

# Enforcement of the Foreign Corrupt Practices Act in the Healthcare Industry and Foreign Bribery’s Adverse Consequences for Patients

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## TABLE OF CONTENTS

I.	INTRODUCTION .....	23
II.	BACKGROUND: THE FOREIGN CORRUPT PRACTICES ACT .....	25
III.	ENFORCEMENT OF THE FCPA IN THE HEALTHCARE INDUSTRY .....	27
	A. <i>Syncor: December 2002</i> .....	27
	B. <i>Schering-Plough: June 2004</i> .....	28
	C. <i>HealthSouth: July 2004</i> .....	29
	D. <i>Micrus: February 2005</i> .....	29
	E. <i>Diagnostic Product Corporation: May 2005</i> .....	30
	F. <i>Immucor: September 2007</i> .....	30
	G. <i>AGA Medical Corporation: June 2008</i> .....	31
	H. <i>Novo Nordisk: May 2009</i> .....	31
	I. <i>Johnson and Johnson: April 2011</i> .....	32
	J. <i>Smith and Nephew: February 2012</i> .....	33
	K. <i>Biomet: March 2012</i> .....	33
	L. <i>Orthofix: July 2012</i> .....	34
	M. <i>Pfizer HCP Corporation: August 2012</i> .....	34
IV.	CONSEQUENCES FOR PATIENTS .....	37
V.	CONCLUSION.....	40

## I. INTRODUCTION

As companies that operate in the healthcare industry increasingly conduct business in foreign countries, they increase their exposure to the Foreign

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Corrupt Practices Act (FCPA or Act),<sup>1</sup> which prohibits payments or offers to pay anything of value to a foreign official in order to obtain or retain business. The pattern of FCPA enforcement actions brought by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) against entities in the healthcare industry over the last decade demonstrates the industry-specific challenges of compliance as well as the harsh sanctions faced by companies and individuals that violate the FCPA, including high fines, bad press, legal fees, and the possibility of a negative impact on stocks or profits.

Particularly in the healthcare sphere, violations of the FCPA result in adverse consequences for patients who require medical services in the locations where violations take place. First, patients are adversely impacted because healthcare entities that pay bribes to foreign officials in order to secure a business advantage hamper competition by precluding stakeholders from competing to provide optimal healthcare services and products to patients at the most competitive prices. Second, illegal payments made to healthcare professionals in order to favor a particular treatment option create a de facto conflict of interest that adversely impacts healthcare professionals' ability to make medical decisions in the best interest of their patients. When healthcare companies violate the FCPA, the ultimate result is ironic—entities that stand to profit by improving outcomes for patients actually harm patients. As a result, it is particularly important for companies operating globally in the healthcare industry to institute robust anti-bribery compliance programs.

This Essay begins by highlighting the most important provisions of the FCPA. Then, this Essay presents summaries of FCPA enforcement actions in the healthcare industry over the last decade to demonstrate the healthcare-specific challenges of compliance and the sanctions that have been imposed. Ultimately, this Essay argues that, in addition to the sanctions that all violators of the FCPA face, violations of the FCPA in the healthcare industry also adversely impact patients by depriving them of optimal medical services at the best prices, and causing the medical advice of healthcare professionals to be tainted by conflicts of interest. As a result, it is particularly important for companies operating in the global healthcare sphere to establish and implement robust compliance programs that incorporate methods of dealing with industry-specific FCPA risks.

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<sup>1</sup>The FCPA amended the Securities Exchange Act of 1934, Pub. L. No. 291, 48 Stat. 881. The FCPA underwent amendments itself in 1988 and 1998. See Foreign Corrupt Practices Act of 1977, Pub. L. No. 95-213, 91 Stat. 1494, *amended by* Foreign Corrupt Practices Act Amendments of 1988, Pub. L. No. 100-418, tit. V, subtit. A, pt. 1, 102 Stat. 1415 *and by* International Anti-Bribery and Fair Competition Act of 1998, Pub. L. No. 105-366, 112 Stat. 3302 (codified as amended in scattered sections of 15 U.S.C.)

## II. BACKGROUND: THE FOREIGN CORRUPT PRACTICES ACT

In general, the FCPA prohibits: (1) the payment or offer to pay anything of value to a foreign official to obtain or retain business (anti-bribery provisions);<sup>2</sup> and (2) the inadequate keeping of books, records, and accounts (books and records and internal controls provisions).<sup>3</sup> Violators of the FCPA face significant penalties.<sup>4</sup> The United States can raise civil<sup>5</sup> and criminal<sup>6</sup> claims against those who face FCPA enforcement action, as well as suspend or revoke the benefits of conducting business in the United States.<sup>7</sup>

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<sup>2</sup> 15 U.S.C. §§ 78dd-1(a)(1)–(2), 78dd-2(a)(1)–(2), 78dd-3(a)(1)–(2) (2006).

