INNOVATION-FUELLED, SUSTAINABLE, INCLUSIVE GROWTH

Working Paper

US Pharma's Business Model: Why It Is Broken, and How It Can Be Fixed

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ABSTRACT

Price gouging in the US pharmaceutical drug industry goes back more than three decades. In 1985 US Representative Henry Waxman, chair of the House Subcommittee on Health and the Environment, accused the pharmaceutical industry of "gouging the American public" with "outrageous" price increases, driven by "greed on a massive scale." Despite many Congressional inquiries since the 1980s, including the case of Gilead Sciences' extortionate pricing of the Hepatitis-C drug Sovaldi since 2014, the US government does not regulate drug prices. UK Prescription Price Regulation Scheme data for 1996 through 2008 show that, while drug prices in other advanced nations were close to the UK's regulated prices, those in the United States were between 74% and 152% higher. Médecins Sans Frontières (MSF) has produced abundant evidence that US drug prices are by far the highest in the world.

The US pharmaceutical industry's invariable response to demands for price regulation has been that it will kill innovation. US drug companies claim that they need higher prices than those that prevail elsewhere so that the extra profits can be used to augment R&D spending. The result, they contend, is more drug innovation that benefits the United States and indeed the whole world. It is a compelling argument, until one looks at how major US pharmaceutical companies actually use the profits that high drug prices generate. In the name of "maximizing shareholder value" (MSV), pharmaceutical companies allocate profits from high drug prices to massive repurchases, or buybacks, of their own corporate stock for the sole purpose of giving manipulative boosts to their stock prices. Incentivizing these buybacks is stock-based compensation that rewards senior executives for stock-price performance.

Like no other sector, the pharmaceutical industry puts a spotlight on how the political economy of science is a matter of life and death. In this paper, we invoke "the theory of innovative enterprise" to explain how and why high drug prices restrict access to medicines and undermine medical innovation. An innovative enterprise seeks to develop a high-quality product that it can sell to the largest possible market at the most affordable price. In sharp contrast, the MSV-obsessed companies that dominate the US drug industry have become monopolies that restrict output and raise price.

1. Drug-Price Gouging to "Maximize Shareholder Value"

The news in September 2015 that pharmaceutical company Turing, led by a 32-year-old hedge-fund manager, had raised the price of a 62-year-old drug from $13.50 to $750.00 focused public attention on price gouging in an industry in which the pursuit of wealth has trumped the improvement of health (Pollack 2015). The day after Democratic presidential candidate Hillary Clinton tweeted that this "price gouging" was "outrageous," the NASDAQ Biotechnology Index plunged by 4.7%, or $15 billion in market capitalization, in a few hours of trading. This reaction demonstrated the importance of the stock market to the fortunes that individuals can reap when pharmaceutical companies can keep drug prices high (Langreth and Armstrong 2015).

The industry trade group Pharmaceutical Researchers and Manufacturers of America (PhRMA) was quick to disown Turing, tweeting that its actions did not "represent the values of PhRMA member companies" (Cha 2015). Yet price gouging in the US pharmaceutical drug industry goes back more than three decades. In 1985 US Representative Henry Waxman, chair of the House Subcommittee on Health and the Environment, accused the pharmaceutical industry of "gouging the American public" with "outrageous" price increases, driven by "greed on a massive scale" (Horowitz 1985).

Despite many Congressional inquiries since the 1980s, including the case of Gilead Sciences' extortionate pricing of the Hepatitis-C drug Sovaldi since 2014 (United States Senate Committee on Finance 2015), the US government does not regulate drug prices. UK Prescription Price Regulation Scheme data for 1996 through 2008 show that, while drug prices in other advanced nations were close to the UK's regulated prices, those in the United States were between 74% and 152% higher (UK Department of Health 1996-2008, 2015; see also Kantarjian and Rajkumar 2015). Médecins Sans Frontières (MSF) has produced abundant evidence that US drug prices are by far the highest in the world (Médecins Sans Frontières 2015).

The US pharmaceutical industry's invariable response to demands for price regulation has been that it will kill innovation. US drug companies claim that they need higher prices than those that prevail elsewhere so that the extra profits can be used to augment R&D spending. The result, they contend, is more drug innovation that benefits the United States and indeed the whole world (see for example Kravitz 1985, Horowitz 1987, Pollack 1988, Rovner 1992, Leary 1995, Mossinghoff 1999, Levin 2001, Nordrum 2015).

It is a compelling argument, until one looks at how major US pharmaceutical companies actually use the profits that high drug prices generate. In the name of "maximizing shareholder value" (MSV), pharmaceutical companies allocate profits from high drug prices to massive repurchases, or buybacks, of their own corporate stock for the sole purpose of giving manipulative boosts to their stock prices.

Incentivizing these buybacks is stock-based compensation that rewards senior executives for stock-price performance (Lazonick 2014b, Lazonick 2014c, Lazonick 2015b, Hopkins and Lazonick 2016).

Like no other sector, the pharmaceutical industry puts a spotlight on how the political economy of science is a matter of life and death. In this chapter, we invoke "the theory of innovative enterprise" to explain how and why high drug prices restrict access to medicines and undermine medical innovation. An innovative enterprise seeks to develop a high-quality product that it can sell to the largest possible market at the most affordable price (Lazonick 2015c). In sharp contrast, the MSV-obsessed companies that dominate the US drug industry have become monopolies that restrict output and raise price.

2. Buyback Boosts to Stock Prices

US pharmaceutical companies claim that high drug prices fund investments in innovation. Yet the 19 drug companies in the S&P 500 Index in February 2015 and publicly listed from 2005 through 2014 distributed 97% of their profits to shareholders over the decade, 47% as buybacks and 50% as dividends (see Table 1). The total of $226 billion spent on buybacks was equivalent to 51% of their combined R&D expenditures. That $226 billion could have been returned to households in the form of lower drug prices without infringing on R&D spending, while providing ample dividends to shareholders. Or it could have been allocated to the development of drugs for high-priority access areas that are otherwise underfunded and underserved.

