FINANCIALIZED CORPORATIONS IN A NATIONAL INNOVATION SYSTEM: THE US PHARMACEUTICAL INDUSTRY

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ABSTRACT

There are widespread claims that a productivity crisis afflicts the US pharmaceutical industry despite the fact that the US institutional environment provides unique advantages for drug R&D. We argue that the explanation for this productivity paradox is the "financialization" of the US pharmaceutical industry. Driven by shareholder-value ideology, the US pharmaceutical industry has adopted a highly-financialized business model. Its key performance metrics are stock-price yield and dividend yield, supported by distributions to shareholders through large-scale stock buybacks and cash dividends. With this financial behavior incentivized by stock-based executive pay, value extraction from corporations for the sake of distributions to shareholders comes at the expense of drug innovation. Simultaneously, however, a number of less-financialized European companies are making use of the US innovation system to outcompete the US companies at home. Arguing that all business enterprises face a tension between innovation and financialization, this paper employs the theory of innovative enterprise as a framework for analyzing the evolution of this tension for pharmaceutical companies operating in the United States. We provide evidence of the highly-financialized character of the major US pharmaceutical companies in the S&P 500 Index, focusing on distributions to shareholders and the stock-based pay of pharmaceutical executives. After documenting the evolution of the US innovation system for drug R&D since the 1980s and summarizing the US product strategies of seven major European pharmaceutical companies, we pose the hypothesis that under a system of corporate governance supporting innovation, the US innovation system could result in a more innovative pharmaceutical industry.

1. US pharma's productivity paradox

The US institutional environment—what evolutionary economists would call its "national innovation system" (Freeman, 1987; Nelson, 1991; Lundvall, 1992)[1]—provides unique advantages for the development and commercialization of pharmaceutical drugs. Through the National Institutes of Health (NIH), the US government provides in excess of $30 billion per year to support life sciences research, implemented through a well-established network of government, nonprofit, university, and hospital research labs. Scientific talent is drawn from around the world to study in American universities and pursue research careers in US government agencies, civil-society organizations (including universities), and business enterprises. The US legal system facilitates the transfer of federally-funded research to business enterprises, and grants pharmaceutical companies 20-year patents on drug discoveries. In addition, under the Orphan Drug Act of 1983, pharmaceutical companies can receive, among other benefits, seven-year market exclusivity from the time that the Food and Drug Administration (FDA) approves a drug for rare and genetic diseases. These companies may also receive various types of research or tax subsidies at federal, state, and local levels (Lazonick & Tulum, 2011).

Adding to these advantages for funding pharmaceutical drug innovation, the United States is the only major nation that does not regulate pharmaceutical drug prices, which are generally at least double in the United States as in other advanced nations (Lazonick et al., 2017). And the US market for pharmaceutical drugs is the largest in the world, with government agencies paying for in excess of 40 percent of these expenditures. High drug prices and economies of scale provide pharmaceutical companies with ample profits that can be allocated to new drug discovery. Indeed, the largest US pharmaceutical companies that are included in the S&P 500 Index spend about 16 percent of revenues on research and development (R&D).

Yet, despite a national system so highly conducive to innovation, there is convincing evidence that a crisis of productivity afflicts the US pharmaceutical industry (Garnier, 2008; Munos, 2009; Paul et al., 2010; Pammolli et al., 2011; Scannell et al., 2012; Rafols et al., 2014; Gleadle et al., 2014; Scannell & Bosley, 2016; Kinch, 2016). We argue that the explanation for this productivity paradox is the "financialization" of the US pharmaceutical industry. Driven by the ideology of maximizing shareholder value (MSV), the US pharmaceutical industry has adopted a highly-financialized business model. Its key performance metrics are stock-price yield and dividend yield, supported by distributions to shareholders in the forms of large-scale stock buybacks in addition to ample cash dividends. With this financial behavior incentivized by stock-based executive pay, value extraction from corporations for the sake of distributions to shareholders can be at the expense of productivity in drug innovation. At the same time, however, a number of less-financialized European companies are making use of the US innovation system to outcompete the US companies in their home market.

The broad implication is clear: A national innovation system depends on both government agencies and business enterprises to engage in investment strategies and build organizational structures that, working in collaboration, generate drug innovation. This article adduces the evidence that the financialized business model is the main reason why US pharmaceutical companies face an ongoing productivity crisis. The article then assesses the evidence that the less-financialized European pharmaceutical companies, which are subject to price regulation in

their home markets, augment their innovative capabilities by tapping into the immense US knowledge base and selling their products in the United States at high, unregulated, prices. Both US and European drug companies face a tension between innovation and financialization, and it is those companies that are governed for innovation that make best use of the formidable national innovation system that exists in the United States.

All business corporations confront a tension between innovation and financialization. The enterprise must invest in *value creation* in order develop the high-quality, low-cost goods and services that enable it to generate revenues on product markets that will yield sufficient profits for a company to emerge and survive as an innovative enterprise.[2] But once a company has been successful as an innovative enterprise, participants in the enterprise, including workers, taxpayers, and financiers, who have contributed to the value-creation process will want to extract some or all of the increased value that innovation has made possible. This *value extraction* will reward those workers, taxpayers, and financiers for their contributions to value creation, but if they extract too much value from the enterprise, they may undermine the financial viability of the company as a going concern—including the financial capacity of the company to renew its investments in the next generation of innovative products.

The tension between innovation and financialization becomes vastly more problematic when the company is governed for the sake of financial interests who have the power to extract far more value for themselves than they have contributed to the value-creation process. And indeed, in an institutional environment dominated by the ideology that a company should be run to "maximize shareholder value" that is precisely what has occurred in the United States (Lazonick & O'Sullivan, 2000; Lazonick, 2017; Lazonick, 2018; Lazonick & Shin, 2019). Corporate executives, Wall Street bankers, and hedge-fund managers have been the beneficiaries of massive distributions of corporate cash to shareholders in the forms of stock repurchases and cash dividends, with their financial gains being out of all proportion to contributions that they have made to the corporations' value-creation processes. Financialization has trumped innovation, and as we have shall see, the US pharmaceutical industry stands out for the extent to which this predatory value extraction has occurred and the damage that it has caused (Lazonick et al., 2017).

In Section 2 of this paper, we outline *the theory of innovative enterprise* as a framework for analyzing the evolution of the tension between innovation and financialization for pharmaceutical companies operating in the US institutional environment. Then, in Section 3 of this paper, we provide evidence of the highly-financialized character of the major pharmaceutical companies included in the S&P 500 Index, focusing on distributions to shareholders and the stock-based pay of pharmaceutical executives.

In Section 4, we document the evolution of the US innovation system for pharmaceutical drug development since the 1980s, emphasizing the ways in which it has sought to support innovation, even as major US pharmaceutical companies have in fact undermined innovation through the financialized corporate resource-allocation behavior that we documented in Section 3. Finally, in the concluding section of this paper, by summarizing the US product strategies of seven major European pharmaceutical companies in the United States, we pose the hypothesis that under a system of corporate governance that supports innovation rather than financialization, the US innovation system could result in a much more innovative pharmaceutical industry that would focus on treating medical problems at affordable costs rather than on

boosting stock yields to increase the financial gains of senior executives and the Wall Street bankers and hedge-fund managers with whom they have become allied.

2. The tension between innovation and financialization

What is the most fundamental driver that motivates a business enterprise to pursue economic growth? Is it profits or products? The conventional neoclassical view of the world sees the pursuit of profit maximization as the firm's objective, with the production and sale of products as simply means to this end. But, as Lazonick (1991; 2002; 2017) has shown, the neoclassical perspective, with its constrained-optimization methodology, lacks a theory of innovative enterprise. The objective of the innovative enterprise is to transform technologies and access markets to generate goods and services that are higher quality and lower cost than those previously available.

From this perspective, profits result from the firm's success in generating innovative products, and the investment of profits to augment the company's innovative capabilities provides the financial foundation for the continued growth of the firm. Indeed, from the perspective of innovative enterprise, the pursuit of profits for their own sake is likely to undermine the social conditions of innovative enterprise, elevating value extraction over value innovation, and giving rise to the productivity disease known as financialization across different industries, including pharmaceuticals (Lazonick, 2013a & 2017; see also Baldwin & Clark, 1992; Froud et al., 2006; Hopkins et al., 2007; Christensen et al., 2008; Andersson et al., 2010; Kessel 2011; Lazonick & Tulum, 2011; Montalban & Sakinç, 2013; Haslam et al., 2013; Gleadle et al., 2014).

The distinction between innovation and financialization can be found in business practice, with the US pharmaceutical industry as a prime example. Through comparative historical case analyses, Tulum (2018) explains how from the 1980s the long-established US company Merck transformed from innovation to financialization, and how the Swiss company Roche, in part through its acquisition of the "New Economy" US company Genentech (founded in 1976), has over the same decades augmented its innovative capabilities within the US market.

Indeed, from the mid-1980s, many US pharmaceutical companies have been founded as essentially financialized entities with the purpose of acquiring patented drugs and using the US innovation system to make profits. Gilead Sciences is the most striking example of a growing number of companies that, in the name of "maximizing shareholder value," exist primarily to extract value from innovation done at other companies (Lazonick et al., 2017; Roy & King, 2016).

To examine how some actors within the economy can extract value in excess to their contributions to the innovation process, one needs an economic theory that explains the processes through which value is created. Only then can one understand the relation among those actors who contribute to value creation and those actors who exercise power over value extraction. In research carried out since the late 1980s, Lazonick (1991, 2002, 2013b, 2017) has constructed the *theory of innovative enterprise* (TIE) framework to analyze the activities and assess the performance of the business enterprise through examining the central social conditions that enhance or inhibit the innovation process and the consequent growth of the firm.

Innovation—the process of creating value—drives the growth of the firm, and with it the growth of the economy, but it also opens up the possibility for financialization—the extraction of the value that has been created by parties whose labor and capital played little if any role in the

value-creation process. Even for an individual working on his or her own, there would be a tension between value creation and value extraction. Should the individual who reaps profits through value creation devote those profits to further value creation, or should he or she benefit from some or all of those profits through value extraction? Once, through the application of the individual's labor effort in combination with the individual's financial investment, the firm has transitioned from a new venture to a going concern, should he or she maintain the prior intensity of effort, or should he or she reduce the amount of time and energy devoted to the value-creation process? At what point and to what extent should the individual turn from value creation to value extraction? These questions become vastly more complicated when it is recognized that a modern business corporation is a highly complex social organization, operating in a highly complex institutional environment, in which the types of individuals who have the power to extract value may not be the types of individuals who have devoted their skills, efforts, and savings to the process of creating value.