<sup>3</sup> *Id.* § 78m(b)(2)(A). The FCPA does not expressly define what it means to pay “anything of value” to a government official, although the phrase has been interpreted broadly. The legislative history surrounding the phrase “anything of value” is not particularly helpful. *See* H.R. REP. NO. 95-831 (1977) (Conf. Rep.). The books and records and internal controls provisions of the FCPA deter companies from making corrupt payments by requiring companies to maintain accurate corporate books. *See* 15 U.S.C. § 78m(b)(2)(A) (2006). The law anticipates that corrupt payments may be logged as ordinary expenditures to give the false impression that a payment was intended for some legitimate expense.

<sup>4</sup> *See, e.g.*, Press Release, U.S. Dep’t of Justice, Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations and Agree to Pay \$450 Million in Combined Criminal Fines (Dec. 15, 2008), *available at* <http://www.justice.gov/opa/pr/2008/December/08-crm-1105.html>.

<sup>5</sup> The FCPA provides for civil penalties of up to \$10,000 for violations of the anti-bribery provisions, and the Attorney General may file a civil injunction action to enjoin a domestic concern from violating the FCPA. *See* 15 U.S.C. § 78ff(c)(1)(B) (2006) (civil penalties for violations by issuers); *id.* § 78dd-2(g)(2)(B) (individual civil penalties against domestic concerns); *id.* § 78dd-2(d)(1) (permanent injunction or temporary restraining order are available).

<sup>6</sup> 15 U.S.C. § 78ff (2006) (stating penalties for violations of the FCPA). Corporations that violate the statute may face a criminal fine of up to \$2 million per violation of the books and records and internal controls provisions, or twice the bribe paid or benefit sought or received (whichever is greater) for violations of the anti-bribery provisions. 18 U.S.C. § 3571(d) (2006); *see also, e.g.*, Press Release, U.S. Dep’t of Justice, Micrus Corporation Enters into Agreement to Resolve Potential Foreign Corrupt Practices Act Liability (Mar. 2, 2005), *available at* [http://www.justice.gov/opa/pr/2005/March/05\\_crm\\_090.htm](http://www.justice.gov/opa/pr/2005/March/05_crm_090.htm) (announcing that Micrus entered into a deferred prosecution agreement to pay \$450,000 in penalties and establish a FCPA compliance program). Corporations that willfully violate the books and records and internal controls provisions can be punished with a criminal fine of up to \$25 million. 15 U.S.C. § 78ff(a) (2006).

<sup>7</sup> U.S. DEP’T OF STATE, FIGHTING GLOBAL CORRUPTION: BUSINESS RISK MANAGEMENT 28 (2001) (“The President has directed that no executive agency shall allow any party to participate in any procurement or nonprocurement activity if any agency has debarred, suspended, or otherwise excluded that party from participation in a procurement or nonprocurement activity.”). The SEC and DOJ also can seek disgorgement of profits. For example, Titan Corporation paid a fine of \$28.5 million, \$15.5 million of which was in

Especially relevant to the healthcare industry, under the FCPA, the definition of “foreign official” includes traditional government employees as well as “instrumentalit[ies] thereof.”<sup>8</sup> In June 2008, AGA Medical Corporation, a privately held Minnesota company, settled FCPA charges for using a Chinese distributor to make improper payments to doctors employed by Chinese government-owned or government-controlled hospitals in exchange for the doctors’ purchase of AGA’s medical products.<sup>9</sup> Thus, doctors and other employees of government-owned or government-controlled healthcare entities are considered “instrumentalit[ies] thereof.”

Despite these restrictions, the FCPA expressly permits “facilitating” or “expediting” payments made to foreign officials, so long as no payments made to a foreign official are used to encourage that official to award new business or to continue business with a particular party.<sup>10</sup> The 1988 amendments to the FCPA created two previously unavailable affirmative defenses: (1) the “local law” defense<sup>11</sup> and (2) the “reasonable and bona fide expenditure” defense.<sup>12</sup> The availability of the “reasonable and bona fide expenditure” defense is limited to defendants who can prove that the expenditures lacked a corrupt purpose.<sup>13</sup> These defenses are of little use when corrupt bribes are made to a foreign official to secure favorable action, which the pattern of enforcement of the FCPA in the healthcare industry illustrates.<sup>14</sup>

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disgorgement, for making improper payments to a foreign official in Benin. Litigation Release No. 19107, U.S. Sec. & Exch. Comm’n, SEC Sues the Titan Corporation for Payments to Election Campaign of Benin President (Mar. 1, 2005), available at <http://www.sec.gov/litigation/litreleases/lr19107.htm>.