In the United States, massive distributions of cash to shareholders are not unique to pharmaceutical companies. From 2005 through 2014, 459 companies in the S&P 500 Index expended $3.8 trillion on buybacks, representing 53% of net income, on top of paying $2.6 trillion in dividends equaling 36% of net income. They held much of the remaining profits abroad, sheltered from US taxation (Rubin 2015). Many of America's largest corporations, Pfizer and Merck among them, routinely distribute more than 100% of profits to shareholders, generating the extra cash by reducing reserves, selling off assets, taking on debt, or laying off employees (Lazonick et al. 2015). Over the decade 2005-2014, Johnson & Johnson, Pfizer, and Merck, the three largest pharma companies, spent an annual average of $3.9 billion, $6.1 billion, and $2.6 billion, respectively, on buybacks, while Amgen, the largest independent biopharma company, spent $3.5 billion per year.

The profits that a company retains after distributions to shareholders are the financial foundation for investment in innovation. These retained earnings can fund investment in plant and equipment, research and development, and, of critical importance to innovation, training and retaining employees (Lazonick 2015b). Dividends are the traditional, and legitimate, way for a publicly listed corporation to provide income to shareholders. They receive dividends for *holding* shares. In

contrast, by creating demand for the company's stock that boosts its price, buybacks reward existing shareholders for *selling* their shares.

Table 1. Stock buybacks and cash dividends, 2005-2014, at 19 US pharmaceutical companies in the S&P 500 Index

Company	REV, $b	NI, $b	BB, $b	DV, $b	R&D, $b	BB/ NI%	DV/ NI%	(BB+DV)/ NI%	R&D/ REV%	Employees 2014
JOHNSON & JOHNSON	629.8	120.9	38.8	56.7	78.2	32	47	**79**	12	126,500
PFIZER	541.2	91.1	60.8	66.6	84.0	67	73	**140**	16	78,300
MERCK	347.7	63.3	26.5	41.3	66.5	42	65	**107**	19	70,000
ABBOTT LABORATORIES	283.6	40.5	9.0	24.1	30.4	22	59	**82**	11	26,000
ELI LILLY	203.9	30.5	3.7	20.3	43.3	12	67	**79**	21	39,135
BRISTOL-MYERS SQUIBB	186.5	35.9	4.6	23.0	36.1	13	64	**77**	19	25,000
AMGEN	157.8	41.5	34.7	4.9	34.5	84	12	**95**	22	17,900
GILEAD SCIENCES	83.8	29.3	17.0	0.0	14.4	58	0	**58**	17	7,000
ALLERGAN	53.7	6.5	4.1	0.6	8.6	62	9	**71**	16	21,600
BIOGEN IDEC	48.7	11.2	10.0	0.0	12.6	89	0	**89**	26	7,550
MYLAN	48.3	2.4	3.6	0.6	4.4	151	23	**174**	9	30,000
ACTAVIS	47.2	-1.5	0.6	0.0	4.0	-42	0	**-42**	8	21,600
HOSPIRA	36.9	2.1	0.6	0.0	2.6	29	0	**29**	7	19,000
CELGENE	35.9	6.7	10.4	0.0	11.7	155	0	**155**	33	6,012
PERRIGO	23.5	1.7	0.3	0.2	0.9	18	14	**32**	4	10,220
ENDO INTERNATIONAL	18.5	-0.4	0.8	0.0	1.5	-187	0	**-187**	8	5,062
REGENERON	8.1	0.7	0.0	0.0	4.9	0	0	**0**	61	2,925
ALEXION	7.0	1.4	0.4	0.0	1.7	27	0	**27**	24	2,273
VERTEX	5.7	-3.9	0.0	0.0	6.1	0	0	**0**	107	1,830
Totals, 19 pharma companies, 2005-2014	**2,767.7**	**479.8**	**225.9**	**238.2**	**446.1**	**47**	**50**	**97**	**16**	**517,907**
Totals, 459 S&P 500 companies 2005-2014	86,893.9	7,120.7	3,751.6	2,539.8	1,736.9	53	36	88	2	24,580,511
19 pharma as % of 459 S&P 500=4.14%	3.19%	6.74%	6.02%	9.38%	25.69%					2.11%

REV=revenues; NI=Net Income; BB=stock buybacks (aka repurchases); DV=cash dividends; R&D=research and development expenditures

Notes: a) The pharmaceutical business of Abbott Laboratories became AbbVie on January 1, 2013. b) In June 2015 Actavis, Plc, domiciled in Ireland, acquired Allergan, and changed the merged company's name to Allergan, Plc. c) In November 2012, US company Watson Pharmaceuticals acquired the Swiss company Actavis, taking its name. d) In October 2013, Actavis acquired the Irish company Warner Chilcott and changed the merged company's name to Actavis, Plc, headquartered in Ireland. e) In September 2015, Pfizer acquired Hospira. f) In February 2014, Endo acquired the Canadian firm Paladin Labs, established global headquarters in Ireland, and was renamed Endo International, Plc.

Source: S&P Compustat database.

The most prominent sharesellers are corporate executives, investment bankers, and hedge-fund managers who can time their stock sales to take advantage of buyback activity done as open-market repurchases. Buybacks also automatically increase earnings per share (EPS) by decreasing the number of shares outstanding. Since EPS has become a major metric by which stock-market traders evaluate a company's performance, buybacks tend to increase demand for a company's stock, thus creating opportunities for stock-market traders to sell their shares at a gain, even in the absence of increased corporate revenues or profits (Lazonick 2015a).

3. Pumping Up Executive Pay

Why do companies buy back their own shares? In "Profits Without Prosperity: Stock Buybacks Manipulate the Market and Leave Most Americans Worse Off," Lazonick argues that the only logical explanation is that stock-based compensation gives senior executives personal incentives to do buybacks to boost stock prices (Lazonick 2014b). There are two main types of stock-based pay: stock options, for which the realized gains depend on the difference between the stock price on the date the option to buy the shares is exercised and the date the option was granted; and stock awards, for which the realized gains depend on the market price of the stock on the date that the award vests (Hopkins and Lazonick 2016).

By using stock buybacks to boost stock prices, executives can augment the gains that they realize from exercising options or the vesting of awards. As shown in Table 2, from 2006 through 2014, the average annual total compensation of the 500 highest-paid US executives (not including billion-dollar-plus outliers) ranged from $14.7 million in 2009 to $33.2 million in 2014, with realized gains from the combination of exercising options and vesting of awards constituting from 66% to 84% of the average annual total pay (Hopkins and Lazonick 2016).[1] Stock-based pay incentivizes executives to take actions that increase the company's stock price and rewards them for doing so. Buybacks serve these purposes.

