Case Study: The Inordinate Power of Big Pharma

by

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Author Biographies

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specialties and research interests coalesce on three major themes: (1) professional talent development, (2) safety and well-being, and (3) teamwork and unit dynamics.

Case Overview

This case study outlines the legal and ethical issues surrounding the development, manufacturing, marketing, and distribution of prescription medications. The name Big Pharma reflects the inordinate power of the major pharmaceutical drug corporations. Big Pharma tests the meaning and reality of corporate social responsibility, as the issues emerging from this industry are at the epicenter of business and society. Students are prompted to reflect on how medicinal products driven by a consumption-oriented culture have influenced how we think about our health and well-being.

What Is Big Pharma?

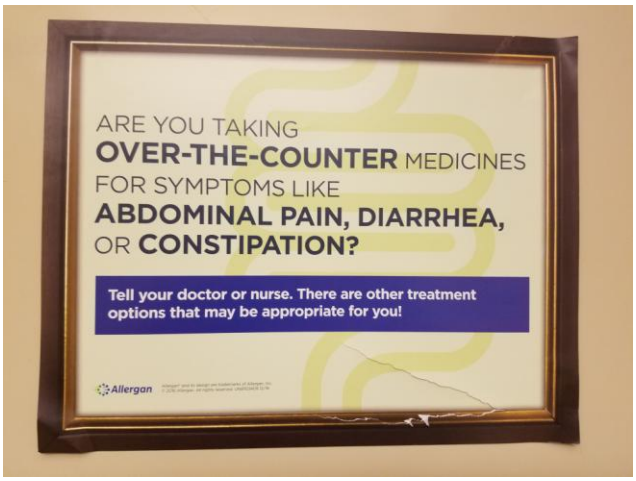
If you live in the United States, you have probably seen a commercial that describes how a serious issue like chronic depression can be easily remedied with a pill. The advertisement displays a collage of happy scenes: families playing football in the park, couples kissing, and friends enjoying outdoor adventures. The message, accompanied by a crescendo of uplifting music, is that depressed people can lead productive and joy-filled lives with this product—despite a disconcerting conclusion with an exhaustive list of potentially life-altering side effects that can accompany the product's use. This sort of direct-to-consumer advertising of prescription drugs and medical devices has been legal since 1997. In 2015, the American Medical Association (AMA) voted that the federal government should ban these advertisements. Yet, these ads continue to appear with disturbing regularity, and the US remains just one of three

countries that allows them, the other two being New Zealand and Brazil.[1] In 2011, the average American household was exposed to 111 televised prescription drug advertisements per month.[2] The Nielsen Co. estimates that there are, on average, 80 drug ads every hour of every day on American television.[3] Given that viewers watch about five hours of television *daily*,[4] this by far exceeds the amount of time most people spend with their physician *annually* (typically 13-15 minutes per visit, four times a year).[567] The ever-expanding means of reaching the consumer continues to invade every area of our lives. Even restrooms are no longer private spaces; this ad appeared in an office building in all of the women's room stalls (see Image 1, below).

The US Food and Drug Administration (FDA), the agency responsible for pharmaceutical regulation, has done little to address the AMA's concern that these ads prompt consumers to seek inappropriate drugs and to believe that there is a pill for every ill, even for conditions that can be treated more effectively via other means (e.g., diet and exercise).[8] Perhaps it is no coincidence that the pharmaceutical industry contributes heavily to the FDA's annual budget. Firms that sell prescription drugs claim their ads educate patients, encourage doctor-patient dialogue, and move people to take more responsibility for their healthcare.[9] To understand what drives these ads, it is necessary to examine the trillion-dollar pharmaceutical industry known as Big Pharma.

Big Pharma is the name ascribed to a consortium of the world's largest drug companies. Sometimes the term is applied to the vast and influential pharmaceutical industry and its trade group in the US, known as the Pharmaceutical Research and Manufacturers of America (PhRMA). Given the overwhelming amount of money made in the global prescription drug business, the industry has inordinate influence over consumers' lives. It is no surprise, then, that Big Pharma is the subject of heated debate amongst many stakeholder groups.[10]

Image 1. Is Advertising in Public Restrooms Invasive or Helpful?



