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DARAPRIM SPECIALTY DRUG PRICING: A CASE STUDY

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Abstract

This case study tells the story of a young, unconventional CEO who executed a perfectly legal, totally unregulated strategy to acquire both great wealth and significant enmity: purchasing an older, neglected, specialty drug (i.e. a drug that has successfully treated a chronic or difficult health condition), significantly increasing its price, and tightly controlling its distribution (Pollack, 2015). These specialty drugs are highly effective in treating disease, but the number of patients desperately needing the drug is modest and stable, making it less attractive for generic drug manufacturers to enter the market. Free from competition, the specialty drug manufacturer can set any price it wants for the specialty drug, wreaking havoc on patients suffering from the disease the drug is designed to cure and the physicians and medical institutions trying to heal them. The purpose of this case is to evaluate this business model and ascertain if it might be appropriate to permit the Food and Drug Association (FDA) to participate in the negotiation of price increases of these specialty drugs.

Turing Pharmaceuticals' pricing strategy for the drug Daraprim

Infectious Disease News broke the story on the September 17, 2015, succinctly capturing what happened: "A recent spike in the price of Daraprim and supply problems have raised concerns among health care providers, expert organizations and the media" (Muoio, 2015a, para. 1). Daraprim (known generically as pyrimethamine) is used to treat the parasitic disease toxoplasmosis that affects cancer and HIV patients who have compromised immune systems (Muoio, 2015a). Turing Pharmaceuticals acquired the drug on August 10, 2015, from Impax Laboratories, and immediately increased its price from $13.50 to $750 per tablet. This price increase dramatically raised the annual cost of treatment for toxoplasmosis to $336,000 for patients weighing less than 132 pounds and $634,500 for patients weighing more than 132 pounds, and, according to the vice chair of the HIV Medicine Association (an organization of

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medical professionals who practice HIV medicine), disproportionately injures the most vulnerable patients who lack insurance or face barriers to health care (Muoio, 2015a).

A significant shortage of supply also accompanied the price increase, crippling the ability of multiple hospitals to obtain pyrimethamine (Muoio, 2015a). Turing Pharmaceuticals admitted the price increase was attributable to its acquisition of Daraprim from Impax Laboratories (Muoio, 2015a). The more likely cause of the supply shortage was Turing Pharmaceuticals' decision to restrict distribution of the drug through a specialty pharmacy to prevent generic drug manufacturers from getting sufficient quantities of Daraprim to conduct the research studies needed to gain FDA approval of a generic version of Daraprim, as explained more fully below.

Alarmed by the shortage of Daraprim, the HIV Medical Association and the Infectious Diseases Society of America (a professional organization representing physicians, scientists and other health care professionals who specialize in infectious diseases) sent a letter protesting the price increase to Turing Pharmaceuticals (Muoio, 2015a). In response, Turing Pharmaceuticals acknowledged their concerns, claimed supply issues were corrected, and pledged to improve the care of patients with toxoplasmosis by developing an innovative treatment for the disease (Muoio, 2015a). This response was troubling to the HIV Medical Association and the Infectious Diseases Society of America, because pyrimethamine is well tolerated, remains effective in treating toxoplasmosis, and has minimal side effects. In short, the explanation for the price increase – funding research studies to find an alternate treatment for toxoplasmosis – was false. There was simply no need to develop an alternate treatment for toxoplasmosis (Muoio, 2015a).

Martin Shkreli: Turing Pharmaceuticals' unconventional CEO

The CEO of Turing Pharmaceuticals who engineered the Daraprim price increase was Martin Shkreli, a 32-year old entrepreneur, who "was raised in working-class Brooklyn, the son of Albanian and Croatian immigrants who worked as janitors" (Lukerson, 2015, para. 7). He dropped out of an exclusive Manhattan high school, and interned at a hedge fund and CNBC's Mad Money show (Smythe & Geiger, 2015, para. 9). He earned a B.A. degree at Baruch College in New York City, started two hedge funds, Elea Capital and MSMB Capital, which invested in biotech, and learned he could make a lot of money directly selling pharmaceutical drugs (Smythe & Geiger, 2015; Lukerson, 2015). In an earlier venture, his pharmaceutical company, Retrophin, purchased old, rarely used drugs and increased their prices, for example raising the price of a drug to treat kidney stones from $1.50 per pill to $30 (Lukerson, 2015).

Turing Pharmaceuticals' Daraprim price increase is not an unusual industry practice

Shkreli's price increase of Daraprim is not unusual in the pharmaceutical industry. As noted in *The New England Journal of Medicine*:

> It seems that a new business model has emerged: companies are acquiring drugs in niche markets where there are few or no therapeutic alternatives in order to maximize their profits. Unlike new brand-name drugs, the patents of the drugs being targeted by this model expired years ago. These companies seem to have

no interest in adding value to the health care system by developing new drugs (Alpern, 2016).

There are abundant examples of the adoption of this new business model. Therapeutics acquired Cycloserine, used to treat multi-drug resistant tuberculosis, and increased its price from $500 to $10,800 for 30 pills. Marathon Pharmaceuticals purchased two heart drugs, Isuprel and Nitropress, in 2013, and quickly quadrupled their prices. Valeant Pharmaceuticals bought those same two drugs from Marathon and raised their prices by 525% and 212% respectively (Pollack, 2015). Mallinckrodt Pharmaceuticals purchased the drug Ofirmev used to treat pain and raised its price from about $450 to $1,020 per 24 vials. Horizon Pharma purchased the drug Vivovo used to treat pain and raised it price from about $200 to $1,678 per 60 tablets (Philosophers on Drug Prices, 2015). Jazz Pharmaceuticals purchased the drug Xylem, used to treat narcolepsy, from Orphan Medical in 2005, and "increased the price 29 percent each year since 2011." (Klugman, 2015, para. 3). In another case, "Actor Gel - used for treating multiple sclerosis - dates from 1952 but in 2007, the price increased 1400% overnight and has been raised 19 times since then" (Klugman, 2015, para. 3).

