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# “Pay to Prescribe”: A Case for Strengthened Enforced of the FCPA in the Global Pharmaceutical Industry in 2017 and Beyond

John T. Jessee Jr.  
*University of Richmond*

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# “PAY TO PRESCRIBE”: A CASE FOR STRENGTHENED ENFORCEMENT OF THE FCPA IN THE GLOBAL PHARMACEUTICAL INDUSTRY IN 2017 AND BEYOND

*John “Jack” T. Jesse Jr.\**

## I. INTRODUCTION

Bribery is an unfortunate, albeit ubiquitous feature of the modern global economy. So long as there are government officials willing to accept illicit payment in exchange for favors,<sup>1</sup> there have been corporations willing to make illegal payments in order to gain some kind of advantage over their competitors.<sup>2</sup> Bribery undoubtedly exists the world over, and runs the gamut from the richest nations to the poorest, though developing nations have been among the hardest hit.<sup>3</sup> Bribes are solicited not only in exchange for routine work that otherwise would not require a bribe, such as providing a company with utility services without undue delay, but also to secure other, more seriously unethical advantages such as improperly awarding government procurement contracts.<sup>4</sup>

One industry that has been particularly rife with bribery is the global pharmaceutical industry.<sup>5</sup> While few, if any, economic sectors have avoided becoming entangled with bribery entirely, pharmaceutical companies have frequently been investigated and charged under the Foreign Corrupt Practices Act, the chief anti-bribery legislation in the United States.<sup>6</sup> Pharmaceutical giants such as Avon, Merck, As-

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\* 3rd year student at The University of Richmond School of Law; Manuscripts Editor, RICHMOND JOURNAL OF GLOBAL LAW AND BUSINESS.

<sup>1</sup> Acceptance of bribery is unfortunately common, especially in developing nations where government workers are often woefully underpaid. See Michael Johnston, *Poverty and Corruption*, FORBES (Jan. 22, 2009), [http://www.forbes.com/2009/01/22/corruption-poverty-development-biz-corruption09-cx\\_mj\\_0122johnston.html](http://www.forbes.com/2009/01/22/corruption-poverty-development-biz-corruption09-cx_mj_0122johnston.html).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> Jonathan Webb, *Why Pharma Faces So Many Corruption Allegations*, FORBES (Feb. 23, 2016), <http://www.forbes.com/sites/jwebb/2016/02/23/why-pharma-faces-so-many-corruption-allegations/#2db503601bd3>; See also Jillian Claire Kohler et al., *Corruption in the pharmaceutical sector: Diagnosing the challenges*, TRANSPARENCY INTERNATIONAL (2016), <http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/> (noting that “pharmaceuticals stands out as a sub-sector that is particularly prone to corruption”).

<sup>6</sup> 15 U.S.C. § 78dd-1, et seq. [hereinafter “FCPA”].

traZeneca, Pfizer-Wyeth, Bristol-Meyers-Squibb, Eli Lilly, and myriad others were all known to be under investigation by the DOJ for potential violations of the FCPA in 2012 alone.<sup>7</sup> Further, as of 2014, two of the top ten highest FPCA disgorgement<sup>8</sup> payments of all time belong to pharmaceutical giants Avon and Pfizer.<sup>9</sup> Such extensive investigation and enforcement activity seems to indicate that U.S. anti-bribery agencies feel that corruption is a very serious issue within the drug industry, and that they are willing to commit significant resources to prosecuting “Big Pharma.”

Several unique features of the pharmaceutical business are believed to create much of the industry’s FCPA-related trouble. Firstly, participating in the global drug industry by nature requires a great deal of contact with foreign officials, perhaps more so than most other industries.<sup>10</sup> Performing many critical pharmaceutical industry functions, for example obtaining government regulatory approval for a new drug, requires frequent and intimate contact with foreign government officials.<sup>11</sup> This frequent, close contact with government officials in turn increases the temptation to bribe, as companies naturally seek to achieve a more efficient and favorable regulatory approval process by “buying off” officials.<sup>12</sup> It is no secret that receiving regulatory approval to sell a drug in a given country is absolutely critical to success in the pharmaceutical industry.<sup>13</sup> Failure to do so can amount to catastrophic losses, as the research and development costs of that drug effectively go to waste if it does not receive regulatory approval for consumption in a given country. Therefore, some pharmaceutical companies have proven that they are willing to do almost anything to gain

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<sup>7</sup> Richard Cassin, *The Corporate Investigations List (June 2012)*, THE FCPA BLOG (Jul. 3, 2012), <http://www.fcpablog.com/blog/2012/7/3/the-corporate-investigations-list-june-2012.html>.

<sup>8</sup> Disgorgement refers to the mandatory re-payment of “ill-gotten gains” that were earned as a result of bribery under the FCPA.

<sup>9</sup> Richard Cassin, *Avon Disgorgement Lands on Top Ten List*, THE FCPA BLOG (Dec. 26, 2014), <http://www.fcpablog.com/blog/2014/12/26/avon-disgorgement-lands-on-top-ten-list.html>.