How does the work of the people, collectively at a point in time and cumulatively over time, contribute to the value-creation process and growth of the firm? In an innovative enterprise, *strategy*, *organization*, and *finance*, the generic activities of any firm, confront the uncertain, collective, and cumulative characteristics of the innovation process. Innovation is *uncertain*: there is no guarantee that the innovation process will generate the higher-quality, lower-cost products that bring economic success, and hence strategy is needed to allocate resources to innovative investment projects. Innovation is *collective*: innovation cannot be done all alone, but rather requires that large numbers of individuals with different functional capabilities and hierarchical responsibilities engage in organizational learning. Innovation is *cumulative*: innovation cannot be done all at once, but requires sustained learning, and hence committed finance, to accumulate the knowledge to generate a high-quality product and then capture a large extent of the market to reap economies of scale and hence low unit costs (Lazonick, 2013b).

The three social conditions of innovative enterprise are *strategic control*, *organizational integration*, and *financial commitment*. Strategic control is a set of social relations that determines the abilities and incentives of those who allocate the firm's resources to invest in inherently uncertain innovation processes. Organizational integration is a set of social relations that mobilizes the skills and efforts of individuals with different capabilities and responsibilities to engage in collective learning. Financial commitment is a set of social relations that sustains the collective learning processes so that learning cumulates from the time at which investments in the innovation processes are made until, through the sale of innovative products, financial returns are generated (Lazonick, 2013b).

An innovative enterprise becomes financialized if and when managerial decisions to allocate productive resources are driven to create gains for a group of people, including the senior executives themselves, that is well in excess of their contribution to the value-creation process. The prime means of what Lazonick and Shin (2019) call "predatory value extraction" are distributions to shareholders in the forms of stock buybacks and cash dividends that come at the expense of workers and taxpayers whose money and labor have contributed to the value-creation process. Legitimizing such a predatory mode of resource allocation is the dominant corporate governance ideology that a company should be run to *maximize shareholder value* (MSV), rooted in the neoclassical theory of the market economy. According to MSV, shareholders

are the only economic actors who take risks and hence are the only actors who have the incentive to allocate resources to their most efficient alternative uses.

Lazonick (2017) critiques this position by arguing that when workers supply their skills and efforts to enable the firm to generate the products that result in future revenues, they take the risk that the future employment and pay that they expect as returns will not be forthcoming, either because the innovative strategy is unsuccessful or because a corporate predator extracts the value that the workers helped to create. Similarly, when, through government agencies, households as taxpayers supply the firm with physical infrastructure and human knowledge, they take risks because the corporate profits out of which the firm pays taxes back to households may not be forthcoming or because the corporations may convince politicians to lower the corporate tax rate. At the same time, the public shareholders, for whom MSV says the firm should be run, take very little risk because they simply buy and sell shares on the liquid stock market, and can sell their shares at any time they choose at a low transaction cost. MSV legitimizes value extraction by those who contribute the least to the value-creation process by ignoring the ways in which innovative enterprises function and perform.

Building on Lazonick and O'Sullivan (2000), Lazonick (2015) summarizes the mode of resource allocation that is necessary for innovation as "retain-and-reinvest": the company retains its money and people and reinvests in productive capabilities, particularly those of the labor force. But at some point in its history, the company's mode of resource allocation may shift from "retain-and-reinvest" to "downsize-and-distribute"; the business enterprise downsizes the labor force through layoffs, pay cuts, and outsourcing and distributes corporate cash to shareholders. The transformation from retain-and-reinvest to downsize-and-distribute implements the transformation from innovation to financialization.

3. The financialization of the US pharmaceutical industry

The US economy depends on the resource-allocation decisions of very large companies. In 2012 (the most recent complete data available), 1,909 companies that had 5,000 or more employees in the United States, averaging 20,366 US employees, had 34 percent of all business-sector employees, 38 percent of payrolls, and 44 percent of receipts (US Census Bureau 2012). Many, if not most, of the largest companies in the United States are highly financialized. Table 1 shows the results of an analysis conducted on the companies listed in the S&P 500 Index. Among all the companies included in the S&P 500 Index in January 2018, the study identified the 466 companies that were publicly listed from 2008 through 2017 to analyze their financial data on the distributions of financial gains to shareholders. The analysis reveals that those 466 companies generated a total of $93.3 trillion revenues and $7.7 billion in profits between 2008 and 2017.

Table 1 also shows that the 466 companies spent 2.2 percent the total revenues, $2 trillion, on activities reported as R&D. The distribution of the financial gains to shareholders in this period however surpassed the money spent on R&D. That comparison is misleading, however, because only about 40 percent of the companies in the S&P 500 Index record any R&D at all. Most of the R&D expenditures are done by high-tech companies in Information-and-communication technologies, aerospace, and pharmaceuticals. Table 1 provides data for 2008-2017 on buybacks, dividends, and R&D expenditures for the 17 US pharmaceutical companies that were in the S&P 500 Index in January 2018.

Table 1 also shows that compared with S&P 500 companies generally, the pharmaceutical companies are highly profitable. High pharmaceutical profits are made possible by high unregulated drug prices. Gagnon and Wolfe (2015) show that US prices of patented drugs in 2014 were about two and a half times those of other OECD countries. With the US price index at 1 in 2014, the OECD average was 0.42, while the French index was slightly over the OECD average, the index for Great Britain and Italy was slightly below the OECD average (Gagnon & Wolfe, 2015, p. 7). We contend that that the data on distributions to shareholders in Table 1 represent conclusive evidence that, for the sake of medical-drug innovation, pharmaceutical drug prices should be regulated.

Table 1. Stock buybacks, cash dividends, and R&D, 2008-2017, at 17 US pharmaceutical companies in the S&P 500 Index in January 2018

COMPANY	REV, $b	NI, $b	BB, $b	DV, $b	R&D, $b	BB/NI, %	DV/NI, %	(BB+DV)/ NI, %	NI/REV, %	R&D/ REV, %	Employees (FY17 end), thousand
JOHNSON & JOHNSON	684	122	45	70	84	37	57	94	18	12	134
PFIZER INC	548	116	56	68	81	48	59	107	21	15	90
ABBOTT [ABBVIE] LABORATORIES	400	59	28	37	45	47	62	109	15	11	128
MERCK & CO INC	398	61	35	47	80	57	77	133	15	20	69
ELI LILLY AND COMPANY	219	28	5	21	49	18	77	95	13	22	41
BRISTOL-MYERS SQUIBB CO	187	36	7	24	44	20	66	87	19	24	24
AMGEN INC	184	48	31	14	35	64	28	93	26	19	21
GILEAD SCIENCES INC	164	64	38	7	23	59	11	70	39	14	10
ALLERGAN PLC	87	13	16	2	12	120	13	132	15	14	18
MYLAN NV	76	5	3	0	5	57	8	65	7	7	35
BIOGEN INC	75	20	14	-	16	69	0	69	27	21	7
CELGENE CORP	67	13	20	-	25	152	0	152	19	37	7
PERRIGO CO	34	(2)	1	0	1	-50	-25	-75	-5	4	6
REGENERON PHARMACEUTICALS INC	23	4	-	-	10	0	0	0	17	45	6
ALEXION PHARMACEUTICALS INC.	16	3	2	-	3	55	0	55	17	20	3
VERTEX PHARMACEUTICALS INC	10	(4)	-	-	8	0	0	0	-34	81	2
INCYTE CORP	5	(1)	-	-	4	0	0	0	-20	78	1
Totals, 17 pharma companies, 2008-17	**3,175**	**587**	**300**	**290**	**526**	**51**	**49**	**100**	**18**	**17**	**602**
Totals, 466 S&P 500 companies, 2008-17	**93,325**	**7,653**	**4,023**	**3,106**	**2,025**	**53**	**41**	**93**	**8**	**2**	**25,075**
17 Pharma as % of 466 S&P 500 =3.6%	**3.4%**	**7.7%**	**7.5%**	**9.3%**	**26.0%**						**2.4%**

REV=revenues; NI=Net Income; BB=stock buybacks (aka repurchases); DV=cash dividends; R&D=research & dev. expenditures – ABBOTT [ABBVIE] LABORATORIES includes the combined financial figures of Abbott Laboratories and the company's pharmaceutical subsidiary, AbbVie, from 2013 to 2017

Source: S&P Compustat database; updated from Lazonick et al. (2017).

Europe's leading pharmaceutical companies appear to be following US-based companies closely when it comes to generating significant earnings as they challenge the US companies in developing and marketing new pharmaceutical products both in the United States and globally. As Table 2 shows, during the period from 2000 to 2017, the net income of Europe's top 10 pharma companies accounted for 15.6 percent of their combined revenues while the net income of the top 10 US-based pharma companies accounted for 18.8 percent of their total revenues. In the last five-year period, from 2013 to 2017, the combined net income of the top 10 US-based pharma companies was slightly higher (19.8 percent of revenues) than their European competitors whose net income accounted for 16.3 percent of revenues in this period. During the period from 2008 to 201, while the top 10 US-based companies expended 17 percent of their revenues on R&D activities, the top 10 European pharma companies spent 15.9 percent.

Table 2. Stock buybacks, cash dividends, and R&D, 2000-2017, Top 10 US vs European Pharmaceutical Firms[3]

	PERIOD	REV $b	NI $b	BB $b	DV $b	R&D $b	BB/NI %	DV/NI %	(BB+DV)/NI %	R&D/REV %	NI/REV %
Top 10 European Pharma	2013-2017	1,515.6	246.8	54.4	164.0	240.9	22.1	66.4	88.5	15.9	16.3
	2008-2012	1,488.4	230.2	49.4	124.7	224.0	21.4	54.2	75.6	15.0	15.5
	2000-2007	1,491.2	224.7	68.5	92.7	209.2	30.5	41.2	71.7	14.0	15.1
	2000-2017	4,495.2	701.7	172.3	381.3	674.1	24.6	54.3	78.9	15.0	15.6
Top 10 USA Pharma	2013-2017	1,593.6	314.9	192.4	168.8	271.1	61.1	53.6	114.7	17.0	19.8
	2008-2012	1,342.9	247.3	88.7	120.3	207.4	35.9	48.7	84.5	15.4	18.4
	2000-2007	1,466.5	267.2	126.0	130.6	225.8	47.2	48.9	96.1	15.4	18.2
	2000-2017	4,403.0	829.3	407.1	419.8	704.3	49.1	50.6	99.7	16.0	18.8

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

Source: S&P Compustat database

As Table 2 shows, in the past five-year period, the top 10 US-based pharma companies led their European competitors only by small margins in terms of allocating resources to support R&D through which the top US and European pharma companies, purportedly, pursue innovative new drugs and economic growth. As evident in Table 2, the top 10 US pharma companies however appear to be more inclined to distribute cash to shareholders through stock buybacks (BB) and cash dividends (DV). During the period from 2008 to 2017, the top 10 US pharma companies boosted payouts to shareholders (BB+DV) to 114.7 percent of net income (NI), while the shareholder payouts by the top 10 European pharma companies accounted for 88.5 percent.