Pharma executives are well represented among the 500 highest-paid executives at US corporations. In the most recent years, as their numbers among the top500 have increased, the average total compensation of the drug executives has soared, with the proportion of their pay derived from exercising stock options substantially higher than the average for the top500 as a whole in 2013 and 2014.

Table 2. 500 highest-paid executives, US corporations, with the proportions of mean total direct compensation (TDC) from stock options and stock awards, and representation of pharmaceutical executives among the top500, 2006-2014

	All US Corporations				Pharmaceutical Corporations				
	TDC, $m	SO/ TDC%	SA/ TDC%	(SO+SA)/ TDC%	TDC, $m	SO/ TDC%	SA/ TDC%	(SO+SA)/ TDC%	No. of pharma execs
2006	24.3	58	18	76	21.8	63	15	79	20
2007	30.0	59	20	78	24.6	66	17	83	12
2008	20.3	50	26	76	23.5	67	14	81	16
2009	14.7	41	25	66	20.3	40	22	62	27
2010	18.6	41	28	69	17.8	46	28	74	17
2011	19.7	42	32	74	18.0	52	22	74	12
2012	30.5	43	40	82	32.5	62	26	88	23
2013	26.5	46	35	81	35.9	66	26	91	32
2014	33.2	43	41	84	45.7	67	22	89	31

TDC=total direct compensation; SO=realized gains from exercising stock options; SA=realized gains from vesting of stock awards
Source: S&P's ExecuComp database

Table 3 shows that biopharma companies launched in the late 1980s and early 1990s account for the explosion in pharma executive pay. Table 4 identifies the six highest-paid pharma executives for each year from 2006 through 2014. Note the prominence, especially in 2012-2014, of executives from four of the companies in Table 3: Gilead Sciences (14 of the 54 cells), Celgene (7), Regeneron (7), and Alexion (3), and also note the extent to which their pay is stock based.[2] Gilead Sciences CEO John C. Martin appears on this top6 list in all nine years, three times in first place, four times in second, and twice in third.

Table 3. Biopharma and the explosion of executive pay, 2012, 2013, and, 2014

	Number of executives in top500					
	2012		2013		2014	
Company (year founded)	No. of exec-utives	Average TDC, $m	No. of exec-utives	Average TDC, $m	No. of exec-utives	Average TDC, $m
GILEAD SCIENCES (1987)	3	41.6	4	74.7	5	82.4
REGENERON (1988)	5	50.7	4	53.0	4	56.6
ALEXION (1992)	4	21.6	4	20.8	2	111.4
CELGENE (1986)	0		3	27.5	1	96.3
VERTEX (1989)	0		1	30.9	0	
Executives, 5 pharma	**12**	**38.7**	**16**	**44.2**	**12**	**79.8**
Executives, 19 pharma	23	31.5	32	35.9	30	46.2
All executives on 500	500	30.3	500	26.2	500	29.7

Source: S&P's ExecuComp database

Table 4. Six highest-compensated pharma executives, 2006-2014, with total compensation in millions of dollars (stock-based pay as % of total compensation)

	#1	#2	#3	#4	#5	#6
2006	John W. Jackson CELGENE $84.5m. (96%)	Sol J. Barer CELGENE $46.1m. (94%)	John C. Martin GILEAD SCIENCES $32.5m. (93%)	Robert A. Essner WYETH $29.6m. (84%)	Fred Hassan SCHERING-PLOUGH $25.4m. (41%)	N. W. Bischofberger GILEAD SCIENCES $24.7m. (95%)
2007	Miles D. White ABBOTT LABS $44.8m. (85%)	John C. Martin GILEAD SCIENCES $35.6m. (93%)	Richard A. Gonzalez ABBOTT LABS $29.4m. (91%)	Henri A. Termeer GENZYME $24.7m. (85%)	N. W. Bischofberger GILEAD SCIENCES $24.1m. (95%)	William C. Weldon J & J $18.7M. (7%)
2008	Robert. J. Hugin CELGENE $74.6m. (97%)	Sol J. Barer CELGENE $59.3m. (94%)	John C. Martin GILEAD SCIENCES $33.1m. (86%)	Miles D. White ABBOTT LABS $27.1m. (52%)	James C. Mullen BIOGEN $24.9m. (72%)	N. W. Bischofberger GILEAD SCIENCES $22.8m. (92%)
2009	Fred Hassan MERCK $89.8m. (63%)	John C. Martin GILEAD SCIENCES $59.2m. (96%)	Robert J. Bertolini MERCK $39.6m. (25%)	Carrie Smith Cox MERCK $36.1m. (51%)	Thomas P. Koestle MERCK $30.9m. (58%)	Sol J. Barer CELGENE $30.4m. (90%)
2010	John C. Martin GILEAD SCIENCES $42.7m. (91%)	David E. I. Pyott ALLERGAN $33.8m. (91%)	James C. Mullen BIOGEN $24.6m. (93%)	C. B. Begley HOSPIRA $23.1m. (90%)	William C. Weldon J & J $19.9M. (21%)	Frank Baldino, Jr. CEPHALON $18.2m. (81%)
2011	John C. Martin GILEAD SCIENCES $43.2m. (90%)	David E. I. Pyott ALLERGAN $33.8m. (91%)	William C. Weldon J & J $24.4m. (32%)	Miles D. White ABBOTT LABS $17.2m. (59%)	John C. Lechleiter ELI LILLY $15.6m. (73%)	Leonard Bell ALEXION $13.3m (71%)
2012	G. D. Yancapoulos REGENERON $129.0m. (96%)	John C. Martin GILEAD SCIENCES $84.0m. (95%)	Leonard S. Schleifer REGENERON $51.5m. (92%)	Robert J. Coury MYLAN $51.3m. (93%)	Leonard Bell ALEXION $40.5m (99%)	Neil Stahl REGENERON $39.7m. (99%)
2013	John C. Martin GILEAD SCIENCES $168.9m. (97%)	Paul M. Bisaro ALLERGAN $113.2m. (95%)	John F. Milligan GILEAD SCIENCES $79.7m. (97%)	G. D. Yancapoulos REGENERON $74.5m. (96%)	Leonard S. Schleifer REGENERON $73.5m. (96%)	Robert. J. Hugin CELGENE $46.4m. (81%)
2014	Leonard Bell ALEXION $195.8m (98%)	John C. Martin GILEAD SCIENCES $192.8m. (97%)	Leonard S. Schleifer REGENERON $101.8m. (97%)	Robert. J. Hugin CELGENE $96.3m. (89%)	John F. Milligan GILEAD SCIENCES $89.5m. (97%)	G. D. Yancapoulos REGENERON $61.9m. (96%)