<sup>10</sup> See Jillian Claire Cohen, *Pharmaceuticals and corruption: a risk assessment*, WORLD BANK, <http://www1.worldbank.org/publicsector/anticorrupt/corecourse2007/Pharmaceuticals.pdf>.

<sup>11</sup> *Id.* at 77-78.

<sup>12</sup> *Id.*

<sup>13</sup> Andrew Ceresney, Director, SEC Div. of Enforcement, Remarks at CBI’s Pharmaceutical Compliance Congress in Washington D.C., (March 3, 2015) (transcript available at <http://www.sec.gov/news/speech/2015-spch030315ajc.html#VPX7KkaSJxU>).

regulatory approval, and bribery is often the vehicle used to achieve that end.<sup>14</sup>

Secondly, many nations other than the United States utilize a public, nationalized healthcare system in which the government itself is the chief provider of healthcare to its citizens. In this kind of healthcare system, doctors also double as public officials, as they are government employees that also often wield considerable influence over the general direction of the nation's medical treatment, notably including broad discretion over drug prescription policies.<sup>15</sup> This means that the FCPA anti-bribery provisions also govern corporate relationships with doctors in a nationalized health system, as the FCPA's text broadly covers dealings with any "foreign official."<sup>16</sup>

Such nationalized healthcare systems create even more opportunity for bribery to rear its ugly head. Doctors in a nationalized healthcare system generally maintain wide discretion in deciding which drugs to prescribe, meaning that drug companies can bribe public doctors to prescribe their brand of drugs more often than necessary, or prescribe them instead of a competitor's drugs.<sup>17</sup> These "kickback" bribery payments to doctors, also known as "pay-to-prescribe" bribes, are a very common source of corruption in the industry. These "pay to prescribe" bribes are perhaps more insidious than bribes aimed at cheating regulatory approval, as they often take the form of more discreet, non-monetary gifts, such as luxurious, all-expenses-paid travel under the guise of an "educational opportunity" or "reward programs" for high-prescribing doctors.<sup>18</sup> Further, "pay to prescribe" bribes can often be harder for enforcement agencies to detect, due to their more subtle nature.<sup>19</sup> Because this sort of "pay to prescribe" bribery has become so commonplace in the modern era, it is the chief type of bribery examined in this paper.

Regardless of the specific form the bribery takes or the exact motives behind it, one thing remains clear—the pharmaceutical industry has a very serious problem with bribery, and that problem continues today largely unabated.<sup>20</sup> This is not to suggest however, that the U.S. government has stood idly by while such behavior occurs. Government enforcement agencies have indeed taken steps to curb improper influence over prescribing, and have commenced several high-profile enforcement actions against the industry in recent years. In 2015

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<sup>14</sup> *Id.*

<sup>15</sup> *Id.*; See also Cohen, *supra* note 10.

<sup>16</sup> 15 U.S.C. §78dd-1(A).

<sup>17</sup> See Ceresney, *supra* note 13.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> See generally Kohler, *supra* note 5.

alone, the SEC prosecuted multiple high-level FCPA violations throughout Big Pharma, including judgments against household names like Bristol-Meyers-Squibb.<sup>21</sup> Unfortunately, however, even these enforcement actions have not eradicated bribery from the pharmaceutical industry, as corruption offenses continue to occur to this day.<sup>22</sup>

Noting this problem, this paper will use these recent FCPA enforcement actions to argue that a revamped and increased enforcement of the FCPA's anti-bribery provisions in the pharmaceutical industry will be an absolutely critical task in 2017 and beyond, as there is much work to be done in cleaning up the industry. The paper will begin by outlining a brief history of the FCPA and examining its basic enforcement provisions. It will then examine the nature of the pharmaceutical industry's bribery through a detailed analysis of several recent high profile enforcement cases within the industry. Lastly, the paper will propose several policy prescriptions as to what changes might be made to the current FCPA enforcement regime in order to continue eradicating bribery within Big Pharma.

## II. A BRIEF HISTORY OF THE FCPA AND ITS ENFORCEMENT

The Foreign Corrupt Practices Act of 1977 ("FCPA"), though now enforced the world over, was initially enacted as a mostly symbolic piece of legislation.<sup>23</sup> The law was in large part passed to show that the U.S. Government was responding appropriately to the high-profile corruption incidents of the era, namely President Nixon's Watergate Scandal.<sup>24</sup> The SEC and other government agencies were concerned not just with the infamous Watergate Hotel break-in, but also the discovery of numerous illegal political contributions that Nixon was found to have received in the aftermath of his impeachment and resignation.<sup>25</sup> Discovery of these suspicious payments to Nixon led to further investigation, and SEC officials soon uncovered that many corporations were using extensive webs of secret bank accounts for il-

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<sup>21</sup> See Bristol-Myers Squibb Co., Exchange Act Release No. 76073, SEC File No. 3-16881 (Oct. 5, 2015), <https://www.sec.gov/litigation/admin/2015/34-76073.pdf>; See also Richard Cassin, *Bristol-Meyers-Squibb Pays \$14 Million to Resolve China FCPA Offenses*, THE FCPA BLOG (Oct. 5, 2015), <http://www.fcpablog.com/blog/2015/10/5/bristol-myers-squibb-pays-14-million-to-resolve-china-fcpa-o.html>.