For 2008-2017, the proportion of earnings distributed to shareholders by the top 10 US-based companies through stock buyback programs was nearly three-times greater than by the top 10 European pharma companies (61.1 percent vs 22.1 percent). As shown in Table 2, during the 18-year period 2000-2017, the US-based companies used buybacks to distribute 49.1 percent of their net income to shareholders, compared with 24.6 percent by the European companies.

Over the decades, pharmaceutical companies have lobbied vigorously against proposed market regulations to control drug prices in the United States. The main argument that the industry lobby habitually raises against drug-price regulation is that the high level of profits available in the US drug market, made possible by high drug prices, enables the companies to accelerate investment in drug innovation. Indeed, in 1994, the industry lobby group, the Pharmaceutical Manufacturers Association changed its name to Pharmaceutical Research and Manufacturers of America (PhRMA) to emphasize the purported focus of the industry on research. PhRMA's argument is that US users of pharmaceutical drugs pay high prices on those drugs successfully developed in the past for the sake of innovative drugs in the future, with a disproportionate amount of the innovative research taking place in the United States.

Given the extent to which, as Table 1 shows, the largest US pharmaceutical companies have been allocating profits derived from high drug prices to distributions to shareholders, in charging these high prices the US companies have been engaged in price-gouging (Lazonick et al., 2017; see also Hemphill & Lemley, 2011; Pollack, 2015; Kantarjian & Rajkumar, 2015). They use high profits to fund distributions to shareholders, and not to augment spending on R&D. As Kesselheim, Avorn and Sarpatwari (2016) show in their extensive literature review on this topic, pharma companies are able to engage in this price-gouging because of patent protection without

price regulation. Furthermore, in many cases even when patent protection has ended, pharma companies can price gouge because they are selling products with highly inelastic demand and barriers to new-frim entry posed by the need to meet product-safety standards.

Unless one can argue that these distributions to shareholders are necessary for pharmaceutical R&D, PhRMA's justification for higher drug prices vanishes. Table 1, which displays the distributions to shareholders and R&D expenditures for the 17 pharmaceutical companies included in the S&P 500 Index in January 2018, undercuts PhRMA's argument. As shown in Table 1, for the decade 2008-2017, these 17 pharmaceutical companies had double the profit margins (NI/REV%) of all companies in the Index (18.5 percent versus 8.2 percent), and the pharma group's average of R&D spending as a proportion of revenues was nearly eight times greater than the Index average. Taken by themselves, these data appear at first to support the industry's claim that the drug companies charge premium prices for innovative drugs to generate a yield on the investments previously made on innovation that is sufficiently large to maintain high levels of investment in innovation to generate new drugs in the future. But Table 1 also shows that over the decade virtually all the profits—99.7 percent—reaped by these 17 pharmaceutical companies were distributed to shareholders. Indeed, distributions to shareholders totaling $590 billion exceeded by 12.1 percent the $526 billion that these companies recorded as spending on R&D. These companies do not need high drug prices to fund their R&D expenditures. They have been using high profits to prop up their companies' stock prices.

In Questions for the Record submitted by Sen. Tammy Baldwin (D-WI) in conjunction with a Congressional hearing on high drug prices in October 2017 (Baldwin, 2017), when pressed on the issue, the PhRMA representative argued that the companies need to distribute cash to shareholders to attract investment capital. But it is retained earnings, not money raised on the stock market that is the foundation of financial commitment to drug development (Lazonick et al., 2017; Lazonick, 2018). With these distributions to shareholders, the pharmaceutical companies are financing the stock market, not being financed by it. Moreover, in distributing cash to shareholders, companies reduce the retained earnings that, for a degree of risk of default, can be leveraged with debt.

Why do these companies engage in this financialized business behavior? As Lazonick et al., (2017) have shown, it is because the stock-based pay of top executives of US pharmaceutical companies incentivizes them to allocate resources to buybacks and dividends to boost corporate stock yields. 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 & Lazonick, 2016).

By using stock buybacks to boost stock prices and hit earnings per share targets, executives can augment the gains that they realize from exercising options or the vesting of awards. As shown in Table 3, from 2008 through 2017, the average annual total compensation of the 500 highest-paid US executives (not including billion-dollar-plus outliers) ranged from $15.8 million in 2009 (when the stock market was down) to $32.1 million in 2017, with realized gains from the combination of exercising options and vesting of awards constituting from 60 percent (in 2009) to 83 percent (in 2015) of average annual total pay (Hopkins & Lazonick, 2016). Stock-based pay

incentivizes executives to take actions that increase the company's stock price and rewards them personally for doing so. Buybacks are a means to these ends.

Table 3. 500 highest-paid executives, US corporations, with proportions of mean total direct compensation from stock options and stock awards, and representation of pharma executives among the top 500, 2008-2017

	All 500 Highest-Paid Executives				Highest-Paid Executives, Pharmaceutical Corporations				
	TDC, $m	SO/TDC, %	SA/TDC, %	(SO+SA)/TDC, %	TDC, $m	SO/TDC, %	SA/TDC, %	(SO+SA)/TDC, %	# of pharma execs.
2008	20.5	48	23	71	18.7	61	14	75	21
2009	15.8	37	23	60	26.6	39	19	58	31
2010	19.6	38	27	65	20.0	43	27	70	25
2011	21.2	39	30	69	16.1	48	18	66	21
2012	32.0	40	38	79	33.6	58	25	83	24
2013	27.2	46	34	79	49.9	66	24	91	36
2014	32.0	45	34	79	72.7	69	19	88	42
2015	34.1	48	35	83	61.3	56	31	88	35
2016	27.1	37	41	78	32.5	50	25	75	27
2017	32.1	46	35	81	41.5	45	38	83	28

Note: TDC=total direct compensation; SO=realized gains from exercising stock options; SA=realized gains from vesting of stock awards; # of pharma execs= Number of pharmaceutical executives. Top 500 Sorted by ExecuComp TOTAL_ALT2: salary, bonus, nonequity, change in the value of pension, realized gains from stock options and stock awards. Pharmaceutical executives from companies with NAICS 325411, 325412, 325413, 325414. Note that some of these executives are at pharmaceutical companies that are not among the 17 pharma companies in the S&P 500 Index, identified in Table 1.
Source: Updated from Lazonick et al. (2017).

From 2008 through 2017, 4.2 to 8.4 percent of the 500 highest-paid executives at US corporations were pharma executives. The number of pharma executives found among the top 500 highest paid executives has increased in the most recent years, and as a group their average total compensation soared to levels that exceed by comparison the already sharply increased pay of the top 500 as a whole. As the average total compensation of the drug executives scaled new heights in 2012 and 2013, stock-based pay accounted for 83 percent and 91 percent of the totals, and their pay soared even higher in 2014 and 2015, with the number of pharma executives among the 500 highest-paid executives reaching as high as 42 in 2014.

Table 4 shows that, among the 17 pharma companies in the S&P 500 Index, a younger set of biopharma companies launched in the late 1980s and early 1990s account for the explosion in pharma executive pay. Table 5, which selects from all pharma executives in the S&P ExecuComp database (and not just from those companies in the S&P 500 Index in January 2018), identifies the six highest-paid pharma executives for each year from 2008 through 2017. Note the prominence, especially in 2013-2016, of executives from three of the biopharma companies in Table 5: Gilead Sciences (15 of the 60 cells), Celgene (6), and Regeneron (10). Also note the extent to which their pay is stock based. Gilead Sciences CEO John C. Martin appears on this top 6 list in all ten years, five times in first place, three times in second, and twice in third.

Table 4. Biopharma and the explosion of executive pay, from 2012 to 2017

Company (year founded)	Number of Executives in top 500											
	2012		2013		2014		2015		2016		2017	
	# of execs.	AVE. TDC, $m	# of execs.	AVE. TDC, $m	# of execs.	AVE. TDC, $m	# of execs.	AVE. TDC, $m	# of execs.	AVE. TDC, $m	# of execs.	AVE. TDC, $m
GILEAD SCIENCES (1987)	3	42.6	4	74.7	5	82.4	5	97.3	2	78.1	2	34.6
REGENERON (1988)	5	51.3	4	53.0	4	56.6	3	66.5	2	83.5	3	128.7
ALEXION (1992)	2	32.0	4	20.8	2	111.3	1	51.6	0			
CELGENE (1986)	0		3	27.5	1	96.3	3	16.8	1	16.0	1	40.5
VERTEX (1989)	0		1	36.6	1	28.9	0		0		3	43.7
Executives, 5 pharma	**10**	**42.0**	**16**	**42.5**	**13**	**75.1**	**12**	**58.1**	**5**	**59.2**	**9**	**61.9**
Executives, 17 pharma	17	39.0	29	37.6	32	48.2	27	46.2	20	34.7	22	41.5
All executives in 500	500	32.0	500	27.2	500	32.0	500	34.1	500	27.1	500	32.1

# of execs.= Number of executives; AVE. TDC= Average total direct compensation
Source: ExecuComp data retrieved January 10, 2019. Updated from Lazonick et al. (2017).

Table 5. Six highest-compensated pharma executives, 2008-2017, with total compensation in millions of dollars (stock-based pay as percent of total compensation)