4. Gilead's Greed

With 12-week treatments for Hepatitis-C Virus (HCV) costing $84,000 for Sovaldi and $94,500 for Harvoni, Gilead Sciences exemplifies the price-gouging drug company. Prior to 2014 Gilead had two blockbuster drugs, with Truvada, launched in 2004, reaching $3.2 billion in sales in 2012, and Atripla, launched in 2006, generating a high of $3.6 billion in 2013. In their first full years on the market, Sovaldi had sales of $10.3 billion in 2014 and Harvoni $13.9 billion in 2015. As a result, Gilead's revenues and profits exploded in these two years (see Table 5).

Table 5. Gilead Sciences, operating data, dividends, and buybacks, 2006-2015

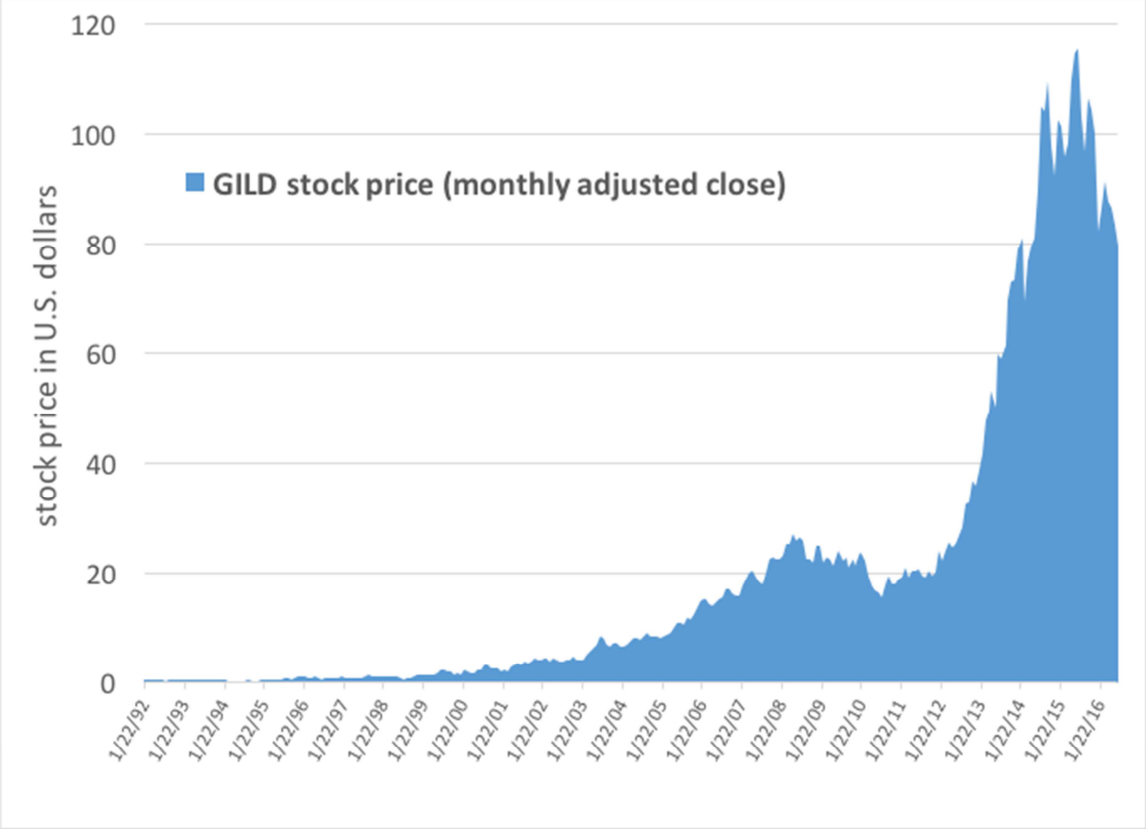
Fiscal year	REV $m	NI $m	BB $m	DV $m	R&D $m	NI/REV %	BB/Ni %	DV/NI %	BB/ R&D	R&D/ REV %	REV/ EMP $m	EMP
2006	3,026	-1,190	545	0	2,778	-39.3	-46	0	0.2	92	1.2	2,515
2007	4,230	1,615	488	0	591	38.2	30	0	0.8	14	1.4	2,979
2008	5,336	2,011	1,970	0	733	37.7	98	0	2.7	14	1.6	3,441
2009	7,011	2,636	998	0	940	37.6	38	0	1.1	13	1.8	3,852
2010	7,949	2,901	4,023	0	1,073	36.5	139	0	3.7	13	2.0	4,000
2011	8,385	2,804	2,383	0	1,229	33.4	85	0	1.9	15	1.9	4,500
2012	9,703	2,592	667	0	1,760	26.7	26	0	0.4	18	1.9	5,000
2013	11,202	3,075	582	0	2,120	27.4	19	0	0.3	19	1.8	6,100
2014	24,890	12,101	5,349	0	2,854	48.6	44	0	1.9	11	3.6	7,000
2015	32,639	18,108	10,000	1,900	2,845	55.5	55	10	3.5	9	4.4	7,500
2006-2015	**114,371**	**46,653**	**27,005**	**1,900**	**16,922**	**40.8**	**58**	**4**	**1.6**	**15**		

REV=revenues; NI=net income; BB=stock buybacks; DV=cash dividends; R&D=research and development expenditures; EMP=employees
Source: S&P's Compustat database

Once Gilead moved into sustained profitability in 2007, it had very high profit margins (NI/REV%), but these margins soared with its most recent blockbusters, as have sales per employee (REV/EMP$m). Pre-Sovaldi/Harvoni, Gilead was already doing substantial buybacks, but these reached massive levels in 2014 and 2015. The result, as the Sovaldi/Harvoni pricing strategy intended, was an exploding stock price from June 2012 (see Figure 1), about six months after its $11.2 billion acquisition of Pharmasset, which had substantially developed sofosbuvir (Sovaldi).