[end of Image 1]

Origins of Big Pharma

Drug companies like Merck, Eli Lilly, and Roche; and chemical companies like Bayer, ICI, Pfizer, and Sandoz have been in business for more than 100 years, going back to a time when most medicines were sold without prescriptions and roughly half were compounded by local pharmacists. During the 1920s and 30s, penicillin and insulin were developed and manufactured, albeit on a modest scale. World War II provided a stimulus to the pharmaceutical industry, as the demand for analgesics and antibiotics escalated. During the post-war period, the implementation of state healthcare systems created a more stable market, both for the practice of prescribing drugs and for their reimbursement.[11] This incentivized commercial investment in research and the manufacture of a wide range of pharmaceutical products. In the ensuing years, consumers benefited from the introduction of over-the-counter products like acetaminophen and ibuprofen, complemented by completely new classes of pharmaceuticals such as oral contraceptives, betablockers, ACE inhibitors, benzodiazepines, and a range of cancer treatments.

During the 1970s, 80s, and 90s, drug development was largely in the hands of multinationals, which prompted the creation of "blockbuster drugs," chemical compounds that were designed to become consumer staples as treatments for extremely common, chronic ailments. For example, the ulcer medication Tagamet quickly reached $1 billion in sales, followed by a succession of other blockbusters like Eli Lilly's Prozac (the first serotonin reuptake inhibitor) and Astra's Omeprazole (the first proton pump inhibitor). Pfizer's cholesterol drug Lipitor became the best-selling drug of all time, with $125 billion in sales over 15 years.

As Table 1 shows, the pharmaceutical industry spends hundreds of millions of dollars annually to market its products. It is currently the seventh largest ad category in the US, investing $6.4 billion in 2016, representing a growth of 64% since 2012 (Swallon, 2017).[12] Spending on direct-to-consumer ads is just a fraction of what the pharmaceutical industry spends marketing directly to health-care providers to prescribe their products. For instance, when drugmakers' direct-to-consumer marketing appeared to be decreasing (as it did in 2012), it turns out that even more money was spent on promoting their wares directly to doctors. Prescription drugs are a massive market: Americans spent $329.2 billion on them in 2013.[13] That works out to about $1,000 per person in the US.[14] By 2014, the global market for pharmaceuticals exceeded $1 trillion in sales, with the world's largest drug companies generating $429.4 billion of that revenue.

Pharmaceuticals strategically promote products expected to become the most profitable. For example, in 2011 Boehringer Ingelheim spent $464 million advertising its blood thinner Pradaxa. The investment appears to have paid off: the drug passed the $1 billion sales mark the following year. Although this might seem like good business sense, critics are concerned that pharmaceutical firms are driven more by self-interest than by their espoused values to serve

society. Pharmaceuticals have an especially robust duty to society, because they have the power to contribute to or deny the ability to live a healthy life.

Table 1. Top US Drug Advertisement Expenditures (2016)[15]

Drug/Maker	**Advertisement** (in USD millions)	**Purpose**
Humira/AbbVie	$439	Anti-inflammatory
Lyrica/Pfizer	$392	Nerve pain management
Eliquis/Bristol-Myers Squibb	$296	Blood thinner
Xeljanz/Pfizer	$258	Anti-inflammatory
Opdivo/Bristol-Myers Squibb	$168	Cancer treatment
Chantix/Pfizer	$151	Smoking cessation
Cialis/Lilly	$150	Erectile dysfunction
Trulicity/Lilly	$142	Increase glucose (diabetes)
Prevnar/Pfizer	$142	Pneumonia vaccine

[end of Table 1]

Government Regulation

Government regulation is designed to ensure that businesses serve the public good, not just their shareholders. But it is debatable whether, when, and how these regulatory efforts are effective. Since the antibiotic era of the late 1940s, discovery and development of pharmaceutical products has evolved into an expensive, time-consuming, cumbersome, and bureaucratic process.[16] The horrific thalidomide scandal in 1961, in which it was discovered that a drug given to pregnant women caused serious birth defects, triggered a government reassessment of state controls. New

regulations were imposed in the US to require efficacy, purity, and safety—greatly increasing research and development costs, particularly in the area of clinical testing. Regulations were viewed as barriers to market entry, forcing a consolidation within the industry.[17]

In subsequent decades, multiple interest groups have emerged, representing the rights of companies and patients alike (e.g., pharmaceutical manufacturers, governmental regulatory authorities, patent officers, academic and clinical researchers, attorneys, and political action committees [PACs]). With huge profits and a thousand paid lobbyists, Big Pharma often gains leverage in how legislation is crafted and/or abandoned. From 1998 to 2014, Big Pharma spent nearly $3 billion on lobbying, drowning out the voices of consumers and the interest groups that represent them.[18]