	#1	#2	#3	#4	#5	#6
2008	Robert J. Hugin CELGENE CORP $74.6m (97%)	Sol J. Barer CELGENE CORP $59.3m (94%)	John C. Martin GILEAD SCIENCES INC $33.1m (91%)	Miles D. White ABBOTT LABORATORIES $30.3m (67%)	William C. Weldon JOHNSON & JOHNSON $25.6m (11%)	James C. Mullen BIOGEN $24.6m (93%)
2009	Fred Hassan MERCK & CO $91.3m (61%)	John C. Martin GILEAD SCIENCES INC $60.4m (94%)	Robert J. Bertolini MERCK & CO $58.5m (17%)	Carrie Smith Cox MERCK & CO $46.2m (40%)	Thomas Paul Koestler MERCK & CO $38.9m (46%)	Sol J. Barer CELGENE CORP $31.4m (87%)
2010	John C. Martin GILEAD SCIENCES INC $42.7m (91%)	David E. I. Pyott ALLERGAN INC $35.3m (87%)	Gregory T. Lucier LIFE TECHNOLOGIES $33.8m (87%)	Martine A. Rothblatt UNITED THERAPEUTICS $31.6m (89%)	William C. Weldon JOHNSON & JOHNSON $25.4m (17%)	James C. Mullen BIOGEN $29.2m (94%)
2011	John C. Martin GILEAD SCIENCES INC $43.2m (90%)	David E. I. Pyott ALLERGAN INC $35.8m (86%)	William C. Weldon JOHNSON & JOHNSON $27.8m (28%)	Miles D. White ABBOTT LABORATORIES $22.6m (45%)	Robert L. Parkinson, Jr. BAXTER INT'L $22.6m (75%)	John C. Lechleiter ELI LILLY $22.1m (51%)
2012	George D. Yancopoulos REGENERON $129.8m (98%)	John C. Martin GILEAD SCIENCES INC $85.5m (94%)	Robert J. Coury MYLAN NV $68.6m (69%)	Leonard S. Schleifer REGENERON $52.5m (93%)	Leonard Bell, M.D. ALEXION $41.6m (91%)	David E. I. Pyott ALLERGAN INC $41.4m (88%)
2013	John C. Martin GILEAD SCIENCES INC $168.9m (97%)	Paul M. Bisaro ALLERGAN PLC $113.2m (95%)	John F. Milligan GILEAD SCIENCES INC $79.7m (97%)	George D. Yancopoulos REGENERON $74.5m (96%)	Leonard S. Schleifer REGENERON $73.5m (96%)	Robert J. Hugin CELGENE CORP $46.4m (81%)
2014	Leonard Bell, M.D. ALEXION $195.8m (98%)	John C. Martin GILEAD SCIENCES INC $192.8m (97%)	Leonard S. Schleifer REGENERON $101.8m (97%)	Robert J. Hugin CELGENE CORP $96.3m (89%)	John F. Milligan GILEAD SCIENCES INC $89.5m (97%)	Rajat Rai AKORN INC $75.8m (97%)
2015	John C. Martin GILEAD SCIENCES INC $232.0m (98%)	George D. Yancopoulos REGENERON $104.5m (97%)	John F. Milligan GILEAD SCIENCES INC $103.4m (97%)	Martine A. Rothblatt UNITED THERAPEUTICS $96.7m (98%)	Norbert W. Bischofberger GILEAD SCIENCES INC $95.5m (98%)	Rajat Rai AKORN INC $67.3m (97%)
2016	John C. Martin GILEAD SCIENCES INC $98.4m (96%)	Leonard S. Schleifer REGENERON $93.6m (96%)	George D. Yancopoulos REGENERON $73.3m (96%)	John F. Milligan GILEAD SCIENCES INC $57.8m (93%)	Robert J. Coury MYLAN NV $56.3 million (20%)	Kenneth C. Frazier MERCK & CO $38.6m (76%)
2017	George D. Yancopoulos REGENERON $267.8m (99%)	Leonard S. Schleifer REGENERON $95.3m (95%)	Jeffrey Marc Leiden VERTEX $78.5m (94%)	John F. Milligan GILEAD SCIENCES INC $48.4m (94%)	Richard A. Gonzalez ABBVIE $41.6 million (75%)	Kenneth C. Frazier CELGENE CORP $41.5m (90%)

Note: Executives are selected from those in ExecuComp at companies with NAICS Codes 325411-325414.
Source: ExecuComp data retrieved January 8, 2019. Updated from Lazonick et al. (2017).

4. Pharmaceutical financialization within the US national innovation system

a. Creating the national innovation system

The financialization of the US pharmaceutical industry is an extreme case of the financialization that afflicts US business corporations more generally. As shown in Table 1, the 466 companies in the S&P 500 Index that were publicly listed from 2008 through 2017 distributed 93.2 percent of their profits to shareholders. Lazonick (2017) has called this financial behavior the "largely legalized looting of the US business corporation." The financialization of the US pharmaceutical industry is even more egregious when, as outlined in Lazonick and Tulum (2011), one considers all the government-funded benefits that the industry receives including massive government spending on life sciences research; world-leading investments by governments and households in educating the science and engineering labor force; patent privileges and other product-market protections; numerous federal, state, and local financial subsidies; and government-financed demand for its products.

Through historical analysis of the enactment of certain drug policies in the United States, Tobbell (2012) documents how the pharmaceutical industry gained political power that enabled it to shape the national innovation system in which it operates.[4] This innovation system enabled the US pharmaceutical industry to become the global leader. At the same time, however, the US pharmaceutical industry and the US medical research community used their political power to resist policy reforms that would constrain, regulate or appropriate their financial gains.

The enactment of the Federal Food, Drug and Cosmetic Act (FDCA) in 1938 established the world's foremost regulatory agency—now known as the Food and Drug Administration (FDA)—to monitor drug safety. With a major change in the FDCA in 1951, the Durham-Humphrey Amendment created the legal basis for what is known as the "prescription drug market," which ultimately required the dispensing of pharmaceutical products with the risk of drug addiction or harmful side effects through prescriptions obtained from physicians. Another major change in the FDCA came with the Kefauver-Harris Amendment of 1962, which for the first time required the pharmaceutical companies to provide the regulators with clinical evidence of the efficacy of drugs prior to being sold on the market.

The Health Maintenance Organization (HMO) Act of 1973 (also known as the Federal HMO Act) was among the first market-based policies intended to rein in the soaring cost of healthcare in the United States. The HMO Act restricts consumer choice in healthcare providers by setting up healthcare units—the HMOs—that households on less expensive health insurance plans would have to use. This model of healthcare provision assumes that the HMOs can be managed to lower the costs of healthcare delivery. According to Starr (1983, p. 403), the HMO Act was the most market-friendly solution that the political conservatives could engineer to curb the growing appetite of progressives for "socialized medicine" in the age of medical inflation.

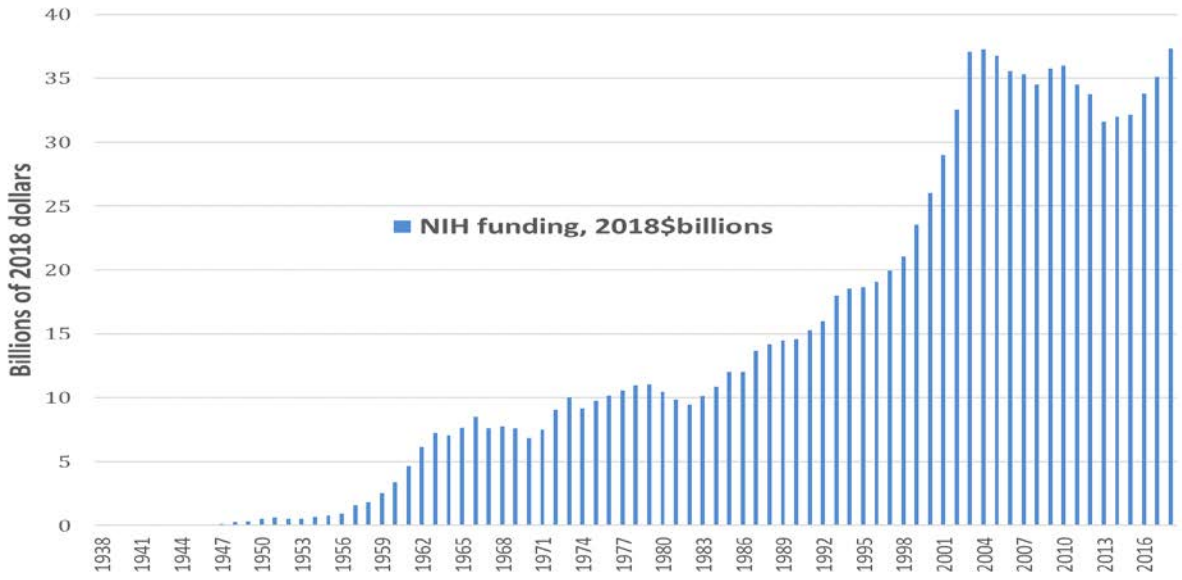
After the passing of the HMO Act, the federal policy efforts to control healthcare costs continued in the 1970s, in the face of anti-regulation resistance that included pharmaceutical manufacturers (Starr, 1983; Brown, 2010). The pharmaceutical industry lobbying efforts in the 1970s through 1980s focused on maintaining the status quo, which essentially meant preventing the federal government from regulating drug prices. Industry rhetoric portrayed government interference in the pharmaceutical market as a major obstacle to innovation—particularly

whenever the federal government considered legislation to rein in soaring drug prices. And US legislators have accepted this free-market (i.e., neoclassical) view of the world.

Yet, dating back to the Morrill Land Grant Act of 1862 which created the national system of public universities, the US government has put in place the most formidable national system of innovation in history (Ferleger & Lazonick, 1993; Ferleger & Lazonick, 1994; Hopkins & Lazonick, 2014). With the launching of the National Institutes of Health (NIH) in the 1930s, this national innovation system included a focus on pharmaceutical drug development. Lazonick and Tulum (2011) underline the critical role that the US government has played for decades in making the investments in scientific and engineering personnel and life-sciences and computer-sciences research that have underpinned pharmaceutical drug innovation in the United States.

Without the funding that the NIH have expended on life-sciences research, there would be no possibility of pharmaceutical innovation in the United States. The 2018 NIH budget was $37.3 billion, up from $34.3 billion in 2017. Figure 1 shows NIH spending, measured in 2018 dollars, on life-sciences research for 1938 through 2018, for a cumulative total of $1.122 trillion over these 81 years. Note the virtual doubling of the NIH budget in real terms between 1996 and 2004. The NIH contends that, on average, every one dollar that they have spent since the US government began funding its biomedical research in 1938 has translated into $2.13 in US pharmaceutical sales (NIH, n.d.). The centrality of NIH funding to US pharmaceutical drug innovation in and of itself justifies government regulation of the prices of the drugs that result from it.

Figure 1. National Institutes of Health funding 1938-2018, 2018$ billion



Source: National Institutes of Health (NIH) Budget, at https://www.nih.gov/about-nih/what-we-do/budget

NIH funding forms a foundation for the elaborate sets of laws and institutions that define the US system of drug innovation. The Bayh-Dole (or Patent and Trademark Law Amendments) Act of 1980 explicitly permits research institutes, including the nation's leading research universities, to transfer the results of federally-funded research to commercial entities (Mowery

et al., 1999). Although the Bayh-Dole Act was initially designed to give small businesses easier access to tax-payer funded technologies carried out in university labs, the bill later expanded beyond "universities" to include all "non-profit" research organizations while dropping the term "small" to include all business, including large defense contractors (Allen, 2009).

The Stevenson-Wydler Technology Innovation Act of 1980 authorized the establishment of "Cooperative Research Centers" (CRCs) to encourage industry-university collaboration and mandated that each federal laboratory establish an "Office of Research and Technology Applications" to actively engage in technology transfer from the labs to commercial enterprises. When Ronald Reagan became US President, he declined to fund the CRCs on the grounds that the provisions of the Bayh-Dole Act offered more autonomy to universities to use their own discretion in the licensing of federally-funded research.

President Reagan later signed the 1986 Federal Technology Transfer Act (FTTA) to eliminate weaknesses of the Bayh-Dole Act and Stevenson-Wydler Act in the transfer of federally-funded research to industry. The FTTA created the "cooperative research and development agreement" (CRADA) to foster the interaction of government and business research efforts, quicken the transfer of technology to business enterprises, and make it easier for businesses to file patents based on this cooperative research. Through CRADAs, FTTA eliminated any resistance on the part of federal laboratories to actively seeking partnerships with industry. In particular, this Act facilitated the transfer of military-sponsored research to civilian uses (Allen, 2009). CRADAs in effect became ways in which the federal government could influence the quality and price of commercial products by requiring that a licensed technology served the health and safety needs of the public and that the products be "reasonably priced" (Arno & Davis, 2001).