<sup>22</sup> See Johnston, *supra* note 1 (discussing the 2016 anti-bribery raid on Novartis' South Korea Operations, and noting that, "This is a structural problem within the industry. . . Corruption will persist. . .")

<sup>23</sup> Michael B. Bixby, *The Lion Awakens: The Foreign Corrupt Practices Act 1977-2010*, 12 SAN DIEGO INT'L L.J. 89, 90 (2010).

<sup>24</sup> *Id.* at 92.

<sup>25</sup> *Id.* at 93.

licit purposes.<sup>26</sup> Further, investigators soon found that these same invisible corporate accounts that were used to curry favor with the Nixon administration were also used to make extensive bribes abroad, as the trail of illicit payments could be linked to many foreign officials as well.<sup>27</sup> Recognizing this very serious problem of secret “slush funds” and extensive use of hard-to-trace bribery payments, Congress passed the FCPA.<sup>28</sup> The FCPA set out to ban giving anything of value (or even promising to give something of value) to a foreign official in exchange for influence, inducement, or improper advantage.<sup>29</sup> The FCPA’s language was groundbreaking in that it not only prohibited this kind of bribery as it pertained to U.S. officials, but rather sought to ban bribery anywhere in the world, by intentionally utilizing the term “foreign official” to criminalize bribery regardless of the locale.<sup>30</sup>

However, though the FCPA featured very strong and idealistic language, the law laid mostly dormant for over two decades. The government only brought a handful of minor enforcement cases before 1998, a year in which the law saw several key amendments that increased its scope.<sup>31</sup> The reasons behind the curious lack of initial enforcement of the FCPA are complex, but in general stem from the law’s initially symbolic intent—the act was likely passed to allow the government to show that it was “tough” on bribery and appease the post-Watergate public outcry for reform without requiring the government to commit the immense resources required to properly enforce the act.<sup>32</sup> Further, the United States was for quite some time the only nation with a global anti-bribery ban on its books, and so U.S. companies complained that actually enforcing the law was “bad business” and would place them at a distinct competitive disadvantage relative to foreign competitors.<sup>33</sup> Apparently heeding this concern, the U.S. Government appeared to “look the other way” regarding foreign corporate corruption for many years.<sup>34</sup>

The FCPA’s period of dormancy, however, met an abrupt end in the early 2000’s, when the U.S. government began to enforce the act with great vigor and severity.<sup>35</sup> Emboldened by a new global anti-bribery norm (which arose after other nations began to acknowledge the economic havoc that bribery was causing in their countries), the

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<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> 15 U.S.C. §78dd-1(a).

<sup>30</sup> *Id.*

<sup>31</sup> Bixby, *supra* note 23, at 103.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 98.

<sup>34</sup> *Id.* at 99-102.

<sup>35</sup> *Id.* at 104.

strengthened financial transparency norms of the Sarbanes-Oxley era, and also newfound concerns that bribery slush funds could be used to finance global terrorism, U.S. enforcement agencies began to aggressively prosecute FCPA violations at a rate that would have been unimaginable only a few years prior.<sup>36</sup> This exponential increase in prosecution has continued to the present day, bringing us to the modern era of FCPA enforcement, where most companies now actively fear potential FCPA prosecution and take great pains to implement effective anti-bribery compliance systems.<sup>37</sup> Overall, the FCPA in the modern era is one of the U.S. government's chief tools in combating white collar and corporate crime, and wields a formidable anti-bribery enforcement scheme.

Interestingly, however, even the new, more fearsome era of FCPA enforcement features a fairly glaring loophole—the “grease payments” exception.<sup>38</sup> While making a gift to a foreign official to secure favors is of course banned by the FCPA, making that same gift to “expedite a routine government action,” (i.e. a “facilitating payment” or “grease payment”) is actually allowed under the current prevailing interpretation of the law.<sup>39</sup> This means that an otherwise illegal bribe paid to ensure that, for example, a foreign government keeps a company's utilities operating as normal or provides the usual police protection during periods of domestic unrest, is perfectly legal under the FCPA because such activities are “routine.”<sup>40</sup> The problem with such a loophole, of course, is that it inherently blurs the contours between a “facilitating payment” and an illegal bribe. To date, the exact boundaries of that line are still unclear, and so the current landscape of FCPA enforcement is somewhat muddled—while companies certainly fear FCPA repercussions and most actively seek to ensure compliance, the relatively ambiguous text of the law and the current “grease payment loophole” make perfect compliance very difficult.<sup>41</sup>

This ambiguity in large part contributes to the problem today—despite FCPA enforcement, bribery is still an ongoing issue, especially in the pharmaceutical industry. Therefore, subsequent sections of this paper will examine this extensive bribery within the pharmaceutical industry using several recent, high profile settlements as a case study.

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<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 109.

<sup>38</sup> 15 U.S.C. §78dd-1(a); Rebecca Koch, *The Foreign Corrupt Practices Act: It's Time to Cut Back the Grease and Add Some Guidance*, 28 B.C. INT'L & COMP. L. REV. 379, 380 (2005).

<sup>39</sup> See Koch, *supra* note 38, at 380-81.