According to reports by nonprofit MapLight, drug companies poured more than $70 million into fighting California's Proposition 61, intended to limit the prices state agencies pay for prescription drugs.[19] The industry often backs legislators who favor their shareholder-driven approach (e.g., $15 million in campaign contributions in one year; 2013-14). The trade group PhRMA is also known for hiring former government employees, who are connected to those in political office. Using these relationships to pursue industry goals, Big Pharma maintains a significant advantage that can be used to override stakeholder interests. Such integrated forms of control contribute to the high cost and limited availability of certain drugs. US citizens pay more than those of any other country for their pharmaceuticals. Big Pharma often points to extensive development costs to justifying its pricing strategies. However, this explanation merits additional consideration.

Aiming to improve American-owned businesses in global markets, Congress enacted a series of laws designed to speed up tax-supported research on new products. One of these laws,

the Bayh-Dole Act of 1980, enabled universities and small businesses to patent and/or license any discoveries from their tax-funded medical research sponsored by the National Institutes of Health (NIH). Prior to this law, taxpayer-financed discoveries belonged to the public domain (i.e., new drugs were available to any company that wanted them). As the result of this legislation, universities that carried out NIH-sponsored work could charge royalties, providing income for non-profit institutions. Legislation was also passed that allowed the NIH to enter into deals with drug companies, transferring NIH discoveries directly to industry.

This wave of legislation also gave a huge boost to the nascent biotechnology industry, thereby paving the way for a tremendous buildup of Big Pharma. Small biotech operations, many of them founded by university researchers, proliferated as much of the burden for the initial phases of drug development shifted from Big Pharma to smaller firms. The smaller firms worked to secure deals with Big Pharma, who would then go to market with their discoveries. When a patent held by a university or a small biotech company is licensed to a pharmaceutical, Big Pharma reaps huge benefits. The laws evolved so that drug companies could rely upon other firms to perform a great deal of the research and development (R&D) for the creation and testing of new drugs.[20] At least a third of the drugs marketed by the major drug companies are licensed from universities or small biotech companies, reflecting the paradox that very small ventures drive a large part of Big Pharma's innovation.[21] The majority of drugs approved in recent years originated at these smaller operations—64% of them last year, according to HBM Partners, a health care investing firm.[22]

There is no question that pharmaceutical firms must make investments. The cost of bringing a drug to market is vague and often unverifiable. Developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade, is estimated

to cost $2.6 million, according to a study by the Tufts Center for the Study of Drug Development.[23] To encourage drug development in the US, regulatory laws permit pharmaceutical firms to set their own pricing and provide protections that are tantamount to limiting free-market competition. Other countries set a limit on what companies can charge based on the benefit of each drug. In theory, it seems prudent to ensure that pharmaceuticals can recoup some of their losses, so they will continue to invest in risk-intensive choices that benefit those in need. Drugs with very small markets present particularly high investment risks. Some drugs do not make it to market. Once a drug is approved, determining a reasonable profit remains controversial. The unintended consequence, however, is that pharmaceutical firms can corner the market on a particular drug and then drive up the price. It is arguable that the prices drug companies charge could be cut dramatically without threatening future investments in R&D or eroding future profits. R&D is a relatively small part of Big Pharma's budget, especially in comparison to the amount spent on sales and marketing. For every dollar spent on R&D, nineteen dollars go to marketing.[24]

Big Pharma = Big Money

Given its mega-profits, the industry has become known for its ability to wield political and social influence over its stakeholders, including the federal government and its agencies, healthcare systems, insurance firms, medical practitioners and administrators, hospitals, and consumers. Big Pharma has become one of the most profitable industries in the US, rivaled only by mining, crude oil production, and commercial banking. The industry has so much power that it has actually shaped how Western medicine and consumers think about their health and well-being.