<sup>8</sup> See Mike Koehler, *The Foreign Corrupt Practices Act in the Ultimate Year of Its Decade of Resurgence*, 43 IND. L. REV. 389, 391–92 (2010).

<sup>9</sup> See Press Release, U.S. Dep’t of Justice, AGA Medical Corporation Agrees to Pay \$2 Million Penalty and Enter Deferred Prosecution Agreement for FCPA Violations (June 3, 2008), available at <http://www.justice.gov/opa/pr/2008/June/08-crm-491.html>.

<sup>10</sup> 15 U.S.C. § 78dd-1(b) (2006).

<sup>11</sup> The narrow “local law” defense allows a “payment, gift, offer, or promise of anything of value” to a foreign official, so long as the payment is in accordance with the written laws of the country in which it occurred. *Id.* § 78dd-1(c)(1).

<sup>12</sup> The “reasonable and bona fide expenditure” defense allows for a “payment, gift, offer, or promise of anything of value” that is considered a “reasonable and bona fide expenditure.” *Id.* § 78dd-1(c)(2)(A)–(B).

<sup>13</sup> See *id.* A payment that is a reasonable and bona fide expenditure and directly relates to the promotion, demonstration, or explanation of products or services, or directly relates to the execution or performance of a contract is not prohibited. *Id.*

<sup>14</sup> For a criticism of the effectiveness of these defenses, see generally Kyle P. Sheahan, *I’m Not Going to Disneyland: Illusory Affirmative Defenses Under the Foreign Corrupt Practices Act*, 28 WIS. INT’L L.J. 464 (2010).

### III. ENFORCEMENT OF THE FCPA IN THE HEALTHCARE INDUSTRY

In the last decade, there has been a surge in FCPA enforcement, especially in the healthcare sector.<sup>15</sup> As healthcare entities gain or seek to gain access to overseas markets, they must model their business strategies and compliance programs to avoid the risk of violating the FCPA.<sup>16</sup> The most significant challenges of compliance with the FCPA in the healthcare industry arise out of the fact that many foreign hospitals, clinics, laboratories, and medical providers are state-owned or state-controlled, which sweeps them into the FCPA's jurisdictional reach.

The following summaries of FCPA enforcement actions illustrate healthcare industry-specific FCPA risks and sanctions. With regard to the negative consequences for patients, violations of the FCPA in the healthcare industry typically occur when bribes are paid: (1) to an influential foreign official in order to secure access to an investment, thus stifling competition; or (2) to a healthcare professional in order to induce the professional to favor the company's products, thus creating a conflict of interest.

#### A. *Syncor: December 2002*

Syncor International Corporation (Syncor), a company that sells and distributes radiopharmaceutical products, settled an SEC enforcement action that alleged that the company's subsidiaries in Taiwan, Mexico, Belgium, Luxembourg, and France made payments to doctors and hospitals to influence purchasing decisions.<sup>17</sup> The SEC found that Syncor employees made commissions and other payments in the form of cash, improper referral fees, personal loans, over-invoicing arrangements, sponsorship to seminars, and gifts in return for referrals and sales of Syncor products. The company consented to the entry of a final judgment

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<sup>15</sup> See *SEC Enforcement Actions: FCPA Cases*, U.S. SEC. & EXCH. COMM'N, <http://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml> (last visited Mar. 8, 2013).

<sup>16</sup> See James A. Barta & Julia Chapman, *Foreign Corrupt Practices Act*, 49 AM. CRIM. L. REV. 825, 855–58 (2012).

<sup>17</sup> Plea Agreement at 2, *United States v. Syncor Taiwan, Inc.*, No. 02-CR-1244-SVW (C.D. Cal. Dec. 9, 2002), available at <http://www.justice.gov/criminal/fraud/fcpa/cases/syncor-taiwan/12-03-02syncor-taiwan-plea-agree.pdf>. Syncor Taiwan was the target of DOJ's investigation and the only Syncor entity to also plead guilty to criminal charges for paying "commissions" to physicians of state-owned hospitals. The commissions were paid in return for the purchase and sale of unit dosages of certain radiopharmaceuticals and for referrals of patients to medical imaging centers owned by Syncor Taiwan. *Id.* at 21–23.

with the SEC without admitting or denying the charges, and paid a \$500,000 civil penalty.<sup>18</sup> Syncor's Taiwan subsidiary plead guilty to DOJ criminal charges and was fined \$2 million.<sup>19</sup> This was the first case where the government charged a company for bribing doctors considered to be foreign officials or "instrumentalit[ies] thereof," which opened the door for similar future prosecutions.

