONAL MATERIALS.

FORM 990, PART IV - PREPAID EXPENSES AND DEFERRED CHARGES

DESCRIPTION	ENDING BOOK VALUE
PREPAID INSURANCE	18,045.
TOTALS	18,045.

FORM 990, PART IV - INVESTMENTS - SECURITIES

DESCRIPTION	ENDING BOOK VALUE
PUBLICLY TRADED SECURITIES	
CORPORATE BONDS	406,652.
CORPORATE STOCK (<5% OWNER)	1,047,988.
FOREIGN BONDS	32,988.
MUTUAL FUNDS	625,933.
U.S. GOVERNMENT OBLIGATIONS	487,592.
TOTALS	2,601,153.

FORM 990, PART IV - OTHER ASSETS

DESCRIPTION	ENDING BOOK VALUE
ACCRUED INTEREST RECEIVABLE	52,829.
CASH SURRENDER VALUE OF LIFE INSURANCE	231,960.
TOTALS	284,789.

FORM 990, PART IV - OTHER LIABILITIES

DESCRIPTION	ENDING BOOK VALUE
ACCRUED EMPLOYEE BENEFITS	315,381.
ACCRUED PENSION LIABILITY	239,719.
TOTALS	555,100.

FORM 990, PART V - LIST OF OFFICERS, DIRECTORS, AND TRUSTEES

NAME AND ADDRESS	TITLE AND TIME DEVOTED TO POSITION	COMPENSATION	CONTRIBUTIONS TO EMPLOYEE BENEFIT PLANS	EXPENSE ACCT AND OTHER ALLOWANCES
DANIEL POPEO 2009 MASSACHUSETTS AVENUE, N.W. WASHINGTON, DC 20036	CHAIRMAN/DIRECTOR 45+ HRS/WK	307,109.	126,250.	NONE
CONSTANCE LARCHER 2009 MASSACHUSETTS AVENUE, N.W. WASHINGTON, DC 20036	PRES-TREAS/DIRECTOR 45+ HRS/WK	279,993.	152,746.	NONE
JOHN POPEO 2009 MASSACHUSETTS AVENUE, N.W. WASHINGTON, DC 20036	VP-SECR./DIRECTOR 3 HRS/WK	NONE	NONE	NONE

NO COMPENSATION IS PAID FOR ANY INDIVIDUAL SERVING AS A DIRECTOR.

FORM 990, PART VI - NAMES OF RELATED ORGANIZATIONS

AMERICAN LEGAL FOUNDATION	(EXEMPT ORGANIZATION)
BUSINESS CIVIL LIBERTIES	(EXEMPT ORGANIZATION)
UNITED STATES LEGAL FOUNDATION	(EXEMPT ORGANIZATION)

SCHEDULE A, PART III - EXPLANATION FOR LINE 2D

SEE FORM 990, PART V. THE ORGANIZATION DID NOT PROVIDE A NONTAXABLE EXPENSE ACCOUNT OR ALLOWANCE TO ANY DISQUALIFIED PERSON.

SCHEDULE A, PART IV-A - OTHER INCOME

DESCRIPTION	2003	2002	2001	2000	TOTAL
OTHER INCOME	5,989.	8,056.	12,281.		26,326.
TOTALS	5,989.	8,056.	12,281.		26,326.

WASHINGTON LEGAL FOUNDATION

Schedule D Detail of Long-term Capital Gains and Losses

Description	Date Acquired	Date Sold	Gross Sales Price	Cost or Other Basis	Long-term Gain/Loss
CAPITAL GAINS (LOSSES) FROM SECURITIES					
EQUITY SECURITIES			3,225.	1,507.	1,718.
CORPORATE BONDS			45,000.	47,093.	-2,093.
TOTAL CAPITAL GAINS (LOSSES) FROM SECURITIES			48,225.	48,600.	-375.
Totals			48,225.	48,600.	-375.

FEDERAL FOOTNOTES
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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.