Pharmaceutical companies strategically produce what increases earnings for their shareholders. But when the zeal for profit becomes an overriding goal, the interests of non-shareholders stakeholders are ignored, as depicted in this 2015 email from Martin Shkreli, former CEO of Turing Pharmaceuticals, maker of Daraprim:

> $1bn here we come. I think it will be huge. We raised the price from $1,700 per bottle to $75,000. So 5,000 paying bottles at the new price is $375,000,000… almost all of it is profit and I think we will get 3 years of that or more. Should be a very handsome investment for all of us. Let's all cross our fingers that the estimates are accurate.[25]

News stories about how Turing acquired the full rights to a 60-year-old generic drug and then promptly raised its price 5000% outline how Shkreli's bold projections complemented his strategy.[26] The drug treats toxoplasmosis, a parasitic infection that is particularly perilous for HIV/AIDS patients. Turing's documents were made public when participants on the House Government Reform and Oversight Committee investigated citizen outrage. Their inquiry confirmed the stark and grotesque reality: Turing had raised the price of Daraprim exorbitantly because it could do so legally. In addition to windwall profits, the company reaped stakeholder backlash that forced Shkreli out. Amidst protests and investigations, fraud charges were brought against Shkreli.[27] His expulsion, however, provided no relief to patients in desperate need of the drug.

Unfortunately, such unseemly pricing strategies are not confined to one greedy executive or a few unethical firms. Pricing decisions are commonly based on the desire to maximize profits. For example, in early 2015 Valeant Pharmaceuticals purchased two heart medications. Taking sole ownership, the company subsequently hiked prices by 525% and 212%,

respectively. In just one year, Valeant garnered $351 million in profits from these two products. But this success was short lived. After the US Attorney's offices subpoenaed the company, its stock price plunged. In another case, Mylan, maker of the EpiPen emergency remedy for anaphylaxis, paid nearly half a billion dollars to settle a Justice Department complaint for misclassifying the drug under Medicaid, while separately facing other legal complaints for overcharging consumers.[28]

Industry professionals argue, however, that the market for medicines is unique. Both Turing and Valeant trade in medicines for uncommon illnesses, so-called orphan drugs (i.e., a small user base for medicines that treat rare diseases/disorders). Because so few patients need these drugs, there is little incentive for others to produce them and little or no competition. Leveraging this power, one Turing PowerPoint presentation strategically underscored the firm's desire to control the market:

- Drugs are typically nondiscretionary and consumers are relatively price-insensitive.
- Typically there is an inverse correlation between prevalence of a disease and the annual cost of treatment.
- Exclusivity (closed distribution) creates a barrier and pricing power.[29]

Turing's internal strategy emphasized hiding costs from patients and avoiding fights with HIV/AIDs advocates and hospitals. But the firms that make headlines are not the only ones raising their prices; prescription medication prices have been rising faster than inflation for years.[30] Even the prices of generic drugs, which are supposed to provide consumers with less expensive options, have climbed. Big Pharma maintains that their motives are to produce additional income to advance the science of treatment, funding not only R&D but also patient

access programs that dispense free or low-cost medicines to the uninsured and reduced co-payments for certain populations. Valeant instituted patient access programs after receiving complaints about its prices. Although a few benefit from these programs, the vast majority of consumers are hit hard by the high price of medication.

Table 2. Five Major Settlements between Big Pharma and the US Department of Justice (2009-14)[31]

Company Name	**Drug Names**	**Settlement**	**Date**
GlaxoSmithKline	Paxil, Wellbutrin	$3 billion	2012
Pfizer	Bextra	$2.3 billion	2009
Abbott Laboratories	Depakote	$1.5 billion	2012
Eli Lilly	Zyprexa	$1.4 billion	2009
Amgen	Aranesp	$762 million	2012

[end of Table 2]

Big Pharma is well known for fraudulent behavior, and drug companies have settled numerous billion-dollar lawsuits (see Table 2), totaling more than $13 billion between 2009 and 2014.[32] Cases often involve misbranding and off-label marketing, giving kickbacks to physicians for prescribing and/or recommending drugs, and strategically aligning with generic companies as a means to keep the overall cost of drugs higher than their justified benefits. Increases in the number and size of these cases have contributed to charges that the government itself has been complicit in the illicit behavior.[33] Pharmaceutical companies are undeterred by fines, legal fees, and settlement payouts, which they seem to view as costs of doing business. The reality is that consumers ultimately pay for government programs through their tax dollars. Cost increases also

contribute to higher insurance premiums, higher deductibles, and decreased coverage. The US is the only major market where pharmaceutical pricing remains unregulated. Mahmud Hassan, director of Rutgers Business School's pharmaceutical management program, says that stakeholders in the US—patients, health insurers, and the government—pay more for their prescribed medicines than those in countries with national health programs, and sometimes double.[34]

