U.S. Pharma’s Business Model: Why It Is Broken, and How It Can Be Fixed

Submission to
the United Nations Secretary-General’s High-Level Panel on Access to Medicines

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February 28, 2016

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SUMMARY

In a companion submission to the High-Level Panel, we attribute high prices, restricted access, and limited innovation in the U.S. pharmaceutical industry to a corporate-governance ideology known as "maximizing shareholder value" (MSV). In this contribution, we explain more fully why MSV results in high prices, restricted access, and limited innovation. Once this profit-driven ideology is debunked, it can be replaced by a product-driven norm of corporate governance that supports innovation in essential medicines at affordable prices. Underpinning this product-driven norm is “the theory of innovative enterprise,” outlined in this paper. As examples of the destructive impact of MSV, we focus on Merck and Pfizer, among the world’s largest pharmaceutical companies. These companies, like others in the U.S. pharmaceutical industry, contend that the high profits that they get from high drug prices enable them to increase R&D investments in new medicines. In fact, over the past five years Merck has distributed $49 billion to shareholders, an amount equal to 186% of its net income – 87% in stock buybacks and 99% in cash dividends. These distributions were 1.3 times Merck’s R&D expenditures. For Pfizer, distributions to shareholders in 2011-2015 were $77 billion, equaling 122% of net income and twice its R&D expenditures. Pfizer’s buybacks were 70% of net income over these five years. Buybacks help boost executives’ stock-based pay; in 2014 Merck’s CEO “earned” $17.6 million, of which 71% was stock-based, and Pfizer’s CEO $22.6 million, 57% stock-based. These companies have exhibited this type of financial behavior for three decades. We conclude with recommendations for how the U.S. government can fix pharma’s broken business model and how, by confronting MSV ideology, international civil-society organizations can exert an influence on corporate governance so that pharmaceutical companies increase availability of and access to the innovative medicines that people around the world so desperately need.
Toward the innovative pharmaceutical enterprise

In a companion submission to the High-Level Panel, we attribute high prices, restricted access, and limited innovation in the U.S. pharmaceutical industry to a corporate-governance ideology known as “maximizing shareholder value” (MSV). In this contribution, we explain more fully why MSV results in high prices, restricted access, and limited innovation. Once this profit-driven ideology is debunked, it can be replaced by a product-driven norm of corporate governance that supports innovation in essential medicines at affordable prices.

Underpinning this product-driven norm is, as outlined below, “the theory of innovative enterprise.” As examples of the destructive impact of MSV, we focus on Merck and Pfizer, among the world’s largest pharmaceutical companies. We conclude with recommendations for how the U.S. government can fix pharma’s broken business model and how, by confronting MSV ideology, international civil-society organizations can exert an influence on corporate governance so that pharmaceutical companies increase availability of and access to the innovative medicines that people around the world so desperately need.

The theory of innovative enterprise

The theory of innovative enterprise provides an analytical framework for understanding how a business enterprise can generate a product that is higher quality (in medicines, more effective and safer) and lower cost (more accessible and affordable) than products previously available. The innovation process that can generate these outcomes is:

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

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

- **Strategic control**: For innovation to occur in the face of technological, market, and competitive uncertainties, executives who control corporate resource allocation must have the abilities and incentives to make strategic investments in
innovation. Their abilities depend on their knowledge of how strategic investments in new capabilities can enhance the enterprise’s existing capabilities. Their incentives depend on alignment of their personal interest with the company’s purpose of generating innovative products.

- **Organizational integration**: The implementation of an innovative strategy requires integration of people working in a complex division of labor into the collective and cumulative learning processes that are the essence of innovation. Work satisfaction, promotion, remuneration, and benefits are important instruments in a reward system that motivates and empowers employees to engage in collective learning over a sustained period of time.

- **Financial commitment**: For collective learning to cumulate over time, the sustained commitment of “patient capital” must keep the learning organization intact. For a startup company, venture capital can provide financial commitment. For a going concern, retained earnings (leveraged if need be by debt issues) are the foundation of financial commitment.