Approved by the FDA in 1953, Daraprim cost only $1 per tablet several years ago. Daraprim's price rose sharply after it was acquired by GlaxoSmithKline. In 2010, Glaxo sold the U.S. marketing rights to Daraprim to CorePharma. Four years later, Impax Laboratories purchased CorePharma, and in August 2015, sold Daraprim to Turing Pharmaceuticals for $45 million (half of the $90 million it raised in its first-round financing). Significantly, prescription sales of Daraprim increased from $667,000 in 2010 to $6.3 million in 2011, even though the number of prescriptions (around 12,700) held steady. In 2014, prescription sales of Daraprim increased to $9.9 million even though the number of prescriptions dropped to 8,821 (Pollack, 2015). The price increase implemented by Shkreli could increase revenues from sales of Daraprim to "tens or even hundreds of millions of dollars if use remains constant" (Pollack, 2015, para. 19).

Shkreli denied the price increase was an attempt to gouge patients and claimed it necessary to permit Turing Pharmaceuticals to remain in business (Boyer, 2015; Lukerson, 2015; Pollack, 2015), and that he should have raised the price even higher, because his investors "expect [him] to maximize profits" (Smythe & Geiger, 2015, para. 12).

Turing Pharmaceuticals promises to reprice Daraprim, but then doesn't

Facing a barrage of publicity condemning the Daraprim price increase, Turing Pharmaceuticals announced plans to reprice Daraprim, stating: "Turing's CEO Martin Shkreli has committed to adjusting the price of Daraprim, but there is no timetable as to when that will occur or at what price point" (Muoio, 2015b, para. 2). One month later, when no price reduction was implemented, 152 health organizations and individuals signed an open letter asking Turing Pharmaceuticals to immediately lower the price of, and improve access to, Daraprim. The letter said: "Patients already affected by the failure of Turing Pharmaceuticals to act on its commitment include pregnant women, children, infants, people with HIV and others with compromised immune systems across the country" (Organizations want Turing to uphold, 2015, para. 2).

Turing Pharmaceuticals then promised to reprice Daraprim before the end of the year. That promise did not satisfy the Infectious Diseases Society of America and the HIV Medicine Association. They objected to the lack of transparency on the details of the price restructuring and Turing Pharmaceuticals' use of a controlled distribution of Daraprim through Walgreen's Specialty Pharmacy, which creates unreasonable hurdles for patients needing the medication (Turing Promises Daraprim Repricing, 2015, para. 5). Those objections went unheeded. While Turing Pharmaceuticals announced plans to provide hospitals with discounts up to 50%, it did not lower the list price for Daraprim (Turing Announces Hospital Discount, 2015). Nor did Turing Pharmaceuticals explain why it failed to keep its promise to lower the price of Daraprim.

Daraprim price increase attracts the interest of Congress

The House Committee on Oversight and Government Reform conducted a hearing on February 4, 2016, to obtain an explanation for the Daraprim price increases. Nancy Retzlaff, the chief commercial officer of Turing Pharmaceuticals, defended the price increases on the basis of ongoing research costs and various treatment discounts (House Committee Hearing, 2016). The Committee acknowledged that generic drugs can cost 80% to 85% less than their brand equivalents and have played an important role in health care by offering lower-cost alternatives. The Committee also determined the approval of generic drugs was significantly delayed because of a backlog of approximately 4,000 applications awaiting FDA action (Developments in the Prescription Drug Market, 2016).

The Senate Special Committee on Aging conducted a hearing on March 17, 2016, to investigate the Daraprim price increases. In her statement, Sen. Susan M. Collins (R-Maine), the Chair of the Committee, identified five components of the business model followed by Turing Pharmaceuticals to maximize its profits: (1) finding an off-patent treatment with no generic competitor; (2) confirming the drug's status as the "gold standard" treatment; (3) assuring the patient pool for the drug is small so as to reduce scrutiny and lower the incentive for other companies to produce generic versions; (4) establishing a closed distribution system or specialty pharmacy to control drug components and ensure an effective monopoly; and (5) enacting a substantial market price increase to maximize revenue (Muoio, 2016). Howard Dorfman, then the former senior vice president and general counsel of Turing Pharmaceuticals, testified that he repeatedly objected to the Daraprim price increases, because they made the drug unavailable to vulnerable HIV and AIDS patients. He also noted that the company lacked any formal study protocol to research the "next generation" of toxoplasmosis therapy (Muoio, 2016). Ron Tilles, interim CEO and Board Chairman of Turing Pharmaceuticals, defended the price increases as necessary to fund research into alternative treatment for toxoplasmosis, and claimed that two-thirds of Daraprim sales are to federal and state health programs that pay Turing Pharmaceuticals only one penny per pill (Muoio, 2016).