An 18-month Congressional inquiry by US Senators Ron Wyden (D-OR) and Charles Grassley (R-IA) probed the rationale for Gilead's Sovaldi pricing strategy, and, in a report issued on December 1, 2015, concluded that "a key consideration in Gilead's decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price" (The Staffs of Senators 2015). But the Wyden-Grassley report made no attempt to probe the influence and impact of Gilead's pricing strategy on its stock price and executives' pay. In our view, the objective of Gilead's executives in setting high prices was not to maximize revenues but rather to "maximize shareholder value" so that soaring stock prices would translate into enormous executive-pay packages.[3]

Figure 1. Gilead Sciences (GILD: NASDAQ) stock price (monthly adjusted close), January 1992-July 2016



Source: Yahoo Finance, monthly data

The greed of Gilead's top executives, sanctioned by MSV ideology, is preventing millions of people with HCV in the United States and abroad from accessing Sovaldi/Harvoni at an affordable cost.[4] What is needed is a business model that shares the gains from innovative medicines with households as taxpayers who fund the government agencies that provide intellectual and financial support to the drug companies, workers whose skills and efforts have developed the drugs, and consumers who have illnesses waiting to be cured or relieved. In contrast, the MSV business model concentrates the gains from innovative medicines in the hands of senior corporate executives who pad their paychecks by doing billions of dollars of stock buybacks to manipulate the company's stock price.

In the process, for millions who cannot afford access to innovative medicines, the life sciences become death sciences. In a hard-hitting article entitled "Gilead's greed that kills," economist Jeffrey Sachs (2015) makes this case:

> Gilead Sciences is an American pharmaceutical company driven by unquenchable greed. The company is causing hundreds of thousands of

> Americans with Hepatitis C to suffer unnecessarily and many of them to die as the result of its monopolistic practices, while public health programs face bankruptcy. Gilead CEO John C. Martin took home a reported $19 million last year in compensation – the spoils of untrammeled greed.

A glance at Table 4 above reveals, however, that Martin's actual compensation in 2014 was $192.8 million. As Hopkins and Lazonick (2016) explain, the "reported $19 million" that Sachs cites is an estimated "fair value" accounting measure of executive compensation that, as can be seen, vastly understates actual compensation. For the decade 2005-2014, the "fair value" measure of Martin's pay totaled $141.5 million but his actual pay, reported to the US Internal Revenue Service, was $717.4 million, of which 95% was stock based.

In 2014 the actual pay packages of the other four Gilead executives named on the company's proxy statement were: John F. Milligan $89.5 million (97% stock based); Gregg H. Alton $52.6 million (97%); Norbert W. Bischofberger $50.7 million (96%); and Robin L. Washington $26.6 million (93%). In 2015 the compensation of Martin was $232.0 million (98%), Milligan $103.4 million (97%), Bischofberger $95.5 million (98%), Alton $33.6 million (94%), and Washington $22.0 million (91%). In the first six months of 2016, even with Gilead's stock price in decline, Martin, who stepped down as CEO in March but remains at the company as executive chairman, "earned" $55.1 million from stock-based compensation. In the first quarter of 2016 Gilead did $8.0 billion in buybacks, thus helping to "create value" for its senior executives as sharesellers. In the second quarter of 2016 Gilead scaled back its buybacks to $1 billion.[5]

In an interview in December 2013, Alton, Gilead vice-president of corporate and medical affairs, defended the price of Sovaldi by saying: "Really you need to look at the big picture. Those who are bold and go out and innovate like this and take that risk, there needs to be more of a reward on that. Otherwise it would be very difficult for people to make that investment" (The Staffs of Senators 2015, p. 108). But whose risks are being rewarded? Over its entire corporate history, Gilead has secured a total of $376 million from public share issues, all between 1991, when it did its IPO, and 1996. Especially since Gilead only began paying dividends in 2015, it is probable that virtually all of those shareholders have long since sold their shares to secure capital gains. Current shareholders are just stock-market traders who have bought outstanding shares. So why are Gilead's senior executives so intent on "creating value" for shareholders who have contributed nothing to the development of Gilead's products? The executive-pay numbers provide the answer.

Gilead is not an innovative company. Among the ten drugs that have generated 97% of Gilead's revenues since 1999, only two contain ingredients fully developed by Gilead researchers. Gilead gained control over the remaining ingredients, including sofosbuvir, the key component of Sovaldi and Harvoni, through acquisitions of companies that had brought the drugs to the later stages of development or had

already put them on the market. And the history of the design and development of the drugs that Gilead sells reveals seminal research that was done with government funding from the National Institutes of Health (NIH).

Indeed, the NIH's 2016 budget of $32.3 billion is, in real terms, triple NIH's annual spending in the mid-1980s (National Institutes of Health 2016). Yet even three decades ago, before companies like Celgene, Gilead, Cephalon, Regeneron, Vertex, and Alexion had been founded, NIH funding was critical to drug innovation. At a meeting with French President François Mitterrand in Silicon Valley in 1984, documented in a *Washington Post* report (Henderson and Schrage 1984), venture capitalist Thomas Perkins, whose firm brought Genentech from startup in 1976 to IPO in 1980, "extolled the virtues of the risk-taking investors who finance the entrepreneurs." The *Post* article goes on to say:

> Perkins was cut off by Stanford University Professor Paul Berg, who won a Nobel Prize for work in genetic engineering. "Where were you guys in the '50s and '60s when all the funding had to be done in the basic science? Most of the discoveries that fueled [the industry] were created back then....I cannot imagine that if there had not been an NIH funding research, that there would have been a biotechnology industry," Berg said.