**From “retain-and-reinvest” to “downsize-and-distribute”**

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

From the 1960s, however, a changing business environment encouraged executives of established U.S. corporations to shift corporate resource allocation from “retain-and-reinvest” to “downsize-and-distribute.” By the 1980s, even in good times, companies began to downsize their labor forces and distribute more earnings to shareholders. Justifying this dramatic transformation in corporate resource allocation was a new ideology that taught that, for the sake of economic efficiency, companies should “maximize shareholder value” (MSV).

The MSV argument is that, of all participants in the corporation, only shareholders make productive contributions without a guaranteed return. All other participants such as creditors, workers, suppliers, and distributors allegedly receive a market-determined price for the goods or services they render to the corporation, and hence take no risk of whether the company makes or loses money. On this assumption, only shareholders, as the sole risk-takers, have an economically justifiable claim to profits.
A fundamental flaw in MSV lies in the erroneous assumption that shareholders are the only corporate participants who bear risk. *Taxpayers* through government agencies and *workers* through the firms that employ them make risky investments in productive capabilities on a regular basis. Households, as taxpayers and workers, may have legitimate economic claims on the distribution of profits.

The National Institutes of Health (NIH), with its 2016 budget of $32.3 billion, is a prime example of how taxpayers invest without a guaranteed return. 7 Drug companies benefit from the knowledge that the NIH generates. As risk bearers, taxpayers fund investments in the knowledge base – as well as physical infrastructure such as roads – required by business, and hence have tax claims on corporate profits. But because profits may not be forthcoming and tax rates can be changed, the returns to taxpayers’ investments are not guaranteed.

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

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

Another fundamental flaw in MSV is that the public shareholders whom it holds up as the only risk bearers typically do not invest in the value-creating capabilities of the company. Rather, as savers or speculators, they buy outstanding shares on the stock market for the sake of dividends and stock-price increases. Public shareholders generally make no productive contributions to the enterprise. Indeed, over the past decade, net equity issues in the United States have been over four trillion dollars in the negative; the U.S. stock markets fund public shareholders rather than vice versa.8

The proponents of MSV advocate that, through stock-based pay, senior executives should be incentivized to “disgorge” corporate earnings as buybacks and dividends to the corporate participants who matter least – just the opposite of the financial commitment needed for innovation.9 These distributions to shareholders generally come at the expense of the stable and remunerative career opportunities that integrate employees into processes of collective and cumulative learning. As for strategic control, any senior executive who sees MSV as the key to corporate success has lost not only the incentive but probably also the ability to allocate corporate resources to potentially innovative investments. 10 In sum, MSV undermines investments in innovation that, if successful, can yield products that are higher quality and lower cost than previously available.
Merck and Pfizer in the thrall of MSV

Major U.S. pharmaceutical companies have the MSV disease, as evidenced by not only massive stock buybacks and exploding executive pay\(^{11}\) but also a “productivity crisis” in drug discovery.\(^{12}\) Companies such as Merck and Pfizer have spent the last two decades living off patented blockbuster drugs, with very little to replace them in the pipeline.\(^{13}\) In the name of MSV, they have been profit-driven. For a company to be an innovative enterprise, however, it needs to be product-driven.

Pfizer’s focus on profits before products began before the 1980s. In the case of Merck, with Roy Vagelos as head of research from 1975 to 1985 and as CEO for the following decade, the company remained highly innovative through investments in organizational learning.\(^{14}\) In the decade that Vagelos headed Merck, the company generated both innovative products and high profits, with profit margins at over 20% for 1985-1994. The gains from innovation enabled Merck to provide its drug for river blindness for free to millions of poor people around the world.\(^{15}\)