The Senate Special Committee on Aging also heard testimony from Shannon Weston, a mother from North Carolina, whose infant daughter contracted congenital toxoplasmosis. Ms. Weston's insurance company denied her claim to cover the $360,000 cost of providing Daraprim, causing her to feel hopeless and depressed at not being able to help her daughter. Fortunately, her local pharmacy obtained pyrimethamine (the generic term for Daraprim) and

compounded it into a serum at significantly less cost (Muoio, 2016). In addition, Adaora Adimora, M.D., professor of medicine and epidemiology at the University of North Carolina, Chapel Hill, and immediate past chair of the HIV Medicine Association, testified that, because physicians are unable to reliably and affordably obtain pyrimethamine for their patients, they have been forced to rely on pharmacists to compound pyrimethamine (Muoio, 2016). The compounding solution, however, is not a feasible alternative, because compounded drugs can only to be prescribed to individually identified patients consistent with federal and state compounded drug formulation laws (Imprimis Pharmaceuticals Announces, 2015, para. 2).

Barriers to development of generic pyrimethamine

As noted above, there is a significant a backlog of approximately 4,000 applications requesting the approval of generic drugs (Silverman, 2016). Drug companies initiate the approval process for generic drugs by filing an "Abbreviated New Drug Applications (ANDAs): Generics." Notably, about 1,800 ANDAs remain pending, because the pharmaceutical companies have not responded to the FDA's request for additional information (Brennan, 2016). Further, the biggest reason for this backlog is the significant increase in the number of ANDAs filed. The average number of ANDAs filed in 2012 was 250; that average increased to 1,022 over the next four years. In short, the increased number in applications filed caused the FDA to fall behind. Notably, the FDA has recently made some progress in reducing the backlog, because Congress authorized the FDA to charge generic drug makers application fees, and the FDA has used those fees to increase the number of facilities inspected, especially those overseas, and to hire staff to speed the application process. Nonetheless, while the FDA reports progress in improving its approval process (Brennan, 2017; Silverman, 2016; Sullivan, 2017), the number of FDA approvals of ANDAs barely keeps pace with the increased number of ANDAs filed (Brennan, 2017).

In addition to the significant backlog of generic drug applications, the approval process for generic drugs employed by the FDA, while less rigorous than the approval process for new drugs, diminishes the chances generic drug manufacturers will produce generic substitutes for drugs like Daraprim, which do not have a significant patient pool. The FDA's generic drug application process requires the applicants to "scientifically demonstrate that their product is bioequivalent (*i.e.*, performs in the same manner as the innovator drug)" (Abbreviated New Drug Application, 2016, para. 3). (An "innovator" drug is the initial drug containing a specific active ingredient approved for a designated use; it is the drug which generic drugs seek to replace.) This means the applicant must establish the generic drug reached the bloodstream in 24 to 36 healthy volunteers, thereby demonstrating the equivalent absorption of the generic drug. In other words, the same amount of the active ingredients get into the patient's bloodstream in the same amount of time as the innovator drug (Abbreviated New Drug Application, 2016).

Furthermore, because drug companies like Turing Pharmaceuticals distribute their specialty drugs through a closed distribution system or specialty pharmacy, generic drug companies lack access to sufficient quantities of the drug to develop scientific evidence of the bioequivalence of the generic drug to the innovator drug (Muoio, 2016). Lacking any competition, drug companies like Turing Pharmaceuticals are free to set whatever price they like for the specialty drug. In his testimony before the above noted Senate Special Committee for the

Aging, Gerald Anderson, the director of the Center for Hospital Finance and Management at Johns Hopkins Bloomberg School of Public Health, noted that the best way to combat the pricing problem is to expedite the FDA approval process for generic drugs. Doing so, he noted, would bring drugs like Daraprim to the market in months rather than years and either discourage companies like Turing Pharmaceuticals from precipitously raising prices or minimize the time the drug company could exact exorbitant prices from patients (Mole, 2015).

Federal regulatory authority to control drug price increases

Neither the FDA nor the Federal Trade Commission (FTC), the two federal regulatory bodies most closely connected to the pharmaceutical industry, have authority to regulate the prices pharmaceuticals charge for their drugs. The FDA confirms its lack of authority on its website, where it states: "FDA has no legal authority to investigate or control the prices charged for marketed drugs" (Frequently Asked Questions, 2016, Q16). While the FTC does have authority to investigate and control the prices charged for marketed drugs, that authority is limited to antitrust surveillance of pharmaceutical services and products (Overview of FTC Antitrust, 2013). Because setting prices on specialty drugs does not constitute monopolization, an agreement not to compete, an agreement to fix prices, an agreement to obstruct innovation, or a tying arrangement, the FTC has no jurisdiction to investigate and control pharmaceutical companies' prices for specialty drugs. Hence the power of pharmaceutical companies to set prices for their specialty drugs, in the absence of antitrust violation, is totally unregulated.

Role of Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the leading research-based pharmaceutical companies in the United States. Its mission is to "conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies" (Our Mission, 2016, para. 1). On March 10, 2016, PhRMA released its "policy solutions for delivering innovative treatments to patients" (Policy Solutions, 2016). In the "Modernizing Drug Discovery, Development and Approval" section of the document, PhRMA cites the significant backlog of ANDAs before the FDA and notes that "on average it currently takes over four years for the FDA to act on a single application" (Policy Solutions, 2016, p. 4). It also warns that, for "serious diseases or conditions in small patient populations, lack of availability of effective medicines with no remaining patent life or regulatory exclusivity, coupled with no or limited brand or generic competition, may constitute an important public health risk" (Policy Solutions, 2016). To combat these problems, PhRMA recommends that the reauthorization of the Generic Drug User Fee Act (GDUFA) should include additional steps to improve ANDA review efficiency, and that financial incentives such as tax credits or targeted grant programs be employed to encourage the development and manufacturing of generic drugs (Policy Solutions, 2016, p. 4).