Washington Legal Foundation
EIN: 52-1071570
Year Ended December 31, 2004

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

	Balance at 12/31/03	Additions	Deletions	Balance at 12/31/04
Furniture	236,908			236,908
Equipment	414,821	51,067	18,962	446,926
Building and Land	3,241,225	79,778		3,321,003
Totals	3,892,954	130,845	18,962	4,004,837
Accum Depr - Furniture	228,995	2,483		231,478
Accum Depr - Equipment	326,487	33,248	18,962	340,773
Accum Depr - Building	933,536	19,310		952,846
	1,489,018	55,041	18,962	1,525,097
	2,403,936			2,479,740

FEDERAL FOOTNOTES
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ATTACHMENT FORM 990, PART VI, OTHER INFORMATION, LINE 82 THE WASHINGTON LEGAL FOUNDATION RECEIVED HUNDREDS OF THOUSANDS OF DOLLARS OF DONATED SERVICES DURING 2004.

Form **8868**
(Rev December 2004)
Department of the Treasury
Internal Revenue Service

Application for Extension of Time To File an Exempt Organization Return

▶ File a separate application for each return

OMB No 1545-1709

- If you are filing for an **Automatic 3-Month Extension, complete only Part I** and check this box . . . . . ▶ [X]
- If you are filing for an **Additional (not automatic) 3-Month Extension, complete only Part II** (on page 2 of this form).

Do not complete Part II unless 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)

Form 990-T corporations requesting an automatic 6-month extension - check this box and complete Part I only . . . . . ▶ [ ]

All other corporations (including Form 990-C filers) must use Form 7004 to request an extension of time to file income tax returns. Partnerships, REMICs, and trusts must use Form 8736 to request an extension of time to file Form 1065, 1066, or 1041.

Electronic Filing (e-file). Form 8868 can be filed electronically if you want a 3-month automatic extension of time to file one of the returns noted below (6 months for corporate Form 990-T filers). However, you cannot file it electronically if you want the additional (not automatic) 3-month extension, instead you must submit the fully completed signed page 2 (Part II) of Form 8868. For more details on the electronic filing of this form, visit *www.irs.gov/efile*.

Type or print	Name of Exempt Organization	**Employer identification number**
File by the due date for filing your return See instructions	WASHINGTON LEGAL FOUNDATION	52-1071570
	Number, street, and room or suite no If a P O box, see instructions 2009 MASSACHUSETTS AVENUE NW	
	City, town or post office, state, and ZIP code For a foreign address, see instructions WASHINGTON, DC 20036	

Check type of return to be filed (file a separate application for each return):

[X]	Form 990	[ ]	Form 990-T (corporation)	[ ]	Form 4720
[ ]	Form 990-BL	[ ]	Form 990-T(sec 401(a) or 408(a) trust)	[ ]	Form 5227
[ ]	Form 990-EZ	[ ]	Form 990-T (trust other than above)	[ ]	Form 6069
[ ]	Form 990-PF	[ ]	Form 1041-A	[ ]	Form 8870

- The books are in the care of ▶ TREASURER

Telephone No. ▶ 202 588-0302 FAX No ▶ _____

- If the organization does **not** have an office or place of business in the United States, check this box . . . . . ▶ [ ]
- If this is for a **Group Return,** enter the organization's four digit Group Exemption Number (GEN) _____ If this is for the **whole** group, check this box ▶ [ ] . If it is for part of the group, check this box ▶ [ ] and attach a list with the names and EINs of all members the extension will cover.

1 I request an automatic 3-month (6-months for a **Form 990-T corporation**) extension of time until 08/15 , 2005 , to file the exempt organization return for the organization named above. The extension is for the organization's return for:
▶ [X] calendar year 2004 or
▶ [ ] tax year beginning _____ , _____ , and ending _____ , _____ .

2 If this tax year is for less than 12 months, check reason [ ] Initial return [ ] Final return [ ] Change in accounting period

3a If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions . . . . . $ _____

b If this application is for Form 990-PF or 990-T, enter any refundable credits and estimated tax payments made. Include any prior year overpayment allowed as a credit . . . . . $ _____

c **Balance Due.** Subtract line 3b from line 3a Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System) See instructions . . . . . $ _____

Caution. If you are going to make an electronic fund withdrawal with this Form 8868, see Form 8453-EO and Form 8879-EO for payment instructions

For Privacy Act and Paperwork Reduction Act Notice, see Instructions. Form **8868** (Rev 12-2004)

JSA
4F8054 3 000

- 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 you are filing for an **Automatic 3-Month Extension, complete only Part I** (on page 1).