<sup>40</sup> *Id.* at 385-86.

<sup>41</sup> *Id.* at 89.

### III. BRIBERY IN BIG PHARMA AND THE FCPA

It is well established that bribery has long been a serious issue plaguing the pharmaceutical industry, and in recent years, it appears that this general maxim has not changed much, if at all.<sup>42</sup> In fact, as recently as October of 2015, Bristol-Meyers-Squibb ran afoul of the FCPA due to the activities of its Chinese subsidiaries and was forced to pay fines to the SEC.<sup>43</sup> Therefore, it is clear that though FCPA enforcement has perhaps reached its highest levels ever, much work remains to be done in cleaning up the pharmaceutical industry in particular.<sup>44</sup> This section of the paper will examine three recent high-profile pharmaceutical enforcement actions that have occurred between 2012 and 2015—the actions brought against Pfizer-Wyeth, Eli Lilly, and Bristol-Meyers-Squibb. These cases were chosen to illustrate several unique bribery issues inherent in the modern Big Pharma landscape—a landscape that hinges on utilizing a mixture of secrecy, clever accounting tricks, and legal loopholes to maintain illegal bribery practices. Further, each case provides an excellent insight into the workings of the ubiquitous “pay to prescribe” bribery scheme, which is seemingly the bribery method of choice in modern Big Pharma.<sup>45</sup>

#### A. *FCPA Enforcement Action Against Pfizer-Wyeth*

Beginning chronologically with the earliest case of the trio—the FCPA enforcement action against Pfizer-Wyeth (hereafter “Pfizer”), it is immediately clear that all is not well in the world of Big Pharma. Pfizer, one of the largest drug companies in the world, was found to have bribed doctors and other health officials in over half a dozen countries, spanning much of the old Soviet Bloc (Bulgaria, Croatia, the Czech Republic, Kazakhstan, Russia, and Serbia), as well as Italy.<sup>46</sup> For its crimes, Pfizer paid a \$60M civil settlement to the SEC, \$15M in criminal penalties to the DOJ, and disgorged over \$44M in illegally earned profits.<sup>47</sup>

The Pfizer case hinged on the company’s fairly egregious use of a “pay to prescribe” scheme, in which the Pharma giant provided both direct and indirect payments to doctors around the globe in exchange

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<sup>42</sup> See Webb, *supra* note 5.

<sup>43</sup> See Cassin, *supra* note 21.

<sup>44</sup> See Bixby, *supra* note 23, at 104-16.

<sup>45</sup> See Ceresney, *supra* note 13.

<sup>46</sup> See Pfizer Inc., Wyeth LLC, SEC Accounting & Auditing Enforcement Release No. 3399, <https://www.sec.gov/litigation/litreleases/2012/lr22438.htm> (Aug. 7, 2012).

<sup>47</sup> *Id.*

for prescribing or otherwise promoting Pfizer products.<sup>48</sup> Further, these payments were disguised using a system of false accounting, which buried the illegal payments within the company's books by disguising them as benign expenses like travel, promotional activities, and marketing.<sup>49</sup> This is an excellent example of the common "pay to prescribe" scheme, and shows the complex financial arrangements that are often used to conceal funds used for bribery.<sup>50</sup> Admittedly, the use of secret bribery "slush funds" is nothing new, and is in fact quite similar to the practices that gave rise to the initial passage of the FCPA.<sup>51</sup> But, in the new post-Sarbanes-Oxley accounting world that features much stricter reporting and transparency requirements, the exact methods of bribery appear to have adapted to become much more sophisticated and subtle. The methods used by Pfizer and others seems to indicate that due to the newly increased financial transparency requirements of the 21st century, corporations have learned to bury bribery funds even more deeply within their sprawling financial statements in order to avoid detection. This trend is worrisome, as it indicates that rather than genuinely seeking to comply with the FCPA's anti-bribery provisions, many actors in the pharmaceutical industry are instead finding increasingly clever workarounds to stay one step ahead of regulators.

### B. FCPA Enforcement Action Against Eli-Lilly

The second major enforcement action examined by this paper is the FCPA action against another U.S.-based Pharma giant, Eli Lilly, which was found to have violated FCPA provisions in Russia, Brazil, China, and Poland, for a period of over fifteen years.<sup>52</sup> For its crimes, Eli Lilly paid a \$29M settlement to the SEC.<sup>53</sup> The Lilly case is particularly illuminating and pertinent to this study, as it featured a perhaps even more shocking example of "pay to prescribe" bribery spanning nearly the entire globe.<sup>54</sup> In Russia, for example, Lilly's subsidiary paid millions of dollars into a suspicious "marketing agree-

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<sup>48</sup> Richard L. Cassin, *Pfizer, Wyeth Pay \$60M in Settlement*, FCPA BLOG (Aug. 7, 2012), <http://www.fcpablog.com/blog/2012/8/7/pfizer-wyeth-pay-60-million-in-settlement.html>.

<sup>49</sup> *Id.*

<sup>50</sup> See Ceresney, *supra* note 13.

<sup>51</sup> See generally Bixby, *supra* note 23.