PhRMA has endorsed the APEC Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector (PhRMA Code, 2016; The Mexico City Principles, 2016). This document contains six guiding principles and addresses seventeen areas in which it seeks to ensure ethical practices are established.

While PhRMA's endorsement of the Mexico Principles is an admirable effort to promote ethical principles and practices and ensure ethical conduct in the pharmaceutical industry, it does not address the issue of sudden and substantial price increases of specialized drugs and the employment of a highly controlled distribution system. Nor do the major pharmaceutical companies address this issue in their mission/purpose/values statements. A review of the mission/purpose/values statements of the twenty-five largest pharmaceutical companies demonstrates that only two companies – AbbVie, headquartered in Chicago, Illinois, and Teva, headquartered in Petah Tikva, Israel – specifically address the issue of affordability of prescription drugs. AbbVie states: "we believe patients need access to quality and affordable medicines." (Our Commitment to Access to Medicines, para. 1). Teva states: "[We are] committed to increasing access to high-quality healthcare for people across the globe, at every stage of life. We do this by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients" (Our Business, para. 2)

Unfortunately, Teva may not be firmly committed to its mission. On December 26, 2016, the attorney generals of 20 states accused Teva and five other pharmaceutical companies of reaching an agreement on sustaining market share, avoiding competition on price, and artificially maintaining high prices for a significant number of generic drugs (Thomas, 2016). Likewise, AbbVie, Inc. may not be totally committed to its mission of providing affordable prices. On September 8, 2014, the FTC filed a complaint in federal district court charging AbbVie, Inc. and its partner, Besins Healthcare, Inc., with filing baseless patent infringement lawsuits against potential generic competitors to delay introduction of lower priced versions of the testosterone replacement drug AndroGel, and, while the lawsuits were pending, of entering into an anticompetitive pay-for-delay settlement agreement with Teva Pharmaceuticals USA, Inc., to further delay generic drug competition (FTC Sues Pharmaceutical, 2014). The federal district court subsequently trimmed the FTC's delay suit against AbbVie, when it ruled Teva Pharmaceuticals did not violate federal antitrust law when it reached agreement with AbbVie to end a patent infringement lawsuit (Bultman, 2015).

Maximizing profits and corporate social responsibility

Advocates of corporate social responsibility (CSR) believe "businesses should balance profit-making activities with activities that benefit society," and "individuals and companies have to act in the best interests of their environments and society as a whole" (Corporate Social Responsibility, para. 17-18). Corporate social responsibility exists in many different forms: donations to charity, influencing government agencies and other companies to treat people and resources more ethically, investing in local communities, developing sustainable technologies, recruiting and hiring a diverse workforce, providing expanded maternity and paternity leave, sponsoring after-school programs, funding local clean-up campaigns, and more closely monitoring the activities of companies in the supply chain (Corporate Social Responsibility). Indeed, in 2010, the International Organization for Standardization released "ISO 26000 – Social Responsibility," which recognizes that business organizations' social responsibility is increasingly being used as a measure of overall performance and gives guidance on "how businesses and organizations can operate in an ethical and transparent way that contributes to the

health and welfare of society" (ISO 26000, 2010, para. 2). That an ISO standard covering CSR has been released to guide business organizations on measuring and reporting overall CSR performance indicates how significantly the CSR movement has advanced and affected global business organizations.

Two CSR scholars have recently developed a model showing how CSR theories can be classified into four groups: (1) instrumental theories, (2) political theories, (3) integrative theories, and (4) ethical theories (Garriga & Mele, 2004). The first group assumes that the corporation is an instrument for wealth creation and that wealth creation is its sole responsibility. Only the economic dimension of the interactions between society and business is considered, and social activity is acceptable only if it is consistent with wealth creation. Corporations can consider, and satisfy the interests of, its stakeholders, provided doing so maximizes the shareholder value. Hence corporate philanthropy and support of social activities are acceptable if they generate profits (Garriga & Mele, 2004).

The second group focuses on connections and interactions between business and society and permits the corporation to engage in social activities and accept social duties and rights if doing so preserves the social power of the corporation. Corporations must use their social power responsibly; if they do not do so, they will lose it. Exercising social power permits corporations to respond to the demands of constituency groups and fulfill the social contract between business and society (Garriga & Mele, 2004).

The third group contends that business depends on society for its existence, and must respond to and integrate social demands, which are viewed as the way society interacts with business. Because responding to social demands confers the mantle of legitimacy and prestige on the corporation, business must scan the environment to identify and respond to social demands to retain and enhance its social legitimacy, acceptance and prestige (Garriga & Mele, 2004).

The fourth group focuses on the ethical requirements that reinforce the relationship between business and society and employs normative stakeholder theory to determine the right thing to do or how to achieve a good society. Stakeholders are those with a legitimate interest in the corporation's activities, and all stakeholders merit consideration for their own sake, not merely for advancing the interest of the corporation or its shareholders. Corporations are required to be attentive to the needs of the various stakeholders and to balance those needs with the needs of the company's shareholders. Doing so requires corporations to have a normative core of ethical principles, such as Kantian principles, Rawls' principles of justice, universal human rights, sustainable development, and the common good of society (Garriga & Mele, 2004).