But, as shown in Table 1, high profits also permitted the company to do substantial stock buybacks on top of dividends at a time when MSV was becoming the unchallenged ideology in corporate America. Once Vagelos stepped down as Merck CEO, innovation largely stopped at the company. According to a number of Merck insiders, his successor Raymond Gilmartin stifled research,\(^ {16}\) and, as suggested by the decadal figures on distributions to shareholders shown in Table 1, under CEO Richard Clark (2005-2010) and current CEO Kenneth Frazier (from 2011), the financialization of Merck has only gotten worse. Since Frazier took over, Merck’s revenues have fallen from $46.0 billion to $39.5 billion, and employment from 94,000 to 68,000. Yet buybacks have been 87% of net income and dividends another 99 percent, while Frazier’s total compensation in 2014 was $17.6 million, of which 71% was stock-based.\(^ {17}\)

Last November Pfizer commanded attention for its plan to acquire Allergan, and thus avoid U.S. corporate taxation by establishing Ireland as its tax home. Pfizer CEO Ian Read moaned that Pfizer’s U.S. tax bill put the company at a “tremendous disadvantage” in global competition. “We’re fighting,” he said in the interview, “with one hand tied behind our back.”\(^ {18}\) Yet from 2011 through September 2015, with Read as CEO, Pfizer’s distributions to shareholders were 4.7 times its U.S. tax payments. If Pfizer is cash-constrained, Read and his board should rethink why they did $45 billion in buybacks in 2011-2015. Perhaps it was the golden handcuffs of stock-based pay; in 2014 Read’s total compensation was $22.6 million, of which 57% was from options and awards.\(^ {19}\)
Table 1. Stock buybacks and cash dividends, Merck and Pfizer, 1975-2015

<table>
<thead>
<tr>
<th></th>
<th>BB $b</th>
<th>DV $b</th>
<th>R&amp;D $b</th>
<th>BB/NI%</th>
<th>DV/NI%</th>
<th>(BB+DV)/NI%</th>
<th>R&amp;D/REV%</th>
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<td><strong>Merck</strong></td>
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<tr>
<td>1975-1984</td>
<td>0.4</td>
<td>1.6</td>
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<td>9.7</td>
<td>44.8</td>
<td>54.5</td>
<td>9.4</td>
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<td>1985-1994</td>
<td>4.8</td>
<td>7.3</td>
<td>8.2</td>
<td>30.3</td>
<td>46.1</td>
<td>76.5</td>
<td>10.8</td>
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<td>1995-2004</td>
<td>26.4</td>
<td>25.8</td>
<td>24.2</td>
<td>46.4</td>
<td>45.5</td>
<td>91.8</td>
<td>7.9</td>
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<td>2005-2014</td>
<td>26.5</td>
<td>42.2</td>
<td>66.5</td>
<td>47.7</td>
<td>75.9</td>
<td>123.5</td>
<td>19.1</td>
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<td>2011-2015</td>
<td>22.7</td>
<td>25.7</td>
<td>37.9</td>
<td>87.0</td>
<td>98.5</td>
<td>185.6</td>
<td>17.2</td>
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<td><strong>Pfizer</strong></td>
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<tr>
<td>1975-1984</td>
<td>0.0</td>
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<tr>
<td>1985-1994</td>
<td>3.2</td>
<td>4.0</td>
<td>8.2</td>
<td>41.7</td>
<td>51.4</td>
<td>93.1</td>
<td>10.5</td>
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<tr>
<td>1995-2004</td>
<td>34.5</td>
<td>21.9</td>
<td>24.2</td>
<td>71.6</td>
<td>45.6</td>
<td>117.2</td>
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<td>2005-2014</td>
<td>60.8</td>
<td>66.6</td>
<td>66.5</td>
<td>52.3</td>
<td>57.3</td>
<td>109.5</td>
<td>15.5</td>
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<tr>
<td>2011-2015</td>
<td>44.7</td>
<td>32.6</td>
<td>39.6</td>
<td>70.4</td>
<td>51.3</td>
<td>121.7</td>
<td>14.3</td>
</tr>
</tbody>
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REV=revenues; NI=Net Income; BB=stock buybacks (aka repurchases); DV=cash dividends; R&D=research and development expenditures
Sources: S&P Compustat database and company 10-K SEC filings.