### B. Schering-Plough: June 2004

Schering-Plough Corporation (Schering), a global pharmaceutical company, allegedly made improper payments through its foreign subsidiary to a charitable foundation in Poland, in order to induce a public official to exert influence over government funds to purchase Schering products.<sup>20</sup> The founder and president of the charitable foundation was also the director of a government health authority in Poland that provided money to purchase pharmaceutical products and influenced the purchase of those products by entities such as hospitals. Although recorded as donations, the SEC found that the director subjectively valued donations to the bona-fide charity and Schering provided the intangible benefit to bribe the public official.<sup>21</sup> Without admitting or denying the allegations, Schering consented to a \$500,000 civil penalty.<sup>22</sup> This was the first instance when a company's charitable contribution was considered to be "anything of value," further expanding the scope of improper payments under the FCPA.

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<sup>18</sup> Consent of Defendant at 1, SEC v. Syncor Int'l, Inc., No. 1:02CV02421 (D.D.C. Dec. 10 2002), available at <http://fcpa.shearman.com/files/7e8/7e8346944579a0844a8fd30f9fa27c45.pdf?i=fa67e6df39b7d75e6307cc22a271c378>.

<sup>19</sup> Plea Agreement, *supra* note 17, at 5. In 2007, six years after Syncor settled with DOJ and the SEC, the SEC brought a civil case against Monty Fu, the chairman of Syncor Taiwan and Syncor International. The complaint alleged that Fu was responsible for ensuring compliance with the books-and-records and internal accounting controls provisions of the FCPA and that he was aware that Syncor Taiwan was making corrupt payments to doctors and hospitals. Fu consented to the entry of a final judgment and to a \$75,000 penalty. See Press Release, U.S. Sec. & Exch. Comm'n, SEC Files Settled Books and Records and Internal Accounting Controls Charges Against Former Chairman of Syncor International Corp. (Sept. 28, 2007), available at <http://www.sec.gov/litigation/litreleases/2007/lr20310.htm>.

<sup>20</sup> Complaint at 2–13, SEC v. Schering-Plough Corp., No. 04-0945 (D.D.C. June 9, 2004), available at <http://www.sec.gov/litigation/complaints/comp18740.pdf>.

<sup>21</sup> *Id.* at 9.

<sup>22</sup> SEC v. Schering-Plough Corp., No. 04-0945 (D.D.C. June 16, 2004), available at <http://fcpa.shearman.com/files/d0d/d0d468cbae3eda3d39ed1c5467d24fc4.pdf?i=fe3d8c1a914ffb7c23b1b024154131c> (order granting entry of final judgment).

### C. HealthSouth: July 2004

DOJ indicted former executives of HealthSouth Corporation (HealthSouth), a provider of outpatient surgery, diagnostic imaging, and rehabilitative healthcare services. Allegedly, the former President and CEO of the In-Patient Division and the former Vice President of Legal Services made and authorized corrupt payments to the director of a Saudi Arabian foundation in order to secure business for HealthSouth.<sup>23</sup> The Saudi foundation was a private nonprofit organization funded by members of the Saudi Royal Family. DOJ alleged that the executives provided corrupt payments to the foundation's director in order to secure HealthSouth staffing and management services at a hospital in Saudi Arabia.<sup>24</sup> To conceal the scheme, the defendants allegedly arranged a sham consulting contract between the director and a HealthSouth-affiliated entity in Australia. Notably, the defendants were acquitted following trial in May 2005.<sup>25</sup>

### D. Micrus: February 2005

Micrus Corporation ("Micrus"), a company that makes and sells medical devices known as embolic coils, entered into a non-prosecution agreement under which it accepted responsibility for promising to pay or for paying doctors money or objects of value at public hospitals in France, Turkey, Spain, and Germany in order to influence them to purchase Micrus embolic coils.<sup>26</sup> Micrus also paid doctors without

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<sup>23</sup> Press Release, U.S. Dep't of Justice, Former HealthSouth Officers Indicted in Connection with Bribery Involving Saudi Hospital (July 1, 2004), *available at* [http://www.justice.gov/opa/pr/2004/July/04\\_crm\\_463.htm](http://www.justice.gov/opa/pr/2004/July/04_crm_463.htm). The U.S. Attorney's Office of the Northern District of Alabama and DOJ indicted HealthSouth employees for conspiracy, violations of the FCPA, and violations of the Travel Act.

<sup>24</sup> Superseding Indictment at 7, *United States v. Thompson & Reilly*, No. CR-04-J-0240-S (N.D. Ala. July 28, 2004), *available at* <http://www.justice.gov/criminal/fraud/fcpa/cases/thomsonr/07-28-04thomson-superseded-indict.pdf>. A licensed attorney allegedly prepared the fake contract. Under the agreement, HealthSouth was to receive \$10 million annually over a five-year term and the director was to be paid \$500,000 per year for a five-year period. The bribe was disguised as a "finder's fee." *See* Press Release, *supra* note 23.