Drug company malfeasance and patient groups' perceptions of pharmaceutical industry

Turing Pharmaceuticals sudden and deleterious price increase of Daraprim is certainly not an isolated example of pharmaceutical industry malfeasance. In his article entitled "Restoring the Pharmaceutical Industry's Reputation," Mark Kessel, chairman of the Foundation for Innovative New Diagnostics, identifies eleven instances between January 2009 and February

2014 in which the U.S. Department of Justice imposed multi-million and multi-billion dollar fines on pharmaceutical companies for illegal marketing, misleading advertisements directly targeting consumers, off-label drug promotion, sales of drugs with known safety risks, and allegations of price fixing and kickbacks in violation of the False Claims Act and the Federal Food, Drug & Cosmetic Act.

Exposure of these harmful activities has resulted in a significant decline in the reputation of the pharmaceutical industry. In 2012, only 34% of the patient groups surveyed thought the pharmaceutical industry's reputation was "Excellent" or "Good," the lowest scores recorded since the survey was initiated in 2011. In 2013, that percentage increased to 34.5%; in 2014, 39.0%, and in 2015, 44.7%, the increases being attributed to the "major pharma companies . . . new strategies to expand their patient centricity" (The Corporate Reputation of the Pharmaceutical Industry, 2016, para. 5). While patient group ratings of the reputation of the pharmaceutical industry have improved, the fact remains that about 55% of the patient groups surveyed think pharmaceutical companies' reputations are less than good. This poses a problem for pharmaceutical companies, because, as Kessel (2014, para. 15) notes, unless the pharmaceutical industry "[refurbishes] its image as an innovative industry searching for cures," pharma will remain "in the crosshairs of regulators."

Of particular concern to Kessel is the immense pressure placed on pharmaceutical companies "to meet Wall Street quarterly earnings expectations. Indeed, today's companies are measured on how well their stock performs and boards of directors incentivize management accordingly to meet Wall Street's demands. The needs of patients are secondary." This causes patients to believe pharmaceutical companies are "focused on improving their earnings rather than the lives of patients." Further the "high price of drugs is a problem increasingly blamed on the pharmaceutical industry," "the burden of high drug costs" is unsustainable for the healthcare system, and "an increasingly strident group of physicians, legislatures and pharmacy benefit managers" question whether the cost of drugs is reasonable. (Kessel, 2014, p. 983-990).

Discussion Questions

1. **Identify the major stakeholders who are directly and indirectly affected by Martin Shkreli's sudden and dramatic price increase for Daraprim and briefly describe how they are affected by the price increase.**

Sudden and dramatic price increases for Daraprim and other specialty drugs has an adverse and direct effect on almost everyone in the pharmaceutical supply chain. Patients are charged higher drug prices and co-pays. Health plans must absorb higher drug prices. Physicians must search for more reasonably priced alternatives and deal with anxious patients. Like physicians, pharmacies dispensing the drugs also must search for alternative medications; unlike physicians, pharmacies have to pay higher prices to acquire the drugs and receive inadequate reimbursements at lower prescribed rates. That means pharmacies will also have to renegotiate their reimbursement agreements or pass the cost to patients. Pharmacy Benefit Managers and consultants hired to forecast pricing trends face increased difficulty to do so

correctly. Pharmaceutical manufacturers face greater scrutiny from the government which demands they justify their prices. Perhaps the only stakeholder affected directly and beneficially is Turing Pharmaceuticals, whose revenues are substantially increased by the higher prices.

Stakeholders indirectly affected include Turing Pharmaceuticals' employees, creditors and investors. The augmented profits earned from the drug price increases lead to larger bonuses for the employees, greater security for the creditors, and enhanced value of the shareholders' investment in Turing Pharmaceuticals.

2. Martin Shkreli justified his Daraprim price increase as a necessary step to keep Turing Pharmaceuticals in business and to meet his shareholders' expectations that he "maximize profits." Please explain how that justification fits into the framework of corporate social responsibility.

As indicated in the case, advocates of corporate social responsibility (CSR) recognize that business organizations should balance profit making activities with activities that benefit society. Doing so develops positive relationships with stakeholders, enhances the perceived value of the company's performance, boosts the company's reputation, and improves society. Shkreli's justification of the Daraprim price increase was to maximize profits for the shareholders. While he concedes he underestimated the ensuing "blowback," he said "of course" he would raise Daraprim's price again, noting the price increase "has stuck" and generated increased revenue (Hopkins, 2016).

At first blush, Shkreli's defense of the drug price increase appears to be significantly out of step with the prevailing view of CSR. Upon closer examination, however, Shkreli's justification may fall within Garriga and Mele's first group of CSR theories, under which (1) corporations are supposed to maximize wealth creation, (2) social activities or considerations are irrelevant unless they are consistent with wealth creation, and (3) stakeholder interests are considered only if doing so maximizes shareholder value. (Garriga & Mele, 2004). Perhaps Shkreli is a CSR advocate after all.

Sadly, Shkreli seems to have overlooked the precept that engaging in CSR is acceptable in order to maximize profits. By moderating the price of Daraprim, Shkreli might have been able to sustain even greater wealth accumulation over a longer period of time and to discourage generic pharmaceutical companies from entering the arena through legitimate means. Unfortunately, Shkreli also appears to have overlooked the nuances of groups 2-4. He ignored the need to protect the social power of Turing Pharmaceuticals. He neglected to recognize and fulfill the social contract obligations of Turing Pharmaceuticals. He failed to incorporate basic, normative ethical principles into his governance model. He certainly illustrates the shortcomings of the first group of social responsibility theories.

Indeed, research findings indicate clearly: (1) that pharmaceutical company engagement in CSR can add value to pharmaceutical company's performance regardless of the company's

size; (2) that pharmaceutical company management should regard CSR as an investment which can reap benefits for the company over time; and (3) pharmaceutical companies should promote their social, economic and environmental contributions in their discussions with stakeholders (Min, Desmoulins-Lebeault, & Esposito, 2017).