As these things go, Berg himself would be appointed to Gilead's board in 1998, and as a company director from 2004 to 2011 regularly exercised his stock options, netting an average of $2.9 million per year.[6]

But the acute problem of access to medicines goes far beyond the actions of individuals or even companies. The Gilead problem is an American problem, and given the centrality of US pharmaceutical research, the American problem is a global problem. The key cause of high drug prices, restricted access to medicines, and stifled innovation, we submit, is a social disease called "maximizing shareholder value." Armed with "the theory of innovative enterprise," policy-makers can take steps to eradicate the MSV disease (Lazonick 2014a).

5. The Theory of Innovative Enterprise and the Flaws in MSV

MSV is a *profit-driven* ideology that results in high drug prices, restricted access to existing medicines, and stifled pharmaceutical innovation. If widespread access to critical medicines at affordable prices is the goal, MSV needs to be replaced by a *product-driven* norm of corporate governance. Underpinning this product-driven norm is "the theory of innovative enterprise" (Lazonick 2012b; Lazonick 2016b).[7] The theory of innovative enterprise provides an analytical framework for understanding how a business enterprise can generate a product that is higher quality (in medicines, more effective and safer) and lower cost (more accessible and affordable) than products previously available.

The innovation process that can generate these outcomes is:

- **Uncertain:** When investments in transforming technologies and accessing markets are made, the product and financial outcomes cannot be known. Hence the need for *strategy*.
- **Collective:** To generate higher-quality, lower-cost products, the enterprise must integrate the skills and efforts of large numbers of people with different responsibilities and capabilities into the learning processes that are the essence of innovation. Hence the need for *organization*.
- **Cumulative:** Collective learning today enables collective learning tomorrow, and these organizational learning processes must be sustained over time until, through the sale of innovative products, financial returns can be generated. Hence the need for *finance*.

The theory of innovative enterprise identifies three social conditions – *strategic control*, *organizational integration*, and *financial commitment* – that can enable the firm to manage the uncertain, collective, and cumulative character of the innovation process.

- **Strategic control:** For innovation to occur in the face of technological, market, and competitive uncertainties, executives who control corporate resource allocation must have the abilities and incentives to make strategic investments in innovation. Their abilities depend on their knowledge of how strategic investments in new capabilities can enhance the enterprise's existing capabilities. Their incentives depend on alignment of their personal interests with the company's purpose of generating innovative products.
- **Organizational integration:** The implementation of an innovative strategy requires integration of people working in a complex division of labor into the collective and cumulative learning processes that are the essence of innovation. Work satisfaction, promotion, remuneration, and benefits are important instruments in a reward system that motivates and empowers employees to engage in collective learning over a sustained period of time.
- **Financial commitment:** For collective learning to cumulate over time, the sustained commitment of "patient capital" must keep the learning organization intact. For a startup company, venture capital can provide financial commitment. For a going concern, retained earnings (leveraged if need be by debt issues) are the foundation of financial commitment.

The theory of innovative enterprise explains how, in the United States during the twentieth century, a "retain-and-reinvest" allocation regime enabled a relatively small number of business enterprises in a wide range of industries to grow to employ tens, or even hundreds, of thousands and attain dominant product-market shares.[8] Companies retained corporate profits and reinvested them in productive capabilities, including first and foremost collective and cumulative learning. Companies integrated personnel into learning processes through career employment. Into the 1980s, and in some cases beyond, the norm of a career-with-one-company prevailed at major US corporations. A steady stream of dividend

income and the prospect of higher future stock prices based on innovative products gave shareholders an interest in "retain-and-reinvest."

From the 1960s, however, a changing business environment encouraged executives of established US corporations to shift corporate resource allocation from "retain-and reinvest" to "downsize-and-distribute" (Lazonick 1992, Lazonick and O'Sullivan 2000, Lazonick 2009, Lazonick 2015b).[9] By the 1980s, even in good times, companies began to downsize their labor forces and distribute more profits to shareholders. Justifying this dramatic transformation in corporate resource allocation was a new ideology that taught that, for the sake of economic efficiency, companies should "maximize shareholder value" (Lazonick and O'Sullivan 2000; Lazonick 2014a).

The MSV argument is that, of all participants in the corporation, only shareholders make productive contributions *without a guaranteed return* (Jensen 1986). All other participants such as creditors, workers, suppliers, and distributors allegedly receive a market-determined price for the goods or services they render to the corporation, and hence take no risk of whether the company makes or loses money. On this assumption, only shareholders, as the sole risk-takers, have an economically justifiable claim to profits.

A fundamental flaw in MSV lies in the erroneous assumption that shareholders are the only corporate participants who bear risk. *Taxpayers* through government agencies and *workers* through the firms that employ them make risky investments in productive capabilities on a regular basis. Households, as taxpayers and workers, may have legitimate economic claims on the distribution of profits.

The National Institutes of Health (NIH), which from 1938 through 2015 spent $958 billion in 2015 dollars on life-sciences research, is a prime example of how taxpayers invest without a guaranteed return (National Institutes of Health 2016). Drug companies benefit from the knowledge that the NIH generates. As risk bearers, taxpayers fund investments in the knowledge base – as well as physical infra-structure such as roads – required by business, and hence have tax claims on corporate profits. But because profits may not be forthcoming and tax rates can be changed, the returns to taxpayers' investments are not guaranteed.

Through the application of skill and effort, workers regularly make productive contributions to the company's future products, and hence prospective profits. Their rewards take the forms of continued employment and career advancement, and hence workers invest in collective and cumulative learning without guaranteed returns. "Retain-and-reinvest" rewards innovative workers. But profits from innovation may not materialize, and even when they do, "downsize-and distribute" may deny these workers shares of profits that, as risk-bearers, they should have received.

As risk bearers, therefore, taxpayers whose money supports business enterprises and workers whose efforts generate productivity improvements have claims on corporate profits if and when they occur. MSV ignores the risk-reward relation for these two types of economic actors in the operation and performance of business corporations.