<sup>25</sup> *United States v. Thompson & Reilly*, No. CR-04-J-240-S, (N.D. Ala. May 20, 2005), *available at* <http://fcpa.shearman.com/files/1dd/1dd0ce4f6addbac340d59e37e33a86fb.pdf?i=10d1bd8507c5dd935f5a25e64b99cfea>.

<sup>26</sup> *See* Plea Agreement at App. A, *United States v. Micrus Corp.*, (D.D.C. Feb. 28, 2005), *available at* <http://www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agree.pdf>.

obtaining proper administrative or legal approval required under foreign jurisdictions. The scheme involved Micrus providing compensation to doctors exceeding the value of the services performed as consultants or advisory board members to Micrus. Under the agreement with DOJ, Micrus agreed to pay a civil penalty of \$450,000.<sup>27</sup>

*E. Diagnostic Product Corporation: May 2005*

Diagnostic Product Corporation (DPC), a company that develops and manufactures medical diagnostic test systems and related kits, settled enforcement actions after its subsidiary, Tianjin DePu Biotechnological and Medical Products Inc. (DePu), allegedly made improper commission payments to doctors and laboratory employees who controlled purchasing decisions at Chinese state-owned hospitals.<sup>28</sup> The commissions represented a certain percentage of sales to the hospitals. Without admitting or denying the allegations, DPC agreed to an SEC sanction of nearly \$2.8 million; DPC also plead guilty to DOJ charges and agreed to pay a fine of approximately \$2 million.<sup>29</sup>

*F. Immucor: September 2007*

Immucor, Inc. (Immucor), a medical equipment company specializing in the manufacturing and marketing of products used in the pre-transfusion diagnostics of human blood, allegedly paid the director of an Italian public hospital cash in order to influence his decision to award Immucor a contract with a government hospital.<sup>30</sup> Immucor's President and CEO, Gioacchino De Chirico, also allegedly agreed to compensate the hospital director for his role at a medical conference that discussed an Immucor product. Immucor's German subsidiary made payments to the

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<sup>27</sup> *Id.* at 2.

<sup>28</sup> Press Release, U.S. Dep't of Justice, DPC (Tianjin) Ltd. Charged with Violating the Foreign Corrupt Practices Act (May 20, 2005), *available at* [http://www.justice.gov/opa/pr/2005/May/05\\_crm\\_282.htm](http://www.justice.gov/opa/pr/2005/May/05_crm_282.htm). DePu allegedly made commission payments totaling \$1.6 million to foreign officials. Although DePu's management knew about, approved, and administered the payments, once DPC learned about the improper transactions, it instructed DePu management to cease all of its corrupt activities. *Id.*

<sup>29</sup> Plea Agreement at 5, United States v. DPC (Tianjin) Co. Ltd., No. 2:05-cr-00482 (C.D. Cal. May 20, 2005), *available at* <http://www.justice.gov/criminal/fraud/fcpa/cases/dpc-tianjin/05-19-05dpc-tianjin-plea-agree.pdf>. DPC entered into a plea agreement that imposed a criminal fine and five-year probationary period.

<sup>30</sup> Complaint at 4–7, SEC v. Gioacchino De Chirico, No. 1:07-cv-2367 (N.D. Ga. Sept. 28, 2007), *available at* <http://www.sec.gov/litigation/complaints/2007/comp20316.pdf>.

director's Swiss bank account and recorded the payments as consulting services.<sup>31</sup> This compensation scheme enabled the director to avoid income tax. Without admitting or denying the SEC's allegations, De Chirico agreed to pay a \$30,000 civil penalty.<sup>32</sup>

*G. AGA Medical Corporation: June 2008*

AGA Medical Corporation (AGA), a company that specializes in manufacturing products designed to treat congenital heart defects, admitted that AGA made corrupt payments to government officials, doctors employed by government-owned or government-controlled hospitals, via AGA's Chinese distributor.<sup>33</sup> In exchange for payments, through kickbacks and commissions, doctors directed the hospitals to purchase AGA medical devices. AGA's Chinese distributor also made payments to Chinese officials in order to have patents on several AGA products approved. Pursuant to the deferred prosecution agreement with DOJ, AGA agreed to pay a \$2 million penalty.<sup>34</sup>

*H. Novo Nordisk: May 2009*

Novo Nordisk (Novo), an international manufacturer of pharmaceutical supplies, made improper payments to Iraqi Ministry of Health officials in order to secure Novo's selection as a provider of humanitarian aid, such as food and medicine, through the U.N. Oil-for-Food Program.<sup>35</sup> To effectuate its scheme, Novo inflated the contract price when submitting bids to the U.N. The company mischaracterized

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<sup>31</sup> *Id.* at 5. Allegedly, De Chirico authorized Immucor's German subsidiary to make the payment to the Swiss account. The subsidiary allegedly recorded the corrupt payments as consulting services, which caused the payments to be paid pursuant to a false invoice and incorrectly recorded in Immucor's books and records. *Id.* at 6.