(3) Do the activities of Turing Pharmaceuticals in suddenly and dramatically raising the price of Daraprim constitute the antithesis of marketing and corporate social responsibility?

The activities of Turing Pharmaceuticals highlight the absence of a fully adopted marketing concept in the pharmaceutical industry. When there is no competition or where demand exceeds supply, firms have the tendency to price at the maximum that the market will allow. Essentially, when monopolies or oligopolies exist the marketing concept slips out the door. Indeed, it is an "anti-marketing" concept when shareholder wealth is increased at the expense of satisfying customer needs. In a firm adopting the marketing concept, the satisfaction of consumer needs is the means to achieve shareholder wealth. However, that only occurs when there is competition and product supply exceeds consumer demand. As Philosophy Professor Chris MacDonald noted, "the market of life-saving pharmaceuticals is not a 'normal' one, structurally let alone ethically," because the ability to pay is "influenced by regulators, insurance companies, charitable foundations, and so on." Hence, a "given price might be neither good nor bad, ethically speaking." Rather, the pricing system as a whole warrants assessment, because the notion of free markets, which permit sellers to charge what the market will bear, is not easily superimposed on the complex market of selling life-saving drugs" (Philosophers on Drug Prices, 2015).

In the case of life-saving pharmaceuticals, this "pricing strategy" is made worse, because the consumer and the payer tend to be two different parties. If the third-party payer does not demand lower prices, then the drug companies engage in the kind of price gouging carried out by Turing Pharmaceuticals. Pharmaceuticals have embraced promotion and product development, branding, and distribution. But pricing is the area in which they linger behind, often choosing pricing strategies that are ethically questionable. Unless transparency or industry-monitored guidelines are adopted, the response to this behavior has traditionally been government intervention through regulation or forced competition. In short, pricing activities such as those committed by Turing Pharmaceuticals is a pre-curser to industry self-regulation or government intervention.

Notably, however, a more limited pricing question is posed by this case: whether the government should have authority to consider affordability of the niche drugs identified by World Health Organization (WHO) as potential targets for opportunistic companies using the business model of sudden and significant price increases on established, effective, and profitable drugs. These drugs lack therapeutic alternatives, target conditions that contribute to high morbidity and even mortality, are produced by one or few manufacturers, and exist in a market that offers little incentive for new entrants. (Alpern, 2016). By authorizing the FDA to

participate in the negotiation of price increases for these niche drugs, the government can conduct a controlled experiment to measure the actual financial impact on pharmaceutical companies and determine whether affordability can serve as a viable component of drug pricing. Moreover, doing so will protect the most vulnerable patients, including (a) immigrants, refugees, and people of low socioeconomic status who do not have access to insurance or public programs and hence lack access to drugs are used for topical or opportunistic infections; and (2) patients who need pyrimethamine, albendazole and cycloserine, and other anti-infective medications which have also had dramatic price increases, and two drugs, praziquantel, used for schistosomiasis and other parasitic infections, and flucytosine used for cyprotococcal meningitis. Critically, 17 anti-infective medications on WHO's list are produced by three or fewer manufacturers and have no therapeutic equivalents. Seven of those drugs treat tuberculosis, while others treat leprosy, strongyloidiasis, malaria or Chagas' disease. All are likely candidates for significant price increases, which will disproportionately affect vulnerable populations in the United States. (Alpern, 2016).

As noted in the case, two CSR scholars have recently developed a model showing how CSR theories can be classified into four groups: (1) instrumental theories, (2) political theories, (3) integrative theories, and (4) ethical theories (Garriga & Mele, 2004).

The fourth group focuses on the ethical requirements that reinforce the relationship between business and society and employs normative stakeholder theory to determine the right thing to do or how to achieve a good society. Stakeholders are those with a legitimate interest in the corporation's activities, and all stakeholders merit consideration for their own sake, not merely for advancing the interest of the corporation or its shareholders. Corporations are required to be attentive to the needs of the various stakeholders and to balance those needs with the needs of the company's shareholders. Doing so requires corporations to have a normative core of ethical principles, such as Kantian principles, Rawls' principles of justice, universal human rights, sustainable development, and the common good of society (Garriga & Mele, 2004).

Requiring drug manufacturers of medications included on the WHO list to consider affordability and authorizing the government to regulate price increases to insure affordability in establishing the prices for those drugs is certainly consistent with the fourth group. The proposal protects patients desperately needing those drugs and requires drug companies to advance the interests of those patients for their own sake, not merely for advancing the interest of the pharmaceutical companies. By focusing on patients needing WHO listed drugs as a vulnerable stakeholder and balancing their needs with the needs of the pharmaceutical companies' shareholders, the normative ethical principles, such as those utilized in fifth discussion question will effectively become pharmaceutical companies' core ethical principles. Furthermore, research demonstrates that corporate social responsibility adds value to corporate financial performance and should be viewed as a long-term investment and that corporate social responsibility programs should be implemented regardless of company size, because investing in stakeholder management creates positive relationships which improve reputation and profitability (Min, 2017).

4. The case study notes that neither the FDA nor the FTC, the two federal regulatory bodies most closely connected to the pharmaceutical industry, has authority to regulate the prices pharmaceuticals charge for their drugs. Do you recommend that such authority be given to either the FDA or the FTC? Explain briefly. Alternatively, do you recommend that the Federal government should have authority to consider affordability of the niche drugs identified by WHO?