Influencing the Medical Community

Doctors, scientists, research organizations, medical journals, teaching hospitals, and university medical schools all accept money from the pharmaceutical industry. Medical researchers sometimes coauthor articles in concert with Big Pharma or receive funds for ghostwriting information that reflects certain results that may ultimately be published in medical journals. Research conducted by scientists associated with pharmaceutical firms has been used to promote (directly or indirectly) many drugs—including antidepressants Paxil and Zoloft, anti-epilepsy drug Neurontin, painkiller Vioxx, and recalled weight loss drug Fen-Phen. It is common practice for a pharmaceutical firm to pay a medical reviewer to write a comprehensive assessment of a new drug for a medical journal.

Accounts of slanted research have appeared in medical journals, despite claims by authors of their unbiased scientific evaluation, separate from any financial ties to the industry. An example that recently came to light was the disclosure that in 1967 the sugar industry paid Harvard scientists to obscure a link between sugar and heart disease.[35] As a result of the misleading information, decades of research examined saturated fat—rather than sugar.[36]

Researchers say that this thwarted a more thorough investigation, which has likely contributed to an increase in the rate of heart disease in the US.[37]

A former editor of the *British Medical Journal* described how the pharmaceutical industry can cleverly use all medical journals.[38] Most, including the *Journal of the American Medical Association*, benefit from advertising dollars from Big Pharma. Drug companies also sponsor clinical trials that researchers are paid to administer. Academics and scientists conduct the research, collecting data and preparing and analyzing the findings. Nevertheless, sponsors often keep the data, prepare additional analyses, and report what supports their own agenda. Drug companies may stage-manage drug trials, revealing the outcomes that put their products in the best light.

Doctors in the US are typically required to take accredited continuing medical education (CME) coursework. The pharmaceutical industry provides a substantial proportion of the annual costs of CME, using this platform as a means to market their products.[39] Drug company representatives are key players within the US healthcare delivery system, educating doctors so they can prescribe drugs appropriately. At the same time, pharmaceutical firms train their representatives to push the newest (often the most expensive) products.[40] As previously described, academic centers can receive royalties from Big Pharma on any drug or technology they help to create and patent, often underwritten with government funds. Columbia University, for example, received nearly $790 million from licensing agreements with biotech and pharmaceutical companies during the 17-year life of its medical school's patent on a method for synthesizing certain biological products.[41]

In the US, there is one pharmaceutical sales representative for every 2.5 office-based physicians.[42] In recent years, however, some facilities have imposed a closed-door policy,

reducing this practice (by some accounts to 1:5).[43] In some cases, physicians may welcome salespeople because they provide free samples, which they can then use for their patients. Big Pharma claims that this practice improves patient care, fosters appropriate medication use, and help millions of financially struggling patients. But scholars have countered that "sampling" is not effective in improving drug access for the indigent, does not promote rational drug use, and raises the cost of care.[44]

Also troubling is that healthcare professionals are continuously encouraged to resolve patients' concerns by prescribing medications. Given the pressure to see more patients in less time, the system pushes physicians to provide quick prescription-driven remedies. Pharmaceutical companies also sponsor symposia and medical conventions, offering medical practitioners opportunities to extend their education. These events often include free travel and other benefits, making it difficult to be anything but favorably inclined towards the sponsoring firms that help subsidize them. In medical schools, preceptors, teachers, department chairs, and deans may sit on drug companies' boards of directors. Money from Big Pharma supports educational programming within many medical schools and teaching hospitals, and company reps gain access to doctors to promote their wares.[45] This reinforces a drug-intensive style of practice.

Hope for the Future?

Big Pharma is largely driven by a fiduciary responsibility to its shareholders and corporate executives. Its profound focus on self-interest places in question how much of what it does benefits society. Over the past several decades, the pharmaceutical industry has become a marketing machine to sell drugs that generate the most profit potential. As Big Pharma wields its

power within the US Congress, FDA, academic medical centers and the medical profession itself, patients may find themselves confused, frustrated about options, and without recourse.