<sup>32</sup> Litigation Release No. 20316, U.S. Sec. & Exch. Comm'n, SEC Files Action Naming Officer of Immucor, Inc., for Violating, and Aiding and Abetting Violations of, Books and Records and Internal Control Provisions of the Securities Exchange Act of 1934 (Exchange Act) (Sept. 28, 2007), available at <http://www.sec.gov/litigation/litreleases/2007/lr20316.htm>.

<sup>33</sup> Deferred Prosecution Agreement at Attachment A, United States v. AGA Medical Corp., No. 0:08-cr-00172JMR (D. Minn. June 3, 2008), available at <http://www.justice.gov/criminal/fraud/fcpa/cases/agamedcorp/06-03-08aga-agree.pdf>.

<sup>34</sup> *Id.* at 6.

<sup>35</sup> Press Release, U.S. Dep't of Justice, Novo Nordisk Agrees to Pay \$9 Million Fine in Connection with Payment of \$1.4 Million in Kickbacks Through the United Nations Oil-for-Food Program (May 11, 2009), available at <http://www.justice.gov/opa/pr/2009/May/09-crm-461.html>.

the improper payments as “after sales services fee[s].” Novo’s Jordanian distributor used the extra money to provide kickbacks to Iraqi government officials, and in effect, caused U.N. monies to fund the corrupt payments. Novo entered into a deferred prosecution agreement with DOJ under which it accepted responsibility and agreed to pay a \$9 million fine.<sup>36</sup> The SEC also secured a final judgment against Novo for approximately \$9 million.<sup>37</sup>

### I. *Johnson and Johnson: April 2011*

Johnson and Johnson (J&J), a global pharmaceutical, consumer product, and medical device company, voluntarily disclosed that its subsidiaries bribed government doctors and pharmacists in various European countries with national healthcare systems to prescribe J&J drugs and purchase J&J products.<sup>38</sup> J&J also paid kickbacks to the Iraqi government to illegally obtain business contracts through the U.N. Oil-for-Food Program. J&J subsidiaries created sham civil contracts, false travel invoices, and used cash and travel payments to bribe public officials. Ultimately, the company acknowledged responsibility in its settlement with DOJ.<sup>39</sup> J&J’s aggregate penalty of \$70 million was the tenth largest FCPA-related fine.<sup>40</sup>

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

<sup>37</sup> Press Release, U.S. Sec. & Exch. Comm’n, SEC Files Settled Books and Records and Internal Controls Charges Against Novo Nordisk for Improper Payments to Iraq Under the U.N. Oil for Food Program (May 11, 2009), *available at* <http://www.sec.gov/litigation/litreleases/2009/lr21033.htm>. During the time when international sanctions on Iraq were high, the U.N. created the Oil-for-Food Program (Program), which allowed Iraq to sell its oil for humanitarian purposes. The Program required that oil proceeds be deposited in a U.N. escrow account and that the money only be used to purchase humanitarian goods and services approved by the U.N. Deferred Prosecution Agreement at 11–13, *U.S. v. Novo Nordisk A/S*, (D.D.C., 2009) (No. 1:09-cr-00126-RJL), *available at* <http://www.justice.gov/criminal/fraud/fcpa/cases/nordiskn/05-06-09novo-agree.pdf>.

<sup>38</sup> Press Release, U.S. Sec. & Exch. Comm’n, Johnson & Johnson to Pay More Than \$70 million in Settled FCPA Enforcement Action (Apr. 8, 2011), *available at* <http://www.sec.gov/litigation/litreleases/2011/lr21922.htm>. J&J engaged in corrupt activities in Greece, Poland, and Romania. *Id.*

<sup>39</sup> Press Release, U.S. Dep’t of Justice, Johnson & Johnson Agrees to Pay \$21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations (Apr. 8, 2011), *available at* <http://www.justice.gov/opa/pr/2011/April/11-crm-446.html>.