Part II Additional (not automatic) 3-Month Extension of Time - Must File Original and One Copy.

Type or print

File by the extended due date for filing the return. See instructions

Name of Exempt Organization: WASHINGTON LEGAL FOUNDATION

Employer identification number: 52-1071570

Number, street, and room or suite no. If a P O box, see instructions: 2009 MASSACHUSETTS AVENUE NW

For IRS use only

City, town or post office, state, and ZIP code. For a foreign address, see instructions: WASHINGTON, DC 20036

Check type of return to be filed (File a separate application for each return):

[X]	Form 990	[ ]	Form 990-T(sec. 401(a) or 408(a) trust)	[ ]	Form 5227
[ ]	Form 990-BL	[ ]	Form 990-T (trust other than above)	[ ]	Form 6069
[ ]	Form 990-EZ	[ ]	Form 1041-A	[ ]	Form 8870
[ ]	Form 990-PF	[ ]	Form 4720		

STOP: Do not complete Part II if you were not already granted an automatic 3-month extension on a previously filed Form 8868.

- The books are in the care of ▶ TREASURER

Telephone No. ▶ 202 588-0302 FAX No. ▶

- If the organization does **not** have an office or place of business in the United States, check this box . . . . . ▶ [ ]
- If this is for a **Group Return,** enter the organization's four digit Group Exemption Number (GEN) _____. If this is for the **whole** group, check this box ▶ [ ]. If it is for **part** of the group, check this box ▶ [ ] and attach a list with the names and EINs of all members the extension is for.

4 I request an additional 3-month extension of time until 11/15/2005.

5 For calendar year 2004, or other tax year beginning _____ and ending _____.

6 If this tax year is for less than 12 months, check reason: [ ] Initial return [ ] Final return [ ] Change in accounting period

7 State in detail why you need the extension

ADDITIONAL TIME IS REQUIRED TO ASSEMBLE THE INFORMATION IN ORDER TO FILE A COMPLETE AND ACCURATE RETURN.

8a If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions . . . . . $

b If this application is for Form 990-PF, 990-T, 4720, or 6069, enter any refundable credits and estimated tax payments made. Include any prior year overpayment allowed as a credit and any amount paid previously with Form 8868 . . . . . $

c **Balance Due.** Subtract line 8b from line 8a. Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System). See instructions . . . . . $

Signature and Verification

Under penalties of perjury, I declare that I have examined this form, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete, and that I am authorized to prepare this form.

Signature ▶ [signature] Title ▶ cpa Date ▶ 8/9/05

Notice to Applicant - To Be Completed by the IRS

[X] We **have** approved this application Please attach this form to the organization's return.

[ ] We **have not** approved this application. However, we have granted a 10-day grace period from the later of the date shown below or the due date of the organization's return (including any prior extensions) This grace period is considered to be a valid extension of time for elections otherwise required to be made on a timely return. Please attach this form to the organization's return.

[ ] We **have not** approved this application. After considering the reasons stated in item 7, we cannot grant your request for an extension of time to file We are not granting a 10-day grace period.

[ ] We **cannot consider** this application because it was filed after the extended due date of the return for which an extension was requested.

[ ] Other _____

_____ By _____ _____

Director Date

Alternate Mailing Address - Enter the address if you want the copy of this application for an additional 3-month extension returned to an address different than the one entered above.

Type or print

Name: BOND BEEBE

Number and street (Include suite, room, or apt. no.) or a P.O. box number: 7315 WISCONSIN AVE, SUITE 200W

City or town, province or state, and country (Including postal or ZIP code): BETHESDA, MD 20814-3208

EXTENSION APPROVED

SEP 15 2005

FIELD DIRECTOR, SUBMISSION PROCESSING, OGDEN