CRADAs became opaque and ineffective instruments of price regulation that undercut demands for the open and direct regulation of drug prices. The "reasonably priced" clause persisted when the federal technology transfer program was reauthorized under the National Competitiveness Technology Transfer Act of 1989. But it was removed with the National Technology Transfer and Advancement Act (NTTAA) of 1996 that amended the Stevenson-Wydler Act to make it more attractive for drug companies to enter into CRADAs. NTTAA placed a cap on the amount of royalties that federal researchers could receive on their inventions. After the removal of the "reasonably priced" clause, the number of CRADA applications increased significantly. The new amended version of the Stevenson-Wydler Act allowed more exclusivity to licensees under a CRADA agreement (Allen, 2009). Among the most notable examples of products developed through CRADAs are Burroughs Wellcome's popular drug, azidothymidine (AZT) for Human Immunodeficiency Virus (HIV) infection, and Bristol-Myers' Taxol (Robinson, 2001). Most of the benefits of the Bayh-Dole Act, the Stevenson-Wydler Act, and FTTA (CRADAs) have gone to small biotechnology start-ups and the nation's leading research universities. In 2010, on the occasion of the 30th anniversary of the Bayh-Dole Act, it was revealed that 154 FDA-approved drugs had been discovered, partly or wholly, by public sector research institutions, with an estimated sales volume of $103 billion (Loise & Stevens, 2010).

Patent protection has been fundamental to the US innovation system. The pharmaceutical industry has benefited from general patent laws, including the 17 years of protection against competition from the time of filing a successful patent that prevailed from 1861 through 1994 and the 20 years of protection in existence since 1995. In addition, there have been special protections applicable to the medical drug industry. In the wake of the recombinant DNA

revolution of the 1970s, in 1980, in Diamond v. Chakrabarty, the US Supreme Court ruled that a genetically modified bacterium could be patented (Eisenberg, 1992).

Following the Supreme Court ruling in favor of Ananda Chakrabarty, as well as the enactment of the Bayh-Dole Act, patenting activities in drug development increased rapidly. Enabling this increase were radical changes in the judicial process so that any court appeal concerning patent litigation is overseen by a single, nationwide appellate court specialized in patent-related matters (Meador, 1992).[5] Despite the opposition from some stakeholders, patent attorneys overwhelmingly supported the new judicial reform, which cleared the House and Senate in 1981, President Reagan signed the Court of Appeals for the Federal Circuit (CAFC) Act, which came into effect in 1982. Comprised of judges who were former patent attorneys, the Court's "patent-friendly" attitude defended the IP rights of patent-holders to protect their IP rights while making it difficult for a plaintiff to challenge the patent-holders (Jaffe and Lerner, 2005; Scherer, 2007; Lee, 2012).

The Orphan Drug Act (ODA) of 1983 provided financial subsidies and market protection for pharmaceutical companies to develop drugs for rare and genetic diseases. Lazonick and Tulum (2011) have shown that these so-called orphan drugs were the foundation for pharmaceutical revenue growth in the 1990s and 2000s. From 1983 through 2017, there 4,437 ODA designations and 670 approvals (Food and Drug Administration [FDA], 2017). ODA also offers R&D tax credits as well as FDA assistance in ensuring the rapid transformation of a promising therapy into an approved marketable drug. Most importantly, ODA incentives include seven-year marketing exclusivity for a specific therapeutic application. Unlike patent protection, which begins at the outset of the drug discovery process, ODA exclusivity begins once the drug has been approved for sale by the FDA. Moreover, the company that has obtained ODA approval does not necessarily require patent protection to have market exclusivity in selling the drug. Orphan drugs, which have typically come with very high price tags, were central to the growth of the leading companies in the biopharmaceutical drug industry, including Amgen, Genentech, Genzyme, Biogen IDEC, Cephalon, and Allergan (Lazonick & Tulum, 2011). Large pharmaceutical companies have also benefited from orphan drugs, either by acquiring smaller biotech companies or by entering into co-marketing deals with them that entail both equity investments and research contracts critical to funding the quest to develop an approved orphan drug (Tulum, 2018).

With all of the government funding and market protection of the pharmaceutical industry, one might assume that the US government would regulate drug prices. But, with the help of neoclassical economics, the industry made the argument that it should be the market, not the government, that determines drug prices. They argued that the market mechanism could kick in when a drug went off patent, with generic producers entering the commercial fray to compete for market share. This market-directed "regulatory" approach was put into force by the Drug Price Competition and Patent Term Restoration Act of 1984, often referred as the Hatch-Waxman Act. Generic competition works in some cases and to some extent, although even then it takes 20 years from the filing of a patent before open generic competition can take place. Although the market entry of generic makers induces some downward pressure on drug prices at first, the patented drug producers often use some of their monopoly profits to bribe generic producers not to enter the market when a drug goes off-patent (I-MAK, 2017). Additionally, as the growing merger and acquisition activities in the generic drug business consolidates the entire sector into

fewer major players, as Gagnon and Volesky (2017) show, the prospects of price competition among generic manufacturers has declined.

When threats of drug-price regulation arose in the 1990s, the established pharmaceutical companies, known as "Big Pharma," and the rapidly growing New Economy biopharma companies joined forces to defeat this interference with so-called "market forces." As already mentioned, in 1994, in the wake of renewed Congressional attention to high drug prices, the Pharmaceutical Manufacturers Association changed its name to the Pharmaceutical Research and Manufacturers of America, or PhRMA, to emphasize that its members were engaged in research activities for the benefit of the US public.

One year after this name change, PhRMA helped to persuade US lawmakers to extend patent protection from 17 years, which had prevailed since 1861, to 20 years, which was in line with changes in intellectual property rights advocated by the World Trade Organization. Focused on securing every possible advantage of government support for the industry while avoiding price regulation, PhRMA has become one of the most powerful lobbies in Washington D.C (Tobbell, 2012). A major policy coup of PhRMA was the Food and Drug Administration (FDA) Act of 1997, which removed any regulatory restriction on television broadcasting of drug information; allowed the drug companies to provide medical professionals with some information in peer-reviewed academic journals on the off-label use of any prescription drug; and granted drug companies an additional six months of data exclusivity on pharmaceutical products developed for children. With the passing of this legislation, direct-to-consumer pharmaceutical advertising went from $360 million in 1995 to $1.3 billion in 1998 and then $5.0 billion in 2006 (Donohue, 2006).

PhRMA is one of more than 500 members of Research!America, formed in 1989 for the purpose of advocating public support for biomedical research. R!A quickly became the umbrella organization for all the stakeholders of NIH funding including major research universities and academic institutes, Big Pharma and other drug companies, disease advocacy groups, professional societies, etc. (Research!America [R!A], n.d.; Slaughter & Rhoades, 1996). In 1992 R!A was in the forefront in lobbying for the Prescription Drug User Fee Act, under which the FDA could charge drug companies fees for reviewing drugs for approval in exchange for faster review times (Goozner 2004, pp. 240-241). Along with R!A, PhRMA played a key role in the successful lobbying efforts to double NIH funding in the late 1990s and early 2000s (Smaglig, 1997; Check, 2002; Relman & Angell, 2002). This expansion of the NIH along with the growing support for life-sciences research from non-governmental sources resulted in the rapid expansion of physical infrastructure to support research to develop innovative therapies (Teitelbaum, 2014; Stephan, 2012). Subsequent to the doubling of the NIH budget in the early 2000s, the 21st Century Cures Act of 2016 was the first major legislative effort to increase funding for the NIH, and included $1.8 billion in new funding over seven years to the National Cancer Institute for the Cancer Moonshot, sponsored by Vice President Joe Biden.

b. The rise of the PLIPOs

As from the 1980s this remarkable national innovation system was being put in place, the largest pharma companies reaped the gains from past innovation, augmented by price-gouging. In 2016 the US prescription drug market amounted to $328.65 billion, representing nearly 10 percent of national health expenditures (Centers for Medicare & Medicaid Services [CMS], 2018),

and accounting for nearly half of the world's $769 billion spent on prescription drug sales in that year.[6] Based on the aggregate spending figures for the decade 2007-2016, 17 percent of total US prescription drug expenditures were paid out of pocket by US patients, with health insurance programs funding the remainder (CMS, 2018). During this period, 44 percent of all prescription drugs sold were accessed through a private health insurance program, and 38 percent through a government healthcare program coordinated by the U.S. Department of Health and Human Services (Medicare, Medicaid), Department of Defense, and Department of Veteran Affairs as well as other subsidized federal and state insurance programs.

The lion's share of the industry's profits has gone to the largest companies. In 2015, the top 10 global pharmaceutical companies accounted for slightly over 50 percent of the prescription drug market in the United States. As US pharmaceutical companies secured more advantages that could increase their profits—ostensibly for the sake of faster, better, and cheaper research into drug development—many of the leading companies also moved sharply from innovation to financialization, as we have shown in Section 3. The US pharmaceutical business model became focused on jacking up drug prices for the sake of jacking up stock prices rather than taking advantage of the manifold benefits for drug innovation that, with the encouragement of PhRMA's lobbying efforts, the US institutional environment bestowed upon the drug manufacturers.

Over the same decades, however, thousands of new drug companies emerged in the United States, using the new technologies of the biotech revolution. Backing these new companies were venture capital firms, themselves representing a new industry devoted to new-firm creation and growth to which the microelectronics revolution had given birth (Lazonick, 2009, ch. 2). The first wave of successful biopharmaceutical companies, such as Genentech, Amgen, Biogen, and Genzyme, in the early 1980s were able to pick "the low-hanging fruit" of drug discoveries made possible by decades of prior NIH funding (Lazonick & Tulum, 2011). With the Bayh-Dole Act, the Stevenson-Wydler Act, the Orphan Drug Act, and the Diamond v. Chakrabarty ruling at their disposal, venture capitalists teamed up with academic scientists to plumb the fledgling new fields in biochemistry such as molecular biology and genetic engineering for potential commercial opportunities. Major US pharmaceutical companies in the United States were reluctant to invest in the new organizational learning that the biotechnology revolution required.

The first-generation of biopharmaceutical companies had already harvested most of the low-hanging-fruit by the mid-1980s, so that the second-generation of biopharmaceutical companies could only tackle more challenging diseases such as cancer (Alafi, 2013). The greater complexity of the learning processes required increased the length of the drug development process from discovery to market. The "New Economy" biotech companies had to attract, retain, and reward teams of scientists and engineers who, in the 1980s, could find secure career employment in the research labs of not only government agencies and civil-society organizations but also "Old Economy" pharmaceutical companies (Lazonick et al., 2014).