<sup>52</sup> See Eli Lilly & Co., SEC Lit. Release No. 22576, <https://www.sec.gov/litigation/litreleases/2012/lr22576.htm> (Dec. 20, 2012); See also Richard Cassin, *Eli Lilly Pays \$29 Million in SEC Settlement*, THE FCPA BLOG (DEC. 20, 2012), <http://www.fcpablog.com/blog/2012/12/20/eli-lilly-pays-29-million-in-sec-settlement.html>.

<sup>53</sup> Eli Lilly & Co., SEC Lit. Release, *supra* note 51.

<sup>54</sup> *Id.*

ment” account, which in a nutshell paid money to those loyal to promoting Lilly’s products.<sup>55</sup> Further, in China, Lilly’s subsidiary used a slightly different “pay to prescribe” scheme, this time making direct gifts to doctors in the form of spa treatments, jewelry, and other impermissible benefits.<sup>56</sup> Though the gifts themselves were somewhat more brazen and obvious, Lilly again took great pains to hide the illicit payments within its books.<sup>57</sup> In Brazil and Poland, payments were made to get Eli Lilly drugs on government-approved prescription reimbursement lists, which would have significantly increased its market share by allowing more government-insured patients to acquire their drugs.<sup>58</sup>

Lilly’s actions are again highly suggestive of a serious problem. Because of the public healthcare systems in nearly all of the countries where it committed FCPA violations, Lilly knew that it could influence the public doctors to prescribe its drugs using various gifts and payments, and did so flagrantly for the better part of two decades. Taken as a whole, the Lilly case shows the lengths to which Pharma giants are willing to go in order to ensure that their products survive stiff competition in public health systems. The Lilly incident further indicates that the current system is structured in such a way that making bribery payments can be so lucrative and beneficial to Pharma companies that they are willing to risk monetary loss, damage to their reputation, or even more serious criminal penalties because the rewards outweigh the perceived risks.

### *C. FCPA Enforcement Action Against Bristol-Meyers-Squibb*

The final case examined in this paper is the FCPA enforcement action levied against Bristol-Meyers-Squibb (hereafter “BMS”) for violations that occurred within its Chinese subsidiary from 2009-2014.<sup>59</sup> For its violations, BMS was assessed around \$14M in total penalties by the SEC.<sup>60</sup> Here, BMS’s violation was quite similar to those committed by Eli Lilly and Pfizer—the company allowed its Chinese subsidiary to dispense cash payments, lavish gifts, travel, entertainment, and other improper gifts to Chinese doctors in exchange for prescription referrals.<sup>61</sup>

The parallels to the Lilly and Pfizer cases do not end there—BMS was also found to have used a great deal of financial trickery,

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<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> See Bristol-Myers Squibb Co. SEC Lit. Release, *supra* note 21.

<sup>60</sup> *Id.*; See also Cassin, *supra* note 21.

<sup>61</sup> *Id.*

including faking invoices, receipts, and purchase orders to disguise the illegally dispensed funds.<sup>62</sup> This is yet another excellent example of the sophisticated and subtle tactics that define modern pharmaceutical bribery. It seems that the days when a person might brazenly approach an official with a suitcase full of cash are over. Unfortunately, the same process is still being carried out in other ways. Now, a would-be briber must use sophisticated accounting techniques, extensive secrecy, and a great deal of discretion in bribing. Thus, the *modus operandi* has changed, but the root of the problem is the same.

Taken collectively, these case studies reveal that there remains a very strong incentive to bribe within the pharmaceutical industry, even in the face of potentially serious consequences. Though BMS, for example, saw two of its competitors punished under the FCPA for nearly identical practices in the two years prior to its own prosecution, it did not act to clean up its own transgressions, and instead wound up facing an FCPA enforcement action of its own.<sup>63</sup> It is therefore quite puzzling that pharmaceutical companies appear to be engaging in the much the same behavior as before, apparently in complete disregard of the punishments levied upon their competitors for committing the exact same offenses.

Though there are many possible inferences one might draw from this somewhat bleak state of affairs, one reasonable conclusion is that international bribery remains an ongoing and severe issue within the pharmaceutical industry, and that it will continue unless significant changes are made. Thus, this paper will proceed by arguing that reforms must be made to the current anti-bribery legal structure in order to rectify this situation.

#### IV. THE CASE FOR REVAMPED AND STRENGTHENED FCPA ENFORCEMENT IN BIG PHARMA: PRESCRIPTIONS FOR 2017 AND BEYOND

Even a cursory glance at the case studies discussed in Section III reveals that bribery remains a very serious, ongoing issue within Big Pharma. The fact that three of the world's leading drug-makers, whose names are so ubiquitous as to be featured in medicine cabinets around the world, were prosecuted for violations in the past four years alone is a very troubling statistic. The obvious conundrum is thus how the U.S. enforcement agencies ought to respond. This section will make several prescriptions as to how a more robust FCPA enforcement regime should proceed against pharmaceutical corporations.

I will begin with a brief overview of the penalties and remedies available under the current FCPA regime. The main remedy available to government enforcement agents under the FCPA is to impose mone-

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<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

tary fines on violators, including a disgorgement of any profits that were illegally earned as a result of the bribery.<sup>64</sup> In assessing such fines, the SEC and DOJ give great weight to the company's degree of cooperation, and the enforcement agencies give significant "cooperation credit" for genuine, fulsome, and pre-emptive cooperation by the corporation.