A variety of arguments and solutions have been advanced both in support and in opposition to the imposition of price controls on drugs. Jared Bernstein, a senior fellow at the Center on Budget and Policy Priorities, argues that in health economics the pursuit of profits is at odds with maximizing social benefits, because economic incentives compel drug companies to pursue drugs that generate the most profits rather than the drugs patients need the most. To solve this problem, Bernstein argues, an expanded National Institutes of Health should undertake pharmaceutical research or subsidize private research so that the ensuing patents are public goods in the public domain and price gouging is eliminated. Windfall rewards can be awarded to scientists who develop the most beneficial medicines in order to insure the incentive to innovate is not stifled (Bernstein, 2016).

Darius Lakdawalla, the Quintiles Professor of p\Pharmaceutical Development and regulatory innovation in the School of Pharmacy at the University of Southern California, argues that imposing price controls on drugs will stifle the introduction of new drugs, because the financial incentive to develop new drugs is diminished. Lakdawalla claims that, if the U.S. Government starts to negotiate prices like other governments do, drug prices will fall 20%, but innovation will fall even more, depriving patients of life saving medications and increasing premature mortality. In short, he says, pushing down drug prices will save little and cost dearly (Lakdawalla, 2015)

Neera Tanden, the president of the Center for American Progress, and Maura Calsyn, its director of health policy, argue that, in order to reduce drug prices, the government should require drug companies either to reinvest a minimum percentage of revenues in research and development or contribute the shortfall to the National Institutes of Health. Doing so will remove the incentive for drug companies to enhance their revenues by charging excessive prices for drugs, particularly those, like Daraprim, which have been on the market for decades (Tanden & Calsyn, 2015).

Paul Howard, a senior fellow and director of health policy at the Manhattan Institute, cites two studies in support of his argument that imposing price controls on drugs will dampen innovation and hurt patients. He advocates private negotiation – such as that undertaken in the Medicare Part D drug program - as a more effective tool in obtaining lower drug prices (Howard, 2015)

Dean Baker, an economist and the co-director of the Center for Economic and Policy Research, argues that giving drug companies patents on drugs that are essential to individuals' health or lives causes people to pay roughly twice as much for drugs than people in other wealthy countries pay. This does not result in better care, he claims; rather, it merely forces people to pay more for the same drugs. He likens this system to firefighters negotiating their pay for extinguishing a fire in a home with family members inside: it produces much worse fire service and many more wealthy firefighters. He recommends ending patent protection for drug companies and doubling or tripling spending on the National Institutes of Health. That solution, he claims, will fund research costs upfront and result in reasonably priced drugs. (Baker, 2016).

Hence it appears that the experts are sharply divided on the issue of imposing price controls on drugs. Those opinions, however, do not address a more limited question posed by this case: whether the government should have authority to consider affordability of the niche drugs identified by WHO as potential targets for opportunistic companies using the business model of sudden and significant price increases on established, effective, and profitable drugs. These drugs lack therapeutic alternatives, target conditions that contribute to high morbidity and even mortality, are produced by one or few manufacturers, and exist in a market that offers little incentive for new entrants. (Alpern, 2016). By authorizing the FDA to participate in the negotiation of pricing for these niche drugs, the government can conduct a controlled experiment to measure the actual financial impact on pharmaceutical companies and determine affordability is a viable component of drug pricing.

5. Determine whether the practice of pharmaceutical companies to seize control of specialty drugs and then dramatically increase their prices is ethical or unethical under the following ethical theories: Act Utilitarianism, Rule Utilitarianism, Kant's Rights Theory and Rawls' Theory of Justice.

It is not clear whether or not Turing Pharmaceuticals' decision to dramatically increase the price of Daraprim from $13.50 to $750 per tablet passes ethical muster. Shkreli's price increase would deemed unethical under the theory of Act Utilitarianism, if it harms patients, their families and treating physicians, and all of the companies in the drug supply line identified in the response to question (1) above, and those harms clearly outweigh any short-term benefits to Turing Pharmaceuticals and its executives, creditors and shareholders. On the other hand, if the benefits to all those affected by the sudden price increase to Daraprim outweigh the detriments produced by the price increase – for example, by enabling Turing to develop a blockbuster drug to successfully treat cancer or multiple sclerosis – then the price increase for Daraprim may be deemed moral. In short, while drug price increases do not support past R&D efforts, if the price increase enables the drug companies to engage in current and future R&D to develop new and highly effective drug treatments, the price increase may be deemed ethical.

Similarly, permitting pharmaceutical companies to abruptly and significantly raise the price of specialty drugs may or may not be a rule of conduct that produces the greatest amount of good for those affected. If sudden and significant price increases is a rule of conduct that

produces the greatest amount of good for all those affected, then that rule of conduct should be followed and the price increases should be allowed. On the other hand, if sudden and significant price increases is not a rule of conduct that produces the greatest amount of good for all those affected, then Turing Pharmaceuticals' sudden price increase for Daraprim is deemed unethical under Rule Utilitarianism.

Under Kant's first categorical imperative, the universalizability and reversibility principle, permitting pharmaceutical companies to abruptly and significantly raise the price of specialty drugs does not appear to be an acceptable universal practice to the players in the pharmaceutical industry. Pharmaceutical companies with expiring patents may approve of the practice, but generic pharmaceutical manufacturers likely do not. Further, Turing Pharmaceutical executives and members of their families would likely disagree with other drug companies' engaging in price gauging by foisting sudden and substantial drug price increases on drugs they need.