With the cost and complexities of drug discovery, Big Pharma has shifted from the development of medicine that targets short-course therapies for acute diseases to the long-term treatment of chronic conditions. Despite a growing clinical need, there is a disturbing lack of investment in producing novel antibacterial agents. Drug options for treatment of infections have become increasingly limited, as antimicrobial resistance becomes increasingly robust. Generic antibiotics are in short supply, and the development of new antibiotics has been severely curtailed. Only four large pharmaceutical companies with antibiotic research programs remained in existence in 2002. As reported by Pew Research in 2016:

> *New discoveries dropped precipitously from the 1980s onward. As a result, the development of antibiotics has declined, with new FDA approvals for these drugs falling from 29 during the 1980s to nine in the first decade of the 2000s. All antibiotics approved for use in patients today are derived from a limited number of types, or classes, of antibiotics that were discovered by the mid-1980s. This is even more concerning than the decline of drug approvals because resistance to one antibiotic often leads to resistance to multiple antibiotics within the same class.*
>
> *Faced with poor discovery prospects and diminishing returns on investment, major drug companies have cut back or pulled out of antibiotic research altogether. This has left much of the remaining discovery work to small, "pre-revenue" companies with no products on the market and limited budgets and R&D capacity. Most industry*

> *antibiotic development programs are primarily focused on modifying existing classes of drugs discovered decades ago to circumvent bacterial resistance and better target difficult-to-treat infections. Though essential, such incremental advances are not likely to meet the looming public health challenge of antibiotic resistance in the long term.*[46]

Pharmaceutical companies face a paradox wherein federal agencies call for antibiotic development even as other federal agencies enact policies limiting the appeal of that very development.[47]

Critics from the medical stakeholder community claim that there is insufficient science guiding pharmaceutical business decisions and that the financial incentives go in the wrong direction. Big Pharma wants consumers to take a pill every day for the rest of their lives. Therefore, they invest in new forms of birth control, cholesterol blockers, and antidepressants that dominate the market. Meanwhile, vaccines have become scarce. Big Pharma and its university partners have been charged with paying little attention to salient issues of public health, and focusing instead on products expected to maximize profits. Critics underscore how Big Pharma has grossly subordinated patient needs in favor of its own investment returns.[48] Allen Frances, Chair of the DSM-IV Task Force, warns that the gradual mislabeling of everyday problems as illness has toxic implications for individuals and society: stigmatizing people, introducing them to potentially harmful medications, misallocating medical resources, and draining the budgets of families and the nation. Wellness has been shifted away from our own naturally resilient and self-healing capacity, into the hands of Big Pharma, who reap multi-billion-dollar profits at our expense.[49]

Big Pharma presents an ironic reality: the industry offers life-saving health benefits, and yet remains one of the least trusted. Addressing this challenge will depend upon increased stakeholder engagement and government activism. US Senator Bernie Sanders (I-VT) asserts that people must be prepared to stand up to powerful special interests like the pharmaceutical industry and Wall Street.[50] Before taking office, President Donald Trump said the pharmaceutical industry was "getting away with murder," and vowed to do something about it.[51] The ability that Big Pharma has to dictate the pricing of drugs in the US creates incentives for it to extract exorbitant prices. Traditional common law remedies have not resulted in deterrence.[52]

Despite public knowledge of Big Pharma's self-serving practices, pharmaceutical companies claim that their mission is to benefit people. Reformers call for restructuring the industry itself, so that it remains grounded in science but is motivated to provide safe and effective drugs for the public. Accomplishing this end will require citizen and stakeholder engagement, demonstrated via a determined commitment to prompt reflection, informed dialogue, and bipartisan reform. To create systemic change, fresh ideas need to be explored.

One plan for tackling the expensive limited access to drugs has emerged from the medical community. The idea is for the US federal government to buy pharmaceutical firms outright, rather than buying the drugs themselves.[53] For example, Hepatitis C kills more Americans than any other infectious disease (Centers for Disease Control and Prevention) and often leads to a need for liver transplants.[54] Gilead Sciences Inc. makes Sovaldi and Harvoni, the two drugs that can swiftly cure this disease, but sells them at prices so high that few can afford them (a 12-week course is $85,000). States restrict their use, telling patients they are not sick enough to justify the cost. The drugs consistently eradicate the virus, which has infected an estimated 2.7 to 3.3 million people in the US. Buying the company instead of the drugs would cut the cost of

treatment by almost two-thirds. The government could then sell off the firm, but sustain the drug rights. This action would cut the cost of treatment, stop disease from spreading, and reduce the number of liver transplants needed.