As startups, the New Economy companies could not realistically hold out the offer of a career with one company that in the 1980s was still the norm in the research labs of the Old Economy companies. Starting with the initial public offering (IPO) of Genentech in 1980, a company that had been founded only four years previously, New Economy startups were able to attract venture capital by the prospect of a relatively quick IPO on the highly speculative NASDAQ stock exchange. So too, these New Economy startups used the offer of stock options to lure

science, engineering, and management talent to work for them. The shares in these options could become very valuable if and when the New Economy company would do an IPO. And indeed, the experience of the 1980s and 1990s was that hundreds upon hundreds of young biopharmaceutical companies were able to go public on NASDAQ within a few years after founding, lacking a commercial product. Rather they functioned as research entities in search of an approved drug. We have dubbed these publicly-listed New Economy pharmaceutical companies "product-less initial public offerings" or PLIPOs (Lazonick & Tulum, 2011), by which we mean both private companies seeking a listing on NASDAQ even without a product and those that have already secured a listing, still without a product.

Established pharmaceutical companies have acquired many young biopharmaceutical firms, providing the equity investors in young ventures with an alternative "exit strategy" prior to an IPO or, for those your firms already listed on the stock market, a substantial premium over the price of a listed stock when acquired. For the period 1988 to 2000, Danzon, Epstein & Nicholson (2007) identified 2,808 M&A pharmaceutical and biotech deals, of which only 165 deals (5.9 percent of the total) were considered to be "transforming mergers," defined as a deal size of either $500 million or 20 percent or more of the company's stock changing ownership. Measured in 1999 dollars, the Danzon et al. study reveals that the total value of the 165 "transforming mergers" was $514 billion, which was nearly 4.4 percent of the value of the M&A deals that had taken place during that period. They argue that looming patent expirations represented the primary motivation behind the large M&A deals. The study also shows that among these young companies, it was those that had achieved steady streams of product revenues that were more likely to be acquired.

In 2016, the US biotech industry (which is largely pharmaceuticals) generated $112.2 billion revenues, with profit margins of 8.2 percent (Ernst & Young [E&Y], 2017). There were 449 public biotech companies in 2016 (E&Y, 2017). In an important study, Pisano (2006) argued that only a small number of biotech companies are in fact profitable and have products to generate a steady stream of revenues. The ability of PLIPOs to raise cash for operations on the speculative stock market sustains these companies—until the stock market crashes, as happened in 2001 and 2008 (Lazonick & Tulum, 2011). E&Y surveys have shown that of all small and mid-size human therapeutics companies in operation, the proportion that had sufficient cash on hand to keep them solvent for two years or less was 54 percent in 1995, 42 percent in 2005, and 45 percent in 2015. In 2016, the proportion of companies with less than two years of cash reserves had risen to 55 percent. Funds secured through establishing R&D partnerships with major US pharmaceutical companies often provide the smaller companies with financial stability, although at the cost of loss of strategic control over some of the company's marketing rights. For its part, Big Pharma has become dependent on PLIPOs for discovering and developing innovative therapies, while PLIPOs depend on Big Pharma to commercialize their products (Kneller, 2005; Kneller, 2010 Schuhmacher et al., 2016).

Relying on the combination of NIH funding and speculative PLIPOs for drug discovery and development, the established pharmaceutical companies have let their own in-house R&D capabilities decline (Higgins & Rodriguez, 2006; Hirschler & Kelland, 2010; LaMattina 2011; Mirowski, 2011, ch. 5). Big Pharma has become even bigger as established companies such as Merck and Pfizer have acquired other established companies to gain access to proven blockbusters with patent life remaining. Then, in the name of MSV, the acquirer pumps out cash to shareholders

from the merged enterprise rather than building in-house capabilities for drug discovery (Montalban & Sakinç, 2013; Lazonick & Tulum, 2015; Lazonick et al., 2017). Indeed, since the late 1990s, Big Pharma's attempts to engage in in-house learning have been undermined by the exit of technical and managerial personnel to try their luck in the PLIPO segment of the industry, further bolstering those within Big Pharma who argue that its own success depends on boosting stock prices to make their stock options more attractive in competing in the market for talent.

c. Big Pharma's financialized "blockbuster" model

High unregulated drug prices support this process of industrial concentration among established drug companies. Of particular importance in these M&A deals is control over blockbuster drugs—those with at least $1 billion in sales in one year—that have a significant number of years of patent life left (Montalban and Sakinç, 2013).[7] The acquiring companies then use the increased profits from the blockbusters that they now control to boost stock prices, with the degradation of Big Pharma organizational learning—the collective and cumulative processes of knowledge creation (Lazonick, 2013)— as the result.

Yet, as we have seen, the industry's trade association PhRMA argues that high drug prices fund the growth of the industry's R&D spending, thus benefiting the public. For example, in its 2016 annual meeting, PhRMA president Stephen Ubl argued that prescription drugs are "a relatively small and stable share of overall health care spending" that improves the quality of life in a cost-effective way (Norman & Karlin-Smith, 2016). PhRMA has consistently used this argument to counter public discussion over the rising cost of healthcare that might result in new legislative attempts to regulate drug prices.

Besides enormous government funding of drug development, the US government is a major procurer of pharmaceutical drugs. The prescription drugs that the US government buys through various different health insurance programs such as Medicare Part D make up a significant portion of product revenues that major drug companies generate. Hence price-gouging is of direct concern to the government programs. In some cases, the gains of a pharmaceutical company from price-gouging the public are extreme. One such case, which Congress has investigated, is Gilead Sciences (Grassley & Wyden, 2015, p. 117; Roy & King, 2016; Lazonick et al., 2017). As we have seen in Section 3, Gilead executives have topped the list of highest-paid executives in the US pharmaceutical industry. The US government, through Medicare Part D and Medicaid programs, is the largest purchaser of Harvoni and Sovaldi, two top selling Gilead products.[8] Analysis based on 2016 Medicare drug spending data reveals that 25 prescription drugs, 36 percent of them belonging to European drug companies and each costing the US government over one billion dollars, generated a total of $44 billion revenues for 16 different drug companies. The amount spent on those 25 products in fact accounted for nearly 31 percent of $141 billion that the US government spent on prescription drugs through the Medicare Part D program.[9]

National health expenditures for prescription drugs have been on the rise in the past decade despite the fact that the US Congress has passed two major landmark policies to tackle the national crisis of soaring healthcare costs. First, in 2009 it passed the Patient Protection and Affordable Care Act, which enabled many uninsured citizens to obtain affordable healthcare. Before the ACA, however, the Bush Administration secured the Medicare Prescription Drug, Improvement, and Modernization (MPDIM) Act, implemented in 2006, that includes a provision

extending prescription drug benefit coverage to include outpatient drug costs for Medicare enrollees through Medicare Part D. Although the Act was celebrated among US retirees, with the new law the Department of Health and Human Services (HHS) forfeited the right to negotiate drug prices with the drug companies. Unlike the Department of Veteran Affairs (VA) that negotiates drug prices, the HHS is banned from negotiating drug prices, assigning the rights to business-sector insurers that implement the Medicare Part D program.

Ironically, many US pharmaceutical companies have been spending more on R&D as the companies have dismantled their early research programs, closed many R&D operations across the globe that came into their possession through M&A activities, and downsized R&D labor forces. Very little is known about the details of R&D data reported by the pharmaceutical companies. But from all the financial information publicly available one might deduce that a significant proportion of the money that the drug companies say that they spend on R&D may be used for other purposes, particularly marketing activities.

For instance, R&D expenditures include post-marketing, or Phase IV, clinical trials, which have become standard procedures in the past decade, extending the length of clinical studies to monitor drug safety and efficacy even after a product has gained regulatory market approval. According to PhRMA, in 2016 Phase IV trials represented 11.4 percent ($7.5 billion) of total US pharmaceutical R&D, while "uncategorized" R&D expenditures were 19.2 percent ($12.6 billion) (PhRMA, 2017). After analyzing the results of these types of post-marketing studies in Germany, Spelsberg et al., (2017) revealed that none of the 558 trials analyzed, which were all sponsored by drug companies, reported a single adverse drug reaction, which the authors argue whether drugs companies avoid publishing the results of any post-marketing study if and when the drug studied shows adverse reaction. If drug companies systematically conceal the negative results of post-marketing studies to prevent significant drop in drug sales, one could question the scientific basis of such post-marketing studies. Challenging the merit of such studies, the authors of the German study could verify that less than one percent of the results from the trials were actually published in scientific journals. It has been argued that, in doing the Phase IV trials, a company seeks to compile clinical evidence to prove a drug's superiority against its many "me-too" competitors (van Thiel & van Delden, 2008). That is, these so-called R&D expenditures are merely marketing research (Malerba & Vonortas, 2009, pg. 89; see also Scherer, 2011; Gale 2012).

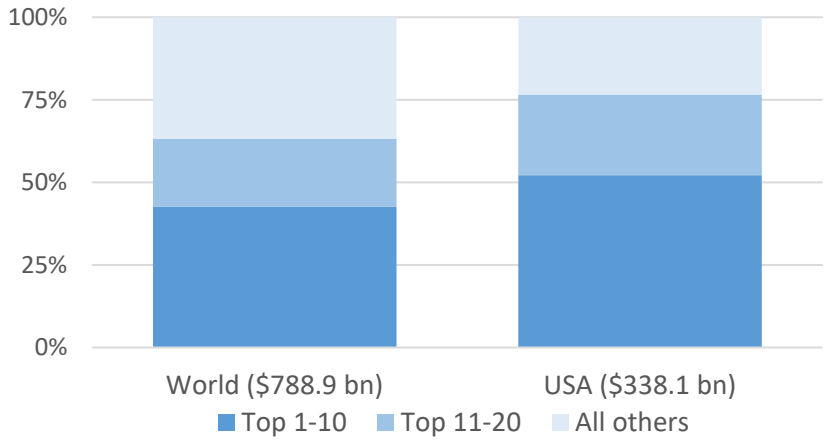
It may be that US pharmaceutical companies deliberately inflate their R&D figures to justify the high prices that they charge for drugs in the United States. Perhaps these companies manipulate their R&D numbers to send a signal to the stock market that, even though they are distributing vast amounts of corporate profits to shareholders, they still have drugs in development in the pipeline that will generate the revenues to drive future profits. Inflated R&D figures may help start-ups justify large sums of funds raised through stock issues raised in initial public offerings and secondary issues. In fact, there is little public information on how US business corporations, including pharmaceutical companies, compile their R&D figures (Hopkins & Lazonick, 2014). A growing body of empirical evidence, however, indicates that, despite all of the support for innovation by the US institutional environment, major US pharmaceutical companies have ceased to function as innovative enterprises (Lazonick & Tulum, 2011; Kessel, 2011; Hopkins et al., 2007; Montalban & Sakinç, 2013; Froud et al., 2006; Haslam et. al,. 2013; Gleadle et al., 2014).