Similarly, by raising the price of Daraprim suddenly and significantly, Turing Pharmaceuticals likely flunks Kant's second categorical imperative, the means only test. Turing Pharmaceuticals coercively treats patients as a means only, because they desperately need the medication to treat life threatening illnesses and are forced to pay the increased price for Daraprim. Likewise, Shkreli lied about the need for the price increase. Shkreli claimed Turing Pharmaceuticals needed the profits to fund research into an alternative drug to treat toxoplasmosis, but the company lacked any formal study protocol to research the toxoplasmosis therapy. Deception, like coercion, violates the means only principle.

Shkreli's engagement in price gauging and deception likely violates Rawls' Equal Liberty and Difference principles, because he denies patients a fundamental right to life saving medication and disrupts the distribution of benefits to patients with significant needs. On the other hand, if the price increases support the development of blockbuster drugs to cure cancer of multiple sclerosis, successfully bringing those drugs to market may maximize the rights of other patients to life saving medication.

Under Rawls' veil of ignorance theory, not knowing what position the participants and affected parties may occupy when the veil is removed, permitting pharmaceutical manufacturers to have unfettered power to suddenly and significantly raise prices on specialty drugs does not appear to be an acceptable practice, unless the price increase leads to the development and availability of successful and blockbuster drugs to treat and cure more significant medical problems. In short, the strategy of suddenly and significantly raising prices on specialty drugs by pharmaceutical companies certainly does not appear to be ethical under Kant's categorical imperatives but may be deemed to be ethical under Rawls' Equal Liberty and Veil of Ignorance principles.

6. The case study demonstrates that the PhRMA code of conduct fails to address the practice of seizing control and raising prices of specialty drugs. Please explain

whether or not you think the PhRMA code of conduct should be amended to address this issue.

While individual pharmaceutical companies can certainly address the issue of affordability of drugs in their mission/purpose/values statements (although almost all do not), it is less clear that addressing the issue in professional codes of conduct or ethical codes will actually diminish the practice of sudden and significant price increases of specialty drugs. While ethics codes have sometimes been effective in guiding and shaping the conduct of professionals in organizations, both in the public and private sectors, "the public is most familiar with corporate ethics failures: Enron, Boeing, and WorldCom in the U.S. [and] Parmalat and Global Crossing in Europe (Gilman, 2005, p. 34)." PhRMA's code of conduct fails to address either the affordability of drugs or the practice of seizing control and raising prices of specialty drugs, because PhRMA's central mission is to represent the leading research-based pharmaceutical companies, some of whom engage in the practice. Indeed, rather than addressing either issue, PhRMA recommends that the FDA should reduce the backlog of ANDAs by improving efficiency of the review process and providing financial incentives to encourage the development of generic drugs. This approach appears to be consistent with its mission of conducting effective advocacy for pharmaceutical and biotechnology research companies.

Conclusion

This case study addresses a highly profitable practice in the pharmaceutical industry: gaining ownership of an older, off-patent drug, which effectively treats a disease affecting a relatively small but stable group of patients, tightly controlling the drug's distribution and thereby making it difficult for competitors to gain FDA approval of generic equivalents, and dramatically increasing the drug's price. While this practice is legal and escapes FDA and FTC regulatory authority, the case provides an excellent opportunity for students to apply key ethical principles – act and rule utilitarianism, Kant's categorical imperatives, and Rawls' equal liberty, difference and veil of ignorance principles – to form an independent judgment about the morality of the practice.

Significantly, PhRMA, which represents the leading research-based pharmaceutical companies in the United States, has addressed the issue of generic drug approval, recognizes it constitutes an important public health risk, and recommends reforms to improve the approval process. Notably, however, while the professional code of the pharmaceutical industry – the APEC Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector – addresses seventeen areas in which it seeks to ensure ethical practices, it fails to address the issue of drug affordability. Nor do the mission/purpose/value statements of all but two of the world's largest pharmaceutical manufacturers. Indeed, given the legal actions instituted against those two companies by the FTC and states attorney generals, their commitment to drug affordability is questionable. Hence, the pharmaceutical industry is left with a significant challenge: reforming the problem of specialty drug pricing and controlled distribution through its professional codes of conduct by enhancing the level of cooperation among adopters, their sense of urgency, and their willingness to comply with the codes.

It is imperative that pharmaceutical companies resolve the crucial issue of affordability if only to restore the confidence of patient groups in the pharmaceutical industry and its reputation and thereby avoid governmental intervention. Drug companies are already under significant pressure to add greater transparency to its drug pricing practices (Pollack, 2015), and House Democrats recently announced a sweeping investigation of the pharmaceutical industry's pricing practices for brand-name drugs to treat diseases including cancer, diabetes, kidney failure and nerve pain (A.P., 2019).

The business model of suddenly and dramatically increasing prices of well established and effective drugs may form an appropriate vehicle to empower the federal government to address affordability. These drugs have already been developed and have been proven effective. They have a substantial though not a blockbuster market, and are profitable. Further, these niche drugs have been identified on the WHO Model List of Essential Medicines, are finite, lack therapeutic alternatives, target conditions that contribute to high morbidity and even mortality, are produced by one or few manufacturers, and exist in a market that offers little incentive for new entrants. In short, these drugs can be targeted to implement the WHO recommendation that they "be available within the context of functioning health systems at all times in adequate amounts . . . and at a price the individual and the community can afford." (Alpern, 2016). By authorizing the FDA to participate in the negotiation of price increases for these niche drugs, the government can conduct a controlled experiment to measure the actual financial impact on pharmaceutical companies and determine affordability is a viable component of drug pricing.

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