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

**How to fix a broken business model**

In our view, a primary policy objective of all government agencies, civil-society organizations, and business enterprises that seek innovative and affordable drugs should be the eradication of MSV as an ideology of corporate governance. MSV is a global problem, but the U.S. pharmaceutical industry is where the ideology operates unconstrained. Let us begin then, by necessity briefly, with steps that the U.S. government can take.

- Ban pharmaceutical companies from doing stock repurchases. Such a ban would go a long way to restoring stable and equitable growth to the U.S. economy in general and a focus on access to medicines in the pharmaceutical industry in particular.20
- Require executive compensation that rewards the success of the pharmaceutical company in generating new medicines at affordable prices. Stock-based compensation rewards executives for draining earnings out of the company rather than mobilizing earnings to invest in innovation.
- Place stakeholders representing households as taxpayers, workers, and consumers on boards of directors of publicly listed pharma companies, along with
shareholders who represent households as savers. Taxpayers and workers invest in business enterprises, while what products pharmaceutical companies make available is literally a matter of life or death for consumers.

- Regulate the price of any drug that has benefitted from government funding, subsidies, and protection (however far upstream in the innovation process) with a view to making the drugs accessible to the largest numbers of people who need them at the most affordable prices. It is folly that the U.S. government provides drug companies with NIH funding, patent protection, and, under the Orphan Drug Act, market exclusivity but does not regulate drug prices.
- Increase the returns to households as taxpayers for their investments in life-sciences research. The Bayh-Dole Act of 1980, which facilitates commercialization of federally funded research, has given too much to business interests, including university scientists who can win (or lose) fortunes in the commercialization process. Within the university, the pursuit by “star scientists” of individual gain from publicly funded research has undermined the collective and cumulative learning that medical research requires.
- Use government funding, in collaboration with innovative businesses, to ensure the “collective and cumulative careers” of life-science researchers, who are the lowest-paid PhDs in the natural sciences. There is evidence that the doubling of the NIH budget between 1998 and 2003 created large cohorts of life-science PhDs while contributing to an even more financialized biomedical industrial complex in which the prospects of collective and cumulative careers became more insecure.

There are a number of international civil-society organizations that have an interest in medical innovation that should be publicizing the dangers of MSV. Let us conclude by looking briefly at what four prominent organizations say about the relation between corporate governance and innovation.

- **Organisation for Economic Co-operation and Development (OECD):** In 1999, OECD issued Principles of Corporate Governance (PCG). This declaration adopts a shareholder-primacy perspective that has survived revisions in 2004 and 2015. PCG defines the function of corporate governance as maintaining the integrity of financial markets, with nothing to say about whether and how corporate governance maintains the integrity of the productive enterprise. Whether intended or not, PCG has served to legitimize MSV around the world. In a public comment on the draft 2015 revision, Lazonick advised that PCG should a) promote “retain-and-reinvest” as a corporate resource-allocation regime, while discouraging “downsize-and-distribute”; b) view employees’ increased earnings as returns on investment in their productive capabilities rather than just a business expense; c) recognize that the proper purpose of the corporation is to produce a competitive product, not book higher profits, and d) advocate that to sustain the corporation’s product-driven purpose, taxpayers and workers should have representation on corporate boards.
• **United Nations (UN):** The UN Global Compact (UNGC) allies itself closely with OECD PCG, but pays more attention to the rights of “other stakeholders” as distinct from shareholders, including labor. Yet, like OECD PCG, UNGC accepts shareholders primacy, and in no way raises questions about the predatory character of MSV, even though its Principle 10 states: “Businesses should work against corruption in all its forms, including extortion and bribery.” In our view, MSV, as practiced in the U.S. pharmaceutical industry, is a form of corruption that raises prices, restricts access, and stifles innovation.