In determining an appropriate dollar value for such fines, it appears that government agencies generally defer to the U.S. sentencing guidelines, which prescribe a broad range of permissible fines based on a number of factors.<sup>65</sup> Issues taken into consideration include the number of employees in the organization; whether high-level personnel were involved in or condoned the conduct; prior criminal history; whether the organization had a pre-existing compliance and ethics program; voluntary disclosure; cooperation; and acceptance of responsibility.<sup>66</sup>

Imprisonment for a period of up to 5 years is also possible in cases where the FCPA violation can be readily attributed to an individual actor.<sup>67</sup> The current enforcement regime thus chiefly consists of levying monetary fines, buttressed by a system of self-reporting and corporate cooperation, as well as imprisonment for individual offenders. Further, it appears that the current regime offers enforcement agencies rather wide discretion in determining appropriate penalties, as the system is characterized by a system of broad guidelines rather than specific prescriptions.

I argue that this basic array of penalties under the FCPA is largely sound, but I propose two incremental policy changes that Congress, the SEC, and the DOJ might implement in a "perfect world." Factors such as political gridlock, lobbying efforts on behalf of the pharmaceutical industry, and other real-world constraints such as budget and manpower shortages might prevent these changes from being perfectly implemented as described. The purpose, therefore, is to simply inject potentially promising ideas into the public debate over how the U.S. might improve its anti-bribery regime in 2017 and beyond. With this disclaimer in mind, I argue that Congress, as well as the SEC and the DOJ, should make two fairly modest changes to the

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<sup>64</sup> 15 U.S.C. §78ff (2002).

<sup>65</sup> THE FCPA PROFESSOR, HOW ARE FCPA FINES, PENALTIES, AND SENTENCES CALCULATED?, <http://fcpaprofessor.com/fcpa-101>.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*; While imprisonment is an effective deterrent as to individual conduct, this paper focuses chiefly on policy at the firm level. For more on individual criminal sentencing under the FCPA, see generally Warin & Speice, *Go Directly to Jail: Sentencing of Individual Criminal Defendants in Foreign Corrupt Practices Act Cases*, 1 BLOOMBERG LAW REPORTS: RISK & COMPLIANCE No. 6, <http://www.gibsondunn.com/publications/Documents/Warin-FCPAByline.pdf>.

FCPA and its enforcement protocol that will provide a significant boost to their efforts in the war against bribery in Big Pharma.

Firstly, I posit that the enforcement agencies ought to substantially increase the dollar-value of fines, disgorgement payments, and other damages that are assessed in FCPA cases involving pharmaceutical companies. Second, I argue that Congress should amend the FCPA to remove the “grease payment” loophole, as the current law is simply too ambiguous, and thus encourages “borderline” behavior that is still effectively bribery.<sup>68</sup> I further argue that these prescriptions work symbiotically, and in fact their efficacy would likely be enhanced if both were implemented simultaneously.

#### A. *Increase Fines and other Monetary Penalties for Pharmaceutical Companies under the FCPA*

My first policy prescription is that enforcement agencies ought to substantially increase the monetary value of fines, damages, and disgorgement payments that are assessed for FCPA violations in the pharmaceutical industry. Given the wide sentencing discretion that is already afforded to the enforcement agencies,<sup>69</sup> this change could likely be accomplished by merely altering internal regulatory policy, avoiding the more arduous task of amending the FCPA itself. This recommendation is admittedly quite simple, but could nonetheless be very effective in reducing bribery within the industry, as I argue that the current level of fines assessed is simply not sufficient to act as an effective deterrent.<sup>70</sup>

A quick glance at the financial statements of the three companies examined by this paper—Eli Lilly, Pfizer-Wyeth, and Bristol-Meyers-Squibb—reveals that each earns well in excess of \$5B in profits each year, and some earned much more. The giant Pfizer exceeded an eye-popping \$22B in profits in 2013.<sup>71</sup> Yet, for their fairly flagrant

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<sup>68</sup> See Koch, *supra* note 38.

<sup>69</sup> See FCPA Professor, *supra* note 65.

<sup>70</sup> This paper originally argued that enforcement agencies should not only increase the range of monetary penalties under the FCPA, but also proportionately increase the value of *benefits* available to good faith cooperating corporations under the cooperation credit system. While this paper was being edited for publication, the DOJ did indeed implement such an overhaul to the cooperation credit system in a new one-year pilot program. Because this policy has already been enacted, the argument has largely been omitted. See Jonathan R. Barr et al., *DOJ Attempts to Encourage Corporate Self-Disclosures With the Announcement of a One-Year FCPA Pilot Program*, BAKER & HOSTETLER LLP, available at <https://www.bakerlaw.com/alerts/doj-attempts-to-encourage-corporate-self-disclosures-with-the-announcement-of-a-one-year-fcpa-pilot-program>.

<sup>71</sup> Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223>.