5. Financialized corporate resource allocation and US pharma's productivity problem

It is certainly possible for US pharmaceutical companies to be innovative in the US environment, given its support for drug development. Since the 1980s, many US pharmaceutical companies have generated innovative drugs. But, as the major pharmaceutical companies listed in Figure 1 have both taken control of larger numbers of blockbuster drugs and become more financialized, their resource-allocation practices have undermined rather than supported innovation in drug development. At the same time, the PLIPO business model, through which much of the innovative research in US drug development has been done, has increasingly become a focus of stock-market speculation and manipulation, both of which tend to undermine investment in innovation (Lazonick, 2017). Given that the prime purpose of the US innovation system is to enable US business enterprises to be innovative, it is ironic, as Tulum (2018) shows, that over the past two decades, major European companies that are far less financialized than their US rivals have been making use of the US innovation system to become world leaders in innovative drug development.

Lazonick (2002) argues that, even within the same institutional environment, the strategy, structure, and performance that characterizes different companies can vary significantly. Even within the same industry, innovative companies are inherently distinctive in the ways in which they transform technologies and access markets. Hence, the appropriate methodology for analyzing possible transitions from innovation to financialization is the company case study that integrates the theory of innovative enterprise with the historical evolution of the company in question. Only through the accumulation of company cases can one develop an understanding of how, why, and to what extent transitions from innovation to financialization occur and the implications of these transitions for economic performance. Aggregate data for an industry, let alone an economy, would systematically fail to capture company-specific differences in the transition from innovation to financialization.

Figure 2. Concentration of drug sales in the US and global prescription drug markets in 2017



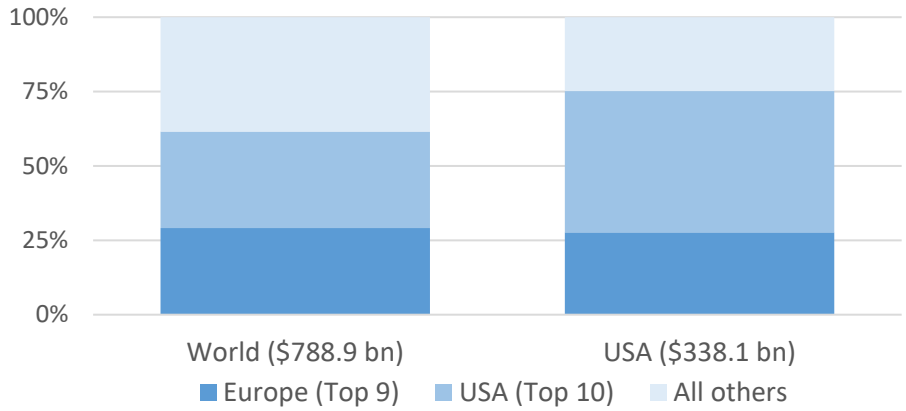
Note: Prescription drug sales include generic drug sales and excludes alliance revenue and royalties. The total USA prescription drug spending for 2017 is CMS estimate.
Source: EvaluatePharma World Preview 2018, Outlook to 2024 and company annual reports

In the case of pharmaceuticals, it is feasible to analyze the global industry as a whole through the accumulation of company cases. Figure 2 shows that ten global pharmaceutical

companies controlled nearly half the US and worldwide prescription drug markets in 2017. The sales of the top 20 companies together accounted for 77 percent of the US prescription drug market while dominating 64 percent of the worldwide prescription drug market.

Figure 3 shows the distribution of total US and worldwide prescription drug sales in 2017, grouped by the regions of the companies, based on the location of their headquarters. While the top nine European pharmaceutical companies accounted for slightly over one-quarter of US prescription drug sales, 10 US-based pharmaceuticals companies accounted for 48 percent of the US market. While the 10 companies on average generated nearly $16.1 billion revenues in 2017, the nine European companies averaged $10.4 billion globally in the same year. Figure 2 and 3 clearly show that European Big Pharma is quickly catching up with US Big Pharma in marketing competitive products.

Figure 3. US and global prescription drug sales of top 20 global pharmaceutical companies in 2017, by location of headquarters and percent share of total prescription drug sales



Source: EvaluatePharma World Preview 2018, Outlook to 2024

These facts confirm the findings of Light (2009), who argues that Europeans have begun to boost their research productivity outperforming U.S. drug firms in pharmaceutical innovation. He shows that European pharmaceutical companies increased their innovative productivity, measured in terms of new chemical entities (NCEs)—that is, novel new therapies with no competing alternatives—from the 1982-1992 period to the 1993-2003 period. This improved performance allowed European companies to outperform their US opponents in the race to bring novel therapies (products with "first-in-class" designation) to market (Light 2009, p. w972; Gambardella et al., 2007).

Tulum (2018) shows that, under MSV's influence, a US-based Merck has abused the US institutional environment by transforming from innovation to financialization. It is possible that European-based pharmaceutical companies that have been protected from the influence of MSV in their home countries by "social market economy" norms would be better positioned to make use of the US environment to enhance their innovative capabilities. The following seven companies are established European drug manufacturers that should be the prime focus of comparative case-study research: Novartis and Hoffmann-La Roche (Switzerland), GlaxoSmithKline and AstraZeneca (UK), Sanofi-Aventis (France), Bayer and Merck KGaA (Germany).

Analysis reveals that these seven companies generated an overwhelming majority of their annual revenues from products whose discovery can be traced back to a US-based institution where the biomedical research necessary for the drug discovery or development took place at some point in the past. In fact, as can be seen in Figures 4a and 4b, while 50 percent of these seven companies' products, out of a total of the 159 medicinal products, originated in the United States. The revenues generated from US-originated products accounted for 55 percent of their global revenues in 2017.

Figure 4. Product portfolios of EU top 7 pharma, number of products and their sales by drug country of original discovery, 2017

Figure 4a. Number of products in portfolio, by country of origin

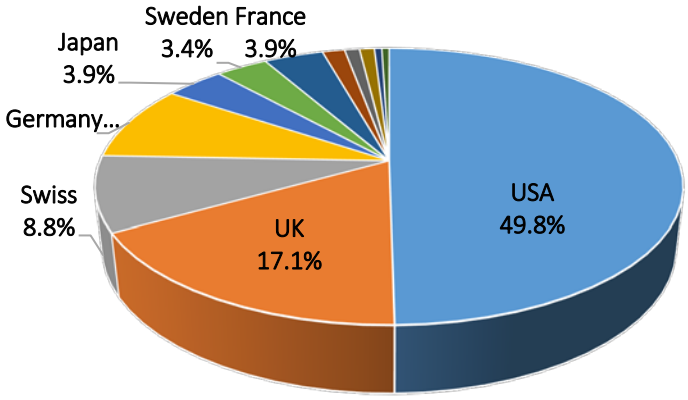
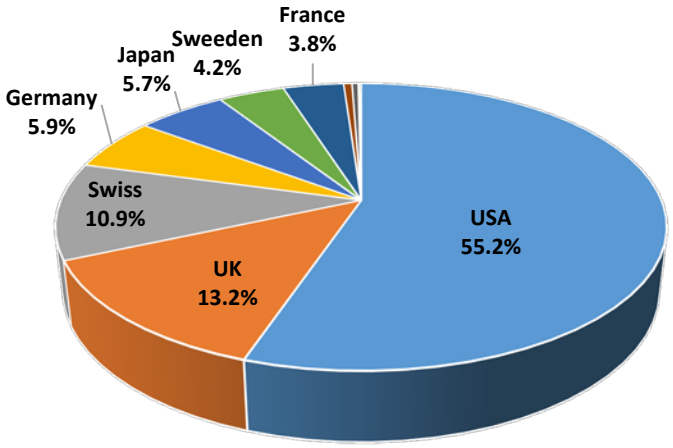


Figure 4b. Revenues, by country of product origin (all companies)



Note: The drug origin refers to the country where the parent institution of a new chemical compound ("Originator") is based. Such institutions are often the original patent holders of the active chemical compounds. In the event that a drug therapy comprised of multiple active chemical compounds that were discovered or developed by different institutions, all those countries where those institutions are based are included in the calculations. In the event that a chemical compound is used in various different therapies, any additional data point is omitted in the calculations.
Source: ADIS R&D Insight, Drugs@FDA: FDA Approved Drug Products, company SEC filings and annual reports

The US government has been outspending all the other nations when it comes to supporting biomedical research. According to Chakma et al., (2014) in an analysis comparing public expenditures on biomedical research globally, US public expenditure in 2012 averaged

$154 per person, while the comparable figure for the EU nations combined was $53 per person. No other region in the world can match the scale of the science and technology infrastructure that, led by government spending, the United States has put in place since the 1940s to support drug innovation.

The data presented in Figure 3 and 4 suggest that the US institutional environment has been critical to the growth of major European pharmaceutical companies. In addition to providing the knowledge base required for drug innovation, the US drug market, with its unregulated prices, has become a major source of European profits, especially from those innovative products developed in the United States. The US institutional environment makes the United States the most lucrative place for global drug companies to launch their innovative new therapies. The question is then to what extent these companies use these high profits for innovation or, alternatively, financialization. To answer this question, we have to look at the social conditions of innovative enterprise that prevail at these European companies and the relation of these social conditions to innovative performance in developing and marketing pharmaceutical drugs.

Table 6 provides basic data on revenues, profits, R&D spending, and presence in the United States of the top seven European pharmaceutical companies. For the purpose of evaluating the "innovation in the USA" hypothesis, Roche is an obvious choice for an initial comparative case study of a major European pharmaceutical company that is highly active in developing and selling drugs in the United States. In 2017, Roche was the largest European pharmaceutical with nearly $54 billion in revenues. It possessed one of the most profitable product portfolios, with the company's net income accounting for 16.6 percent of total revenues and had one of the highest concentration of revenues generated from pharmaceuticals (77.3 percent). Roche also had a prominent presence in the United States.

Table 6. Pharmaceutical product revenues and percent share in total revenues by EU top 7 companies, 2017

Company	(USD mil)		% of REV-Total			% of REV-Rx	
	No. of Drugs	REV-Total	REV-Rx	NI	RD	REV-Rx, USA	REV-159
Roche	26	54,387	77.3	16.6	21.2	49.7	93.4
Novartis [a]	20 (31)	49,109	67.2	15.7	18.3	33.7	74.4
GlaxoSmithKline [b]	27	39,242	57.2	7.2	14.8	43.8	81.9
AstraZeneca	29	22,465	89.7	12.8	25.6	30.6	93.9
Bayer [c]	15	39,567	48.1	9.3	12.9	25.1	76.6
EMD [d]	7	17,320	45.7	17.0	14.0	21.3	70.1
Sanofi	35	39,612	71.7	24.4	15.6	32.4	76.5

Note: REV-Total: Total Revenues (US$ bn); REV-Rx: Revenues from pharma products; REV-Rx, USA: United States [or North America] pharma [or healthcare] revenues; REV-159: Revenues from 159 products identified for the study; NI: Net Income; RD: Research and development. [a] REV-Rx excludes the sales of generics (Sandoz) and eye care (Alcon) divisions; [b] REV-Rx excludes vaccines sales. [c] REV-Rx, includes all segments; [d] REV-Rx, USA includes North America sales. Also, any revenue figures published in foreign currencies are converted into $US using the annual average of exchange rates in 2017 provided by companies in their annual reports. GSK figures in British pound, AstraZeneca and Novartis figures in USD, and Roche figures in Swiss franc were converted into $US.