Another basic flaw in MSV is that the public shareholders whom it holds up as the only risk bearers typically do not invest in the value-creating capabilities of the company. Rather, as savers or speculators, they buy outstanding shares on the stock market for the sake of dividends and stock-price increases. Public shareholders generally make no productive contributions to the enterprise. Indeed, from 2006 through 2015, net equity issues in the United States were *over four trillion dollars in the negative*; US stock markets fund public shareholders rather than vice versa.[10]

The proponents of MSV (see Jensen 1986; Jensen and Murphy 1990) advocate that, through stock-based pay, senior executives should be incentivized to "disgorge" corporate earnings as buybacks and dividends to the corporate participants who matter least – just the opposite of the financial commitment needed for innovation. These distributions to shareholders generally come at the expense of the stable and remunerative career opportunities that integrate employees into processes of collective and cumulative learning. As for strategic control, a senior executive who sees MSV as the key to corporate success has lost not only the incentive but probably also the ability to allocate corporate resources to potentially innovative investments. In sum, MSV undermines investments in innovation that, if successful, can yield products that are higher quality and lower cost than previously available.

Major US pharmaceutical companies have the MSV disease, as evidenced by not only massive stock buybacks and exploding executive pay (Lazonick et al. 2014, Hopkins and Lazonick 2016) but also a "productivity crisis" in drug discovery (Pisano 2006, Cockburn 2007, Munos 2009, Lazonick and Tulum 2011, Pammolli et al. 2011, Khanna 2012, DeRuiter and Holston 2012). Companies such as Merck and Pfizer have spent the last two decades living off patented blockbuster drugs, with very little to replace them in the pipeline (Phillips 2014, McGrath 2014a, McGrath 2014b). In the name of MSV, they have been profit-driven. For a company to be an innovative enterprise, however, it needs to be product-driven.

Pfizer's focus on profits before products began before the 1980s. In the case of Merck, with Roy Vagelos as head of research from 1975 to 1985 and as CEO for the following decade, the company remained highly innovative through investments in organizational learning (Hawthorne 2003, Vagelos and Galambos 2004). In the decade that Vagelos headed Merck, the company generated both innovative products and high profits, with profit margins at over 20% for 1985-1994. The gains from innovation enabled Merck to provide its drug for river blindness for free to millions of poor people around the world (Vagelos and Galambos 2004, pp. 251-253).

But, as shown in Table 6, high profits also permitted the company to do substantial stock buybacks on top of dividends at a time when MSV was becoming the unchallenged ideology in corporate America. Once Vagelos stepped down as Merck CEO, innovation largely stopped at the company. According to a number of Merck insiders, his successor Raymond Gilmartin stifled research (Hawthorne 2006, p. 30), and, as suggested by the decadal figures on distributions to shareholders shown in Table 6, under CEOs Richard Clark (2005-2010) and Kenneth Frazier (from 2011), the financialization of Merck has only gotten worse. Since Frazier took over, Merck's revenues have fallen from $46.0 billion to $39.5 billion, and employment from 94,000 to 68,000. Yet buybacks have been 87% of net income and dividends another 99%, while Frazier's total compensation in 2014 was $17.6 million, of which 71% was stock based. [11]

Table 6. Stock buybacks and cash dividends, Merck and Pfizer, 1975-2015

	BB $b	DV $b	R&D $b	BB/ NI%	DV/ NI%	(BB+DV)/ NI%	R&D/ REV%
Merck							
1975-1984	0.4	1.6	2.3	9.7	44.8	**54.5**	9.4
1985-1994	4.8	7.3	8.2	30.3	46.1	**76.5**	10.8
1995-2004	26.4	25.8	24.2	46.4	45.5	**91.8**	7.9
2005-2014	26.5	42.2	66.5	47.7	75.9	**123.5**	19.1
2011-2015	22.7	25.7	37.9	87.0	98.5	**185.6**	17.2
Pfizer							
1975-1984	0.0	1.2	2.3	0.0	43.1	**43.1**	5.5
1985-1994	3.2	4.0	8.2	41.7	51.4	**93.1**	10.5
1995-2004	34.5	21.9	24.2	71.6	45.6	**117.2**	17.8
2005-2014	60.8	66.6	66.5	52.3	57.3	**109.5**	15.5
2011-2015	44.7	32.6	39.6	70.4	51.3	**121.7**	14.3

REV=revenues; NI=Net Income; BB=stock buybacks (aka repurchases); DV=cash dividends; R&D=research and development expenditures
Sources: S&P Compustat database and company 10-K SEC filings.

In November 2015 Pfizer commanded attention for its plan to acquire Allergan, and thus avoid US corporate taxation by establishing Ireland as its tax home. Pfizer CEO Ian Read moaned that Pfizer's US tax bill put the company at a "tremendous disadvantage" in global competition. "We're fighting," he said in the interview, "with one hand tied behind our back" (Rockoff et al. 2015). Yet from 2011 through September 2015, with Read as CEO, Pfizer's distributions to shareholders were 4.7 times its US tax payments. If Pfizer is cash-constrained, Read and his board should rethink why they did $45 billion in buybacks in 2011-2015. Perhaps it was the golden handcuffs of stock-based pay; in 2014 Read's total compensation was $22.6 million, of which 57% was from options and awards (Lazonick et al. 2015).

From 2010 to 2015, Pfizer's revenues fell from $67.8 billion to $48.9 billion, mainly because of expiration of patents on some of the company's blockbuster drugs, and employment was slashed from 110,600 to under 78,000. Pfizer has long since lost the capability to generate its own drug products. Since 2001 the company has launched only four internally-developed products, the last one in 2005. Driven by profits rather than products, Pfizer has been, for even longer than Merck, the antithesis of an innovative enterprise.

6. How to Fix a Broken Business Model

In our view, a primary policy objective of all government agencies, civil-society organizations, and business enterprises that seek innovative and affordable drugs should be the eradication of MSV as an ideology of corporate governance. MSV is a global problem, but the US pharmaceutical industry is where the ideology operates unconstrained. Here are, by necessity briefly, steps that the US government can take to bring the MSV disease under control:

- Ban pharmaceutical companies from doing stock repurchases. Such a ban would go a long way to restoring stable and equitable growth to the US economy in general and a focus on access to medicines in the pharmaceutical industry in particular (Lazonick 2016a).[12]
- Require executive compensation that rewards the success of the pharmaceutical company in generating new medicines at affordable prices. Stock-based compensation rewards executives for draining earnings out of the company rather than mobilizing earnings to invest in innovation.
- Place stakeholders representing households as taxpayers, workers, and consumers on boards of directors of publicly listed pharmaceutical companies, along with shareholders who represent households as savers.
- Regulate the price of any drug that has benefitted from government funding, subsidies, and protection (however far upstream in the innovation process) with a view to making the drugs accessible to the largest numbers of people who need them at the most affordable prices (Trouiller et al. 2001).
- Increase the returns to households as taxpayers for their investments in life-sciences research. The Bayh-Dole Act of 1980, which facilitates commercial-ization of federally funded research, has given too much to business interests, including university scientists, who can make fortunes in the commercialization process. Within the university, the pursuit by "star scientists" of individual gain from publicly funded research has undermined the collective and cumulative learning that medical research requires (Wright 1986; Krimsky 2003).
- Use government funding, in collaboration with innovative businesses, to ensure the "collective and cumulative careers" of life-science researchers, who are the lowest-paid PhDs in the natural sciences (Lazonick et al. 2014, Hopkins and Lazonick 2014). There is evidence that the doubling of the NIH budget between 1998 and 2003 created large cohorts of life-science PhDs while contributing to an even more financialized biomedical industrial complex in which the prospects

> of collective and cumulative careers became more insecure (Teitelbaum 2008, Cyranoski et al. 2011, Stephan 2012, Teitelbaum 2014).

It is folly that the US government provides drug companies with NIH funding, patent protection, and, under the Orphan Drug Act, market exclusivity but does not regulate drug prices. In testimony to US Congress, Rohit Malpani (2015), MSF Director of Policy and Analysis, countered the drug companies' contention that higher prices generate profits that are reinvested in new drug development by arguing that "the sole reliance on high medicine prices, backed by monopolies, is a flawed paradigm for funding innovation" that

> leads to unaffordable prices while failing to stimulate innovation for diseases disproportionately affecting developing countries, where patients have limited purchasing power. Our current innovation model is also failing patients in developed countries, as with antibiotic resistance. In spite of the need for new antibiotics, pharmaceutical companies, including Pfizer, the world's largest, have abandoned antibiotic drug development. Since antibiotics must be affordable and used sparingly, the industry response has been to withdraw.

We agree. Companies that are concerned with profits, not products, tend to be uninterested in allocating resources to the development of drugs that promise low profit margins. When the US government has sought to regulate drug prices, pharmaceutical companies have argued that they need high prices to fund investments in innovation. The fact is, however, that the largest drug companies allocate all of their profits and more to buybacks and dividends. Legitimized by MSV, "downsize-and-distribute" has enabled the senior pharma executives who make these resource-allocation decisions to secure enormous compensation for themselves.

The innovative drugs that are available are unaffordable while innovative drugs that hundreds of millions of people need are unavailable. Considering its terrible performance in the name of MSV, and its dependence on government for life-sciences research, market protection, and product demand, the US pharmaceutical sector is in need of a corporate-governance revolution. Aided by government regulation and progressive social norms, US pharmaceutical companies need to reject MSV and begin the transformation to innovative enterprise.

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NOTES:

[1] We begin the series in 2006 because of changes in the availability of relevant executive-pay data in that year. See Hopkins and Lazonick 2016.

[2] Among executives from companies founded in the late 1980s or early 1990s, Table 4 also includes one executive from Cephalon, which was founded in 1987 in Pennsylvania and acquired by the Israeli company Teva in May 2011.

[3] For an analysis of the relation between financialization and Gilead's drug pricing, see Roy and King (2016).

[4] In March 2014, Gilead granted Egypt the price of $900 for a 12-week treatment of Sovaldi. See Fick and Hirschler (2014). One suspects that the pricing concession to Egypt was a condition of the deal that Pharmasset founder Raymond Schinazi, who was originally from Egypt, made with Gilead in the 2011 sale of Pharmasset. See Cookson (2014). Under Congressional scrutiny and with revenues rolling in, Gilead extended that price to other low-income nations. As of August 2015, Gilead had made a 12-week treatment of Sovaldi available in 101 countries for $900 (http://www.gilead.com/~/media/files/pdfs/other/hcv%20access%20fact%20sheet%20%20101615.pdf) .

[5] Note that the Securities and Exchange Commission does not require that companies reveal, at the time or after the fact, the precise days on which they do open-market repurchases. Monthly buybacks are reported in 10-Q filings with the Securities and Exchange Commission.

[6] Insider trade data, filed on SEC Form 4, show that between 2004 and 2011, when he retired from Gilead's board, Berg's realized gains from exercising stock options were $23.1 million.

[7] The "theory of innovative enterprise" builds upon a wide range of studies on the social conditions that support innovation at the national, industry, and company levels (see www.theAIRnet.org)..

[8] Over the last century, large corporations have dominated the US economy. In 2012, the 1,909 companies with 5,000 or more employees in the United States were only 0.03% of all firms, but, with an average employment of 20,366, employed 34% of the US business-sector labor force while covering 38% of all payroll expenditures and generating 44% of all revenues. See United States Census Bureau (2016).

[9] These changes included the failure of the conglomerate movement of the 1960s, Japanese competition, the rise of Silicon Valley startups, and the transformation of Wall Street from investing in companies to trading in their securities. See Lazonick (1992), Lazonick and O'Sullivan (2000), Lazonick (2009), Lazonick (2012a), Lazonick (2014a). On the pharmaceutical industry, see Lazonick and Tulum (2011).

[10] Board of Governors of the Federal Reserve System (2016). Net equity issues are all corporate stock issues minus those shares withdrawn from the market through stock repurchases and merger-and-acquisition activity.

[11] We have recalculated Merck's reported net income in 2014 to exclude a gain $11.4 billion from the sale of a business that Merck recorded as an offset to expenses. Compensation data are from the company's DEF 14A (proxy statement) filings with the US Securities and Exchange Commission.

[12] A number of prominent US politicians, including Senator Tammy Baldwin (D-WI), Vice-President Joseph Biden, and Senator Elizabeth Warren (D-MA), are outspoken critics of stock buybacks, and Senator Baldwin has been active in questioning the US Securities and Exchange Commission about why it permits them. See Lazonick (2016a). See also the website of the Academic-Industry

Research Network: www.theAIRnet.org. Ken Jacobson and William Lazonick are writing a history of how the SEC adopted Rule 10b-18 in November 1982, giving US corporate executives license to do massive buybacks without fear of being charged with manipulating the company's stock price.