FCPA violations, the trio was fined only \$29M, \$60M, and \$19M, respectively.<sup>72</sup> While these settlement figures may appear quite robust to the lay reader, it is apparent that these fines are insufficient when they are weighed against the enormous sums that these pharmaceutical corporations earn in profits each year— in my opinion, a true “drop in the bucket” that does not constitute a genuine threat to their ability to conduct ongoing operations. Thus, I argue that these fines are simply not substantial enough to act as an effective deterrent to bad corporate behavior— it is not hard to imagine an executive “shrugging off” a \$20M fine as merely a “bad day” when the company that they lead earns many times that amount in a given week.

The relatively modest fines assessed under the current system create a dangerous calculus for those within the pharmaceutical industry. Clearly, at least some Big Pharma executives that are engaging in a cost-benefit analysis of whether to commit a potentially illegal act feel that they are better off skirting the FCPA’s rules, or even flagrantly violating them in some cases, as evidenced by the industry’s continuing violations despite the known risks of an enforcement action. Though we obviously cannot know their subjective mindsets for certain, it is not unreasonable to conclude that many pharmaceutical industry actors have simply determined that the potential profits earned by “bribing to the top” of a given market in most cases far exceed the middling fines that the SEC or DOJ might assess, even when considering that all profits earned as a result of the bribery must theoretically be disgorged.

To date, only one fine levied against a pharmaceutical company under the FCPA is featured on the FCPA Blog’s “Top 10” list, which compiles the largest FCPA settlements to date, as of the end of 2016.<sup>73</sup> That statistic is puzzling, given that the level of bribery in the pharmaceutical industry is notoriously high, and that the giant companies within the industry could certainly afford to pay larger fines.<sup>74</sup> Fines similar to the record FCPA damages paid by telecom giants Siemens (\$800M) and Alstom (\$772) or those levied against oil titan Halliburton/KBR (\$579M) seem wholly appropriate for very serious FCPA violations, and given that pharmaceutical companies are in the same financial “ballpark” as those companies that received some of the largest fines ever, it seems necessary to increase fines toward that range.<sup>75</sup>

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<sup>72</sup> See Cassin, *supra* notes 21, 48, 52.

<sup>73</sup> See Richard Cassin, *Teva Announces \$519m Settlement*, FCPA BLOG (Dec. 22 2016), <http://www.fcpablog.com/blog/2016/12/22/teva-announces-519-million-fcpa-settlement.html> (discussing Teva Pharmaceuticals’ \$519M FCPA fine in December 2016, good for the fourth highest penalty on the FCPA Blog’s “top ten” list. Prior to this settlement, however, no pharmaceutical fines had cracked the top 10.)

<sup>74</sup> Anderson, *supra* note 71.

<sup>75</sup> *Id.*

Thus, this first policy prescription essentially acknowledges the obvious—Big Pharmaceutical companies are some of the wealthiest corporations in the world by almost any measure, and in fact boast the highest profit margins of any industry.<sup>76</sup> Therefore, if the SEC and the DOJ are seeking to “scare” the pharmaceutical industry into FCPA compliance, they must substantially increase the potential punishments that they may administer, or “become scarier,” for lack of a better term.

In sum, I argue that the law must quickly adapt to remove any incentives whatsoever to bribe in the pharmaceutical industry. A simple, yet effective step towards that goal is to increase fines and other damages. As it stands, the law is inadvertently tempting pharmaceutical actors to bribe, as the profits that can be realized in doing so often outweigh the relatively modest fines that have been assessed to date. Once the financial calculus of deciding whether to bribe is changed, it follows logically that actors within the pharmaceutical industry will have to think much harder before deciding to violate the FCPA.

#### *B. Close the “Grease Payment” Loophole*

A second, and perhaps more ambitious suggestion, is to close the “grease payment” or “facilitating payment” loophole that is currently plaguing FCPA enforcement.<sup>77</sup> Generally speaking, the “grease payment” loophole refers to a provision of the FCPA that actually permits certain small acts of bribery—i.e., a “facilitating or expediting payment” to a foreign official in order to secure a “routine governmental action.”<sup>78</sup> This exception is technically limited to small payments that are made to ensure delivery of “ordinary” government services, which encompasses granting permits and visas, providing police protection, mail service, prompt inspections, utility services, or any “routine” other services “of a similar nature.”<sup>79</sup> However, I argue that the “grease payment” loophole must be closed because it can poison an executive’s decision-making process and inadvertently incentivize bribery, merely by acknowledging the existence of a permissible category of bribery.

I note that this suggestion has already been the subject of considerable scholarship, and that the subject likely merits a paper or book of its own.<sup>80</sup> Further, many other Western anti-bribery regimes, such as the UK Bribery Act, have already taken steps to remove any “facilitating payment” language from their statutes, and have moved

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<sup>76</sup> *Id.*

<sup>77</sup> 15 U.S.C. §78dd-1(a); *See Koch, supra* note 38.

<sup>78</sup> 15 U.S.C. § 78dd-2(b).

<sup>79</sup> *Id.*

<sup>80</sup> *See generally Koch, supra* note 38.

to categorically ban bribery of any sort.<sup>81</sup> I also note that implementing this suggestion would most likely require Congress to amend the FCPA itself, rather than merely change regulatory directives, admittedly increasing the difficulty of enacting such a policy. Therefore, I will address this suggestion as narrowly as possible, solely as it pertains to alleviating the current bribery issues in the pharmaceutical industry.