• **World Health Organization (WHO):** In its publication *Good Governance or Medicines: Model Framework*, WHO defines “corruption” as “the use of entrusted power for private gain.” By this definition, a CEO who allocates corporate earnings to manipulative stock buybacks is acting in a corrupt manner. The theory of innovative enterprise and the critique of MSV that flows from it inform all four of the specific objectives of the WHO *Good Governance for Medicines* program:
  1. To raise awareness of the impact of corruption in the pharmaceutical sector and use this awareness to inform the national health policy agenda;
  2. To increase transparency and accountability in medicine regulatory and supply management systems;
  3. To promote individual and institutional integrity in the pharmaceutical sector; and
  4. To institutionalize good governance in pharmaceutical systems by building national capacity and leadership.

• **Médecins Sans Frontières (MSF):** MSF has been in the forefront of advocating global access to affordable medicines. In recent testimony to U.S. Congress, MSF Director of Policy and Analysis Rohit Malpani countered the drug companies’ contention that higher prices generate profits that are reinvested in new drug development by arguing that “the sole reliance on high medicine prices, backed by monopolies, is a flawed paradigm for funding innovation.” He continued that the flawed innovation paradigm leads to unaffordable prices while failing to stimulate innovation for diseases disproportionately affecting developing countries, where patients have limited purchasing power. Our current innovation model is also failing patients in developed countries, as with antibiotic resistance. In spite of the need for new antibiotics, pharmaceutical companies, including Pfizer, the world’s largest, have abandoned antibiotic drug development. Since antibiotics must be affordable and used sparingly, the industry response has been to withdraw.
We agree. As we have shown in our two submissions to the High-Level Panel, companies that are concerned with profits, not products, tend to be uninterested in allocating resources to the development of drugs that promise low profit margins. When the U.S. government has sought to regulate drug prices, pharmaceutical companies have argued that they need high prices to fund investments in innovation. The fact is, however, that the largest drug companies allocate all of their profits and more to buybacks and dividends. Legitimized by MSV, “downsize-and-distribute” has enabled the senior pharma executives who make these resource-allocation decisions to secure enormous compensation for themselves.

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


3 Over the last century, large corporations have dominated the U.S. economy. In 2012, the 1,909 companies with 5,000 or more employees in the United States were only 0.03% of all firms, but, with an employment average of 20,366, employed 34% of the U.S. business-sector labor force while covering 38% of all payroll expenditures and generating 44% of all revenues. United States Census Bureau, “Statistics of U.S. Businesses,” Data on “U.S., NAICS sectors, larger employment sizes” at http://www.census.gov/econ/susb/


7 National Institutes of Health, “*Budget.*” Total NIH investment in life-sciences research from 1938 through 2015 was $958 billion in 2015 dollars.


15 Vagelos and Galambos, Medicine, Science, and Merck, pp. 251-253.


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


21 See Patrice Trouiller, Els Torreale, Piero Olliaro, Nick White, Susan Foster, Dyann Wirth, and Bernard Pécoul, "Drugs for neglected diseases: a failure of the market and a public health failure," Tropical Medicine and International Health, 6, 11, 2001: 945-951.


See OECD, *G20/OECD Principles of Corporate Governance*.


UN Global Compact, Global Corporate Governance Forum, and International Finance Corporation, *Corporate Governance: The Foundation for Corporate Citizenship and Sustainable Business*, 2009. For example (p. 4): “Corporate governance refers to the way that Boards oversee the running of a company by its managers, and how Board members are held accountable to shareowners and the company. This has implications for company behavior not only to shareowners but also to employees, customers, those financing the company, and other stakeholders, including the communities in which the business operates.” See also World Health Organization, World Intellectual Property Organization, World Trade Organization, *Promoting Access to Medical Technologies and Innovation*, WHO-WIPO-WTO, 2012.

UN Global Compact, *Corporate Governance*. For example (p. 2): “A well-governed company takes a longer-term view that integrates environmental and social responsibilities in analyzing risks, discovering opportunities and allocating capital in the best interests of shareowners. There can be no better way to restore public confidence in both businesses and markets and build a prosperous future.” Georg Kell, Executive Director, UN Global Compact.

Ibid., p. 6


These specific objectives are quoted as they appear in ibid., p. 7.