<sup>40</sup> See *SEC Enforcement Actions: FCPA Cases*, U.S. SEC. & EXCH. COMM’N., <http://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml>. In a parallel action, the SEC and DOJ alleged that DePuy, through a Greek distributor it later acquired, paid bribes to public

*J. Smith and Nephew: February 2012*

Smith and Nephew, plc (S&N plc), a global medical company that sells orthopedic, endoscopy, and wound-care products, conducts business through its wholly owned subsidiary Smith and Nephew, Inc. (S&N Inc.), a global manufacturer and supplier of orthopedic medical devices.<sup>41</sup> S&N Inc. created false marketing arrangements under which it sold its products at full price to its distributor and then paid the distributor a discount in the form of a kickback to an offshore shell company, which the distributor controlled. The distributor used funds it received as a slush fund to provide cash incentives and other things of value to publicly employed Greek doctors to provide incentives to purchase S&N products. S&N plc entered into a settlement with the SEC and agreed to pay \$5.4 million;<sup>42</sup> S&N Inc. entered into a deferred prosecution agreement with DOJ, acknowledged responsibility, and agreed to pay a penalty of \$16.8 million.<sup>43</sup>

*K. Biomet: March 2012*

Biomet Inc. (Biomet), a manufacturer and seller of medical devices worldwide, admitted that it made direct and indirect corrupt payments to publicly employed doctors through its subsidiaries and distributors in Argentina, Brazil, Spain, and China to ensure the purchase of Biomet medical devices.<sup>44</sup> Payments were in the form of kickbacks, cash, and

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doctors in Greece who chose DePuy's products. J&J entered into a deferred prosecution agreement for the DePuy charges, acknowledged wrongdoing, and consented to a \$21.4 million penalty. Plea Agreement at 1, *United States v. DePuy, Inc.*, No. 1:11-cr-00099-JBD (D.D.C. Jan. 14, 2011), *available at* <http://www.justice.gov/criminal/fraud/fcpa/cases/depuy-inc/04-08-11depuy-dpa.pdf>.

<sup>41</sup> Complaint at 2–9, *SEC v. Smith & Nephew plc*, No. 1:12-cv-00187 (D.D.C. Feb. 6, 2012), *available at* <http://www.sec.gov/litigation/complaints/2012/comp22252.pdf>. The transactions were disguised as commissions and marketing payments to the off-shore shell companies on the books and records. *Id.* at 8.

<sup>42</sup> *SEC v. Smith & Nephew plc*, No. 1:12-cv-00187 (GK) (D.D.C. Mar. 6, 2012), *available at* <http://fcpa.shearman.com/files/66e/66e4575dd7b3239773de2f06a014b493.pdf?i=0c3aacbe97d9147d34ee9fc186f81621>.

<sup>43</sup> Deferred Prosecution Agreement at 5, *United States v. Smith & Nephew, Inc.*, No. 1:12-cr-00030-RBW (D.D.C. Feb. 1, 2012), *available at* <http://www.justice.gov/criminal/fraud/fcpa/cases/smith-nephew/2012-02-01-s-n-dpa.pdf>. Among the factors considered when entering into the deferred prosecution agreement, DOJ stated that S&N Inc. cooperated fully, took remedial measures, and investigated and disclosed its misconduct. *Id.* at 2.

<sup>44</sup> Deferred Prosecution Agreement at 14–20, *United States v. Biomet, Inc.*, No. 1:12-CR-00080-RBW (D.D.C. Mar. 6, 2012), *available at* <http://legaltimes.typepad.com/>

travel arrangements; sham invoices were used to justify the payments. Under the deferred prosecution agreement with DOJ, Biomet agreed to pay over \$17 million;<sup>45</sup> under the SEC settlement Biomet agreed to disgorge over \$5 million.<sup>46</sup>

*L. Orthofix: July 2012*

Orthofix International N.V. (Orthofix), a company focused on the development, manufacture, and distribution of surgical and non-surgical medical devices, allegedly paid bribes to Mexican officials through a subsidiary in Mexico in return for a Mexican government social service agency and its hospitals' purchase of Orthofix products.<sup>47</sup> Orthofix's subsidiary also agreed to pay Mexican officials a percentage of collected sales revenue in order to win the right to sell Orthofix products to two Mexican hospitals. The agency created fictitious companies and sent invoices to Orthofix after it provided incentives such as cash, laptop computers, televisions, and appliances. Under the deferred prosecution agreement with DOJ and final judgment with the SEC, which Orthofix acknowledged to be true and accurate, the company disgorged \$5.2 million and agreed to a \$2.22 million fine.<sup>48</sup>

*M. Pfizer HCP Corporation: August 2012*

Pfizer Inc. (Pfizer), a global pharmaceutical company, signed a deferred prosecution agreement under which it admitted that it bribed

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files/fraud.fcpa.biomet.dpa.pdf. Numerous executives, managers, and auditors, including a U.S.-based Senior Vice President, knew of the improper payments. *Id.* at 15. The bribes were recorded as "consulting fees," "commissions," "royalties," and "scientific incentives" in Biomet's books and records. *Id.*

<sup>45</sup> *Id.* at 5.