The mere existence of a category of “permissible” bribery creates a dangerous and false dichotomy. If bribery of all stripes was made categorically illegal—regardless of whether the favor being solicited is “routine” or not, it stands to reason that most companies would know that they ought to steer clear of the practice entirely. But, the current loophole that legally permits *some* bribes, but not others, naturally encourages actors to push the limits of “permissible” bribery as far as possible. Pharma executives know that if they can somehow construe their actions as being within the safe harbor of a “grease payment,” they are generally safe from FCPA enforcement.<sup>82</sup> Worse, many of the government activities that pharmaceutical industry actors pay bribes in exchange for might readily be construed as “routine”—is a payment made to entice a doctor to prescribe a drug really any different than one made to an official to ensure that a company will be afforded proper police protection? While the answer to the former is less clear, the latter action is in fact explicitly permitted as a “facilitating payment” under the statute. This false distinction opens the door for pharmaceutical executives to assert that their more flagrant bribery is permissible as well, as it could be argued to be “of a similar nature.”<sup>83</sup>

Thus, it is evident that engaging in this sort of line drawing as to which bribes are allowed is inherently problematic. Allowing some kinds of bribes and not others fatally undermines the powerful moral argument that bribery of *any* sort is simply wrong. Permitting some bribes can instead portray bribery as a “sliding scale” of wrongs, with some types of bribery arbitrarily deemed more acceptable than others.<sup>84</sup> Thus, I argue that a categorical ban on all types of bribery, regardless of whether a payment is intended as a “facilitating payment” or not, is absolutely necessary to move towards a bribery-free pharmaceutical industry.

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<sup>81</sup> See Ben Hallman, *Bribery Law Loophole Leads to Confusion and Abuse*, *Lawyers Say*, HUFFINGTON POST (Apr. 26, 2012), [http://www.huffingtonpost.com/2012/04/26/bribery-law-walmart-foreign-corrupt-practices-act-loophole\\_n\\_1450474.html](http://www.huffingtonpost.com/2012/04/26/bribery-law-walmart-foreign-corrupt-practices-act-loophole_n_1450474.html).

<sup>82</sup> *Id.*

<sup>83</sup> 15 U.S.C. § 78dd-2(b).

<sup>84</sup> *Id.*

This recommendation works in conjunction with my proposal to increase monetary fines outlined in subsection “A.” If both proposed changes were put in place simultaneously, the anti-bribery landscape in Big Pharma would look quite a bit different. In such a world, the calculus of deciding whether to bribe will have drastically changed. Executives would appreciate that all bribery is illegal, regardless of its type; that fines for committing this bribery would be so punitive as to be extremely dangerous to their companies’ ongoing viability; and that they could self-report any good-faith violations that do occur or “whistle-blow” without hesitation.<sup>85</sup> In this new world, bribery as a whole would simply appear to be a less appealing option, and so it follows logically that corruption within the pharmaceutical industry would in turn be reduced. Facing a new set of rules, I argue that far fewer pharmaceutical actors would be tempted to bribe, and a degree of normalcy could return to the industry.

## V. CONCLUSION

It is now widely accepted that bribery is a truly damaging practice that has far-reaching negative effects on the modern global economy.<sup>86</sup> Bribery causes market distortions, reduces economic output, and undermines faith in a democratic, capitalist society.<sup>87</sup> Bribery even creates dangerous and occasionally lethal situations: shoddily-built skyscrapers and bridges have collapsed in nations such as Turkey and China after building inspectors were bribed to look the other way and expedite construction.<sup>88</sup> It is therefore critical that the U.S. government implement and enforce as robust an international anti-bribery regime as possible.

Though the FCPA has risen to achieve unprecedented levels of anti-bribery enforcement around the globe, and compliance with the law appears to be increasing on the whole, the pharmaceutical industry seems to be particularly resistant to its reaches, as similar violations occur within the industry year after year.<sup>89</sup> Therefore, it is abundantly clear that some legal reform is required to address bribery in the global pharmaceutical industry in 2017. Delaying action is simply not an option, as maintaining the status quo will only lead to more of the same kinds of unethical behavior.

Though my policy prescriptions as to the direction that FCPA enforcement should take in 2017 are admittedly somewhat lofty, they do not seem to be manifestly unreasonable. In fact, with the proper

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<sup>85</sup> See Barr, *supra* note 70.

<sup>86</sup> See Johnston, *supra* note 1.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> See Cassin *supra* notes 9, 21, 48, 52, 73.

political climate and degree of motivation, each could be implemented without much upheaval. Further, it is not difficult to see the profoundly positive effects such changes might have. By fundamentally altering the calculus that a pharmaceutical company must consider before directing its company to bribe, it is possible to reduce the seemingly insatiable temptation to solicit bribes in order to gain an edge over the competition. In sum, implementing a more robust FCPA enforcement regime will have wide-ranging benefits, chiefly the creation of a more ethical pharmaceutical industry that re-directs its focus to where it ought to be: developing and providing the best possible medications to as many patients as possible.