The idea of having the government purchase corporate shares at full price on the open market may seem far-fetched, but it represents the kind of thinking that can promote needed change. Experts say that if the federal government treated illnesses as public health issues, rather than as Medicaid budget problems, innovative ideas like this one would be more likely to emerge.[55] They argue that the government needs to focus explicitly on curing and saving patients, and to move away from reinforcing practices such as prescription-based care and drug dependency, which benefit the industry but harm citizens.

Leaders of Big Pharma corporations must be held liable for the misconduct they participate in or enable. Prosecutors need to be able to exact penalties that are potent enough to affect corporate behavior, such as fines that involve garnishing 15% of a firm's annual profits. Some suggest that Big Pharma be regulated like public utilities.[56] If the government regulated drug pricing, as it does for pricing electricity, it would likely prompt competition between companies and drive the prices lower, benefiting all, including government programs. The convergence of IT and healthcare is another path that might prompt a shift in the Big Pharma model. Big data, apps, and mobile health are starting to transform healthcare and diagnostics in a significant way, with Apple and Google acting as steadfast disruptive catalysts. Medicines paired with companion diagnostics may be an increasingly leveraged strategy to gain market access. At present, AstraZeneca, Roche, Novartis and Sanofi are progressing as much as 60–80% of their clinical portfolios with companion diagnostics.[57] In the era of personalized and precision medicines, this strategy will likely translate into medicines accompanied with apps or wearable

devices that help patients monitor key parameters and manage their diseases. How big pharma adapts to this 'beyond-the-pill' model will be an interesting development during the 2015–2025 period.[58]

In broader terms, academic institutions need to educate the next generation of business leaders to view social responsibility and governance as key components in the calculation of value and profit. It is not enough to increase the value of corporate stock in the short term. Firms must incorporate a stakeholder perspective, accompanied by a longer-term profit horizon. Big Pharma, affecting the health and welfare of every citizen, is at the intersection of business and society. How this industry moves forward presents one of the biggest ethical challenges of the 21st century, seeking a balance between capitalism and the corporation's duty to its share- and stakeholder constituents.

Critical Thinking Questions

1. Consider two powerful industries, so-called Big Pharma and Big Tobacco. The former can save lives; the latter is accused of taking them. Yet, there are some disturbing similarities between these industries. Identify and discuss these commonalities and their causes. In light of your response, what recommendations do you have for leaders of pharmaceutical companies?

2. In a capitalistic-driven economy, do large corporations have a duty to serve their stakeholders? If so, to what extent?

3. Is government regulation necessary? As a future business leader, how would you establish a balance, ensuring that the free market rewards performance while also constraining unethical behavior and excessive greed?

4. Americans spend billions of dollars annually on prescription medications. As the US population ages, this spending will only increase. What are the implications of this reality, in terms of sustainability? When does the statement "better living through chemistry" become problematic?

5. Beyond penalizing Martin Shkreli and other corporate leaders like Andy Fastow and Jeff Skilling (Enron) for their illicit actions, what is needed to encourage ethical leadership within large corporations?

Case Summary

The trillion-dollar pharmaceutical industry is commonly known as Big Pharma. The industry grew tremendously in the decades after World War II, especially after legislation in the 1980s gave private companies more rights to profit from drugs developed with public funding. Although it is subject to government regulations, Big Pharma is able to operate in the US on a largely free-market basis, giving shareholders priority over patients and other stakeholders. Large sums are spent on marketing drugs, lobbying elected officials, and settling lawsuits for fraud and other violations. Ethical concerns center on the need for government policymakers and industry decision makers to address the concerns of multiple stakeholders in a sustainable way.

Case Analysis

Unethical behavior in pharmaceutical firms is manifest systemically within the health care industry, now a deeply entrenched element of modern Western culture. Prescription drugs are prevalent in our lives, largely as a result of drug companies' short-term bottom-line performance orientation. Business often takes a shareholder approach that aims for securing financial gains that lack a sustained commitment to longer-term consequences and the implications they may have on the well-being of others. The cost to citizens is greater dependency on large corporations, which thrive on the backs of consumers. Government regulation can help, but laws are insufficient. Ethical corporate behavior depends upon honorable corporate leadership. The next generation of leaders must make ethical decisions that address both short- and long-term concerns and reflect the interests of multiple stakeholders—not just shareholders.