Sources: Company SEC filings and annual reports

Tulum (2018) applies the theory of innovative enterprise to the case of Roche to show how the combination of strategic control, organizational integration, and financial commitment enabled this company to make use of the national innovation system in the United States to become a world even as Merck—the comparative US case study in Tulum (2018)—turned from innovation to financialization over the same time period in the same institutional environment. It is beyond the scope of this paper to summarize the main firm-level findings of that research. Tulum is currently completing case studies of Pfizer in the United States and Novartis in Switzerland, and has begun work on the cases of AstraZeneca and GlaxoSmithKline.

In terms of the "national innovation system" research presented in this paper, it is important for legislators and regulators to understand the governance, structure, and performance of innovative enterprise to ensure that the institutions that they put in place to support innovation do not in fact encourage financialization on the part of the companies upon which we rely to bring innovative drugs to market. Of particular importance, not just for the pharmaceutical industry but for the US economy more generally is legislation and regulation concerning the widespread practice of stock buybacks. As Lazonick and his colleagues have shown in a number of empirical studies,[10] "stock buybacks manipulate the market and leave most Americans worse off"—to quote the subtitle of his *Harvard Business Review* article "Profits Without Prosperity" (Lazonick, 2014). Consideration of how and why US companies have turned from innovation to financialization raises a host of issues concerning corporate governance, employment relations, and investment finance that, in line with the arguments in this paper, are treated in a forthcoming book by Lazonick and Shin (2019) on "predatory value extraction."

The companies that grew up in the United States and became financialized have been abusing the US institutional environment as they continue to make use of the massive NIH funding and other government support to develop new drugs while increasing drug prices to increase profits for the sake of boosting their stock prices.

What we have found for the case of the US pharmaceutical industry is that major pharmaceutical companies that seek greater financial gains by controlling the revenues from patented blockbuster drugs run into problems related to strategic control, organizational integration, and financial commitment for innovating new drugs to replace the blockbuster revenues when the patents expire—what is known as the "patent cliff." During the period leading up to a major patent cliff, senior pharmaceutical executives in the United States tend to focus on the acquisition of other drug companies to access their pipelines of innovative drugs to replace the aging drugs. In the process, the in-house innovative capability of Big Pharma degrades further, manifested by layoffs of once-valued employees and the downsizing of corporate R&D spending. The strategic goal of the company is profits, not products, and the purpose of the profits is to boost the company's stock price. If the goal of public policy is to generate effective medicines at affordable costs for a wide range of diseases, our findings for the US pharmaceutical industry call for inquiry into the deleterious impacts of the prevailing ideology that companies should be run to "maximize shareholder value."

The MSV problem is not just an American disease. Since the late 1990s, global institutions such as the OECD have been promoting for the wider acceptance of MSV ideology, thus legitimizing financialization around the world. If there is one lesson that Europeans—and the rest of the world—should be learning from this new "American challenge," it is that MSV is destructive of innovation. The future success of the European pharmaceutical companies to

innovate within the US institutional environment depends upon their ability to maintain a home-base governance system that supports innovation and suppresses financialization.

NOTES

[1] For an approach to understanding the US national innovation system using the "social conditions of innovative enterprise" framework that we apply in this paper, see Lazonick and Tulum (2011); Hopkins and Lazonick (2014).

[2] In the context of US pharmaceutical market, what constitutes "value" created by the pharmaceutical companies can be a controversial issue. One of the most recognized critics of product innovation pursued by the US pharmaceutical industry, Angell (2005) explains how the incremental character of drug innovation offers marginally low, if any, utility to patients. In comparison to existing drugs, subsequently launched drugs that are popularly referred as "me-too" often provide no significant improvement in patient health proportionally when considering the price that patients have to pay for the "me-too" alternatives.

[3] The top 10 US-based pharmaceutical companies are Pfizer, Merck & Co., Johnson & Johnson, AbbVie (combined with Abbott financial figures for the period from 2013 to 2017 to ensure the consistency of the data during the period ensuing the separation of AbbVie from its parent company, Abbott Laboratories), Gilead, Amgen, Bristol-Myers-Squibb, Eli Lilly, Allergan, and Celgene. The European top 10 are Novartis, Roche, Sanofi, GSK, AstraZeneca, Bayer, Novo Nordisk, Shire, Merck KGaA, and UCB.

[4] An appendix to this paper provides a timeline of government policies that have shaped the US institutional environment for the pharmaceutical industry (taken from Tulum, 2018).

[5] Jaffe and Lerner (2005) show that the number of patents granted since the creation of the Court of Appeals for the Federal Circuit (CAFC) tripled from 62 thousand per year in 1983 to 187 thousand per year in 2004 (p. 29).

[6] *EvaluatePharma* calculates the worldwide drug sales based on the prescription drug sales of the top 500 biopharmaceutical companies in the world.

[7] Although the development of "blockbuster" products still appears to be Big Pharma's top market strategy, Gagnon (2015) argues that there is a new trend where some Big Pharma companies appear to be switching from a "blockbuster" to a "nichebuster" model, given that, referring to the data in Fegraus and Ross (2014), specialty drugs such as Sovaldi and Harvoni account for nearly a quarter of the total prescription drug expenditures even though such drugs make up only one percent of the total drugs prescribed for patients in the world.

[8] Harvoni and Sovaldi, two top selling Gilead products, ranked 1st and 28th in the list of top pharmaceutical products that the US government purchased through the Medicare Part D program, and 1st and 12th in the list of top pharmaceutical products that the US government purchased through Medicaid, in 2016. Through Medicare Part D and Medicaid, the US government paid $8.1 billion (before rebates, the amount of which is unknown) for the two products, which accounted for 35.4 percent of the $19.3 billion in revenues Gilead generated from product sales in the US and 27 percent of the company's $30 billion in global sales in 2016.

[9] The Medicare Part D program is implemented through private insurers who, on behalf of CMS, administer this tax-payer subsidized prescription drug benefit program for eligible Medicare recipients. Those implementing the program may receive rebates through negotiating for price discount arrangements with drug companies prior to purchasing prescription drugs that insurees need. The amount reported by CMS for FY2016 however doesn't reflect such rebates, and despite those rebates, Gagnon and Wolfe (2015) argues, medicinal products with "artificially inflated" prices continue to drive the cost of prescription drugs for Medicare patients.

[10] See the work at https://www.ineteconomics.org/research/experts/wlazonick and https://hbr.org/search?term=william+lazonick&loaded=2.

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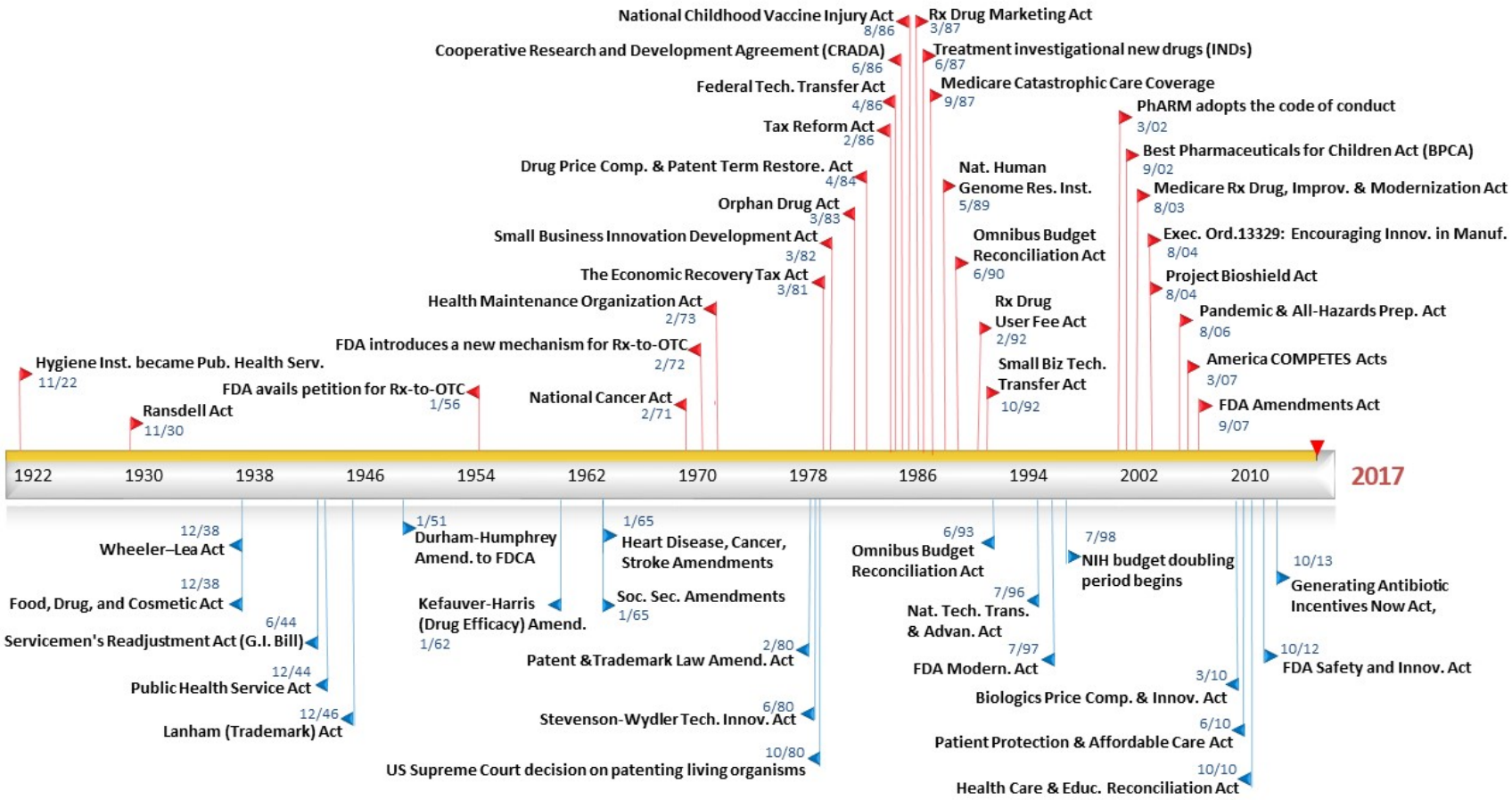
Appendix 1. Timeline of major policies that have shaped the institutional environment in the US pharmaceutical industry



Source: Author's own illustration from Tulum (2018)