Critical Thinking Questions and Suggested Answers

1. Consider two powerful industries, so-called Big Pharma and Big Tobacco. The former can save lives; the latter is accused of taking them. Yet, there are some disturbing similarities between these industries. Identify and discuss these commonalities and their causes. In light of your response, what recommendations do you have for leaders of pharmaceutical companies?

Both industries have a shareholder-driven approach, which contributes to a short-term focus on quarterly returns. Corporate leaders who do not take the time to incorporate stakeholder-driven concerns into their mission, strategy, and operations are likely to favor self-interest over social responsibility. Addressing this problem will require a desire within the business community to examine, define, and measure profit in a more holistic manner. This translates into extending the

earnings reporting cycle, including metrics for social responsibility to determine a firm's worth, and caring about benefiting people and the planet, as well making money.

2. In a capitalistic-driven economy, do large corporations have a duty to serve their stakeholders? If so, to what extent?

A corporation is a legal entity designed to provide a platform for doing business. What gives a firm its morality is its leadership; people provide the character strength behind a firm's day-to-day operations. Leaders vary in their perceptions and interpretations of responsibility. Capitalism encourages a focus on the fiduciary responsibility to serve shareholders' interests. However, a business driven entirely by self-serving goals jeopardizes its longevity. When firms ignore their other stakeholders, they may erode or even destroy the relational trust necessary for sustaining business transactions. It is a corporate leader's ethical duty to address the needs of non-shareholder stakeholders, while also focusing on returns to shareholders.

3. Is government regulation necessary? As a future business leader, how would you establish a balance, ensuring that the free market rewards performance while also constraining unethical behavior and excessive greed?

Government regulations cannot ensure ethical and moral decision-making and action in business. It will not be enough to raise the regulatory bar. Instead, we need a new bar with alternative metrics that work to instill positive ethical development. As a society, we need to elevate our concept of a corporation's worth. Individually and collectively, we must learn to take responsibility for using our consumer and political power, directing it to represent our values. As a future business leader, one can help to ensure a more balanced approach to 'doing well and

doing good' in industry by redefining ethical performance standards. Performance needs to exceed the moral minimum imposed by government regulation. Those taking the leadership helm can form alliances, collaborating with others to counter the predominant shareholder-driven approach. Ethics training must go beyond discussions of adherence to compliance requirements. Employees need encouragement to develop their personal and collective moral strength. Leaders can inspire others to become ethical role models, who care about others and want to engage in right action in business. Excessive self-interest can be countered by rewarding employees for how they go about achieving their performance goals, not just paying them for hitting their revenue targets and short-term quarterly demands.

4. Americans spend billions of dollars annually on prescription medications. As the US population ages, this spending will only increase. What are the implications of this reality, in terms of sustainability? When does the statement "better living through chemistry" become problematic?

Rates of diabetes, high cholesterol, and high blood pressure have increased as the American diet has changed from original food-sourced nutrients to processed chemical-laden foodstuffs. Our health would improve if we focused on the preventative measures of diet and exercise. Once we become sick, we turn to the quick fix of pills, rather than imposing the lifestyle changes necessary to improve our health and well-being. An over-reliance on chemistry moves society away from more natural ways of staying healthy. Americans spend billions of dollars annually on prescription medications. As the population ages, this spending will continue to expand, to a level that is clearly unsustainable (given our current healthcare structure). Many individuals may experience reduced quality of life or even early death because they lack access to essential

medications. This problem is complex, as will be the solution: restructuring the drug payment system and reemphasizing a more holistic lifestyle. Ideally, this crisis will prompt our society to heed the wisdom that an ounce of prevention is worth a pound of cure, and to expand our focus to include sustaining wellness as well as treating illness. .

5. Beyond penalizing Martin Shkreli and other corporate leaders like Andy Fastow and Jeff Skilling (Enron) for their illicit actions, what is needed to encourage ethical leadership within large corporations?

If, as a society, we seek to increase ethical business practices, we must approach the problem of immoral executive behavior from multiple directions. First, there must be consequences for any executive whose prioritization of financial earnings results in illicit and/or unethical behavior. These would include prison sentences and financial penalties, hits to their personal finances and their firm's bottom line. Second, we need to find ways to reward firms that conduct business ethically and remove barriers to ethical action, making it not only more desirable but also easier to do the right thing.

Endnotes

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