<sup>46</sup> Press Release, U.S. Sec. & Exch. Comm'n, SEC Charges Medical Device Company Biomet with Foreign Bribery (Mar. 26, 2012), available at <http://www.sec.gov/news/press/2012/2012-50.htm>. The SEC stated that the government's proactive investigation of bribery within the medical device industry led to the discovery of Biomet's misconduct. *Id.*

<sup>47</sup> Complaint at 3–4, SEC v. Orthofix Int'l N.V., No. 4:12-CV-419 (E.D. Tex. July 10, 2012), available at <http://www.sec.gov/litigation/complaints/2012/comp22412.pdf>. Orthofix's subsidiary falsely recorded the bribe-related expenses on its books and records as "promotional expenses," payments for medical equipment, and training-related expenses. Orthofix lacked the proper internal controls to identify this illicit activity and failed to implement FCPA compliance programs. *Id.* at 4–6.

<sup>48</sup> Press Release, U.S. Sec. & Exch. Comm'n, SEC Charges Orthofix International with FCPA Violations (July 10, 2012), available at <http://www.sec.gov/news/press/2012/2012-133.htm>.

publicly employed regulators and government healthcare professionals, including officials in Croatia, Russia, Bulgaria, and Kazakhstan, in exchange for regulatory and formulary approvals, sales, and increased prescriptions of Pfizer products.<sup>49</sup> The government healthcare professionals received various things of value, such as travel benefits and bonuses based on percentage of sales, in return for the promise to purchase Pfizer products, meet a specific targeted Pfizer prescription goal, and add Pfizer products to government lists and into bidding. Pfizer agreed to pay a \$15 million fine. Notably, the SEC separately charged Wyeth LLC (Wyeth), a company acquired by Pfizer in 2009, with additional FCPA violations.<sup>50</sup> Without admitting or denying the allegations, Wyeth agreed to a settlement under which it paid a total of \$18.8 million.

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While the summaries above focus on prosecutions under the FCPA's anti-bribery provisions, almost all of these enforcement actions also included violations under the FCPA's books and records and internal controls provisions.<sup>51</sup> For example, Micrus recorded inflated payments to doctors as stock options, honorariums, and commissions.<sup>52</sup> Similarly, Novo recorded corrupt payments to the Iraqi government officials as "commissions."<sup>53</sup> The high likelihood that corrupt payments are logged as ordinary expenditures to give the false impression that a payment was intended for some legitimate expense provides the SEC, which enforces

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<sup>49</sup> Deferred Prosecution Agreement at A-1-A-15, *United States v. Pfizer H.C.P. Corp.*, No. 1:12-CR-00169 (D.D.C. Aug. 7, 2012), available at <http://www.justice.gov/criminal/fraud/fcpa/cases/pfizer/2012-08-07-pfizer-dpa.pdf>.

<sup>50</sup> Complaint at 4-9, *SEC v. Wyeth LLC*, No. 1:12-cv-01304 (D.D.C. Aug. 7, 2012), available at <http://www.sec.gov/litigation/complaints/2012/comp-pr2012-152-wyeth.pdf>. Following Pfizer's acquisition of Wyeth, Pfizer identified potential improper payments. *Id.* at 5. The SEC alleges that Wyeth subsidiaries in China, Indonesia, Pakistan, and Saudi Arabia made improper payments to government doctors and other health care professionals to receive business. *Id.* The inaccurate books and records of Wyeth's subsidiaries were consolidated in the financial reports of Wyeth, and Wyeth failed to devise and maintain an appropriate system of internal accounting controls. *Id.* at 9. Certain payments were made following Pfizer's acquisition of Wyeth without Pfizer's knowledge. *Id.* at 2.

<sup>51</sup> AGA was prosecuted under only the anti-bribery provisions. The following issuers, their subsidiaries, or individuals affiliated with the companies were charged with violations of the books and records and internal controls provisions of the FCPA: (1) Syncor, (2) Schering, (3) HealthSouth, (4) Micrus, (5) Diagnostics, (6) Immucor, (7) Novo, (8) J&J, (9) S&N plc, (10) Biomet, (11) Orthofix, and (12) Pfizer.

<sup>52</sup> Plea Agreement at App. A, *United States v. Micrus Corp.*, (Feb. 28, 2005), available at <http://www.justice.gov/criminal/fraud/fcpa/cases/micrus-corp/02-28-05micrus-agreee.pdf>.

<sup>53</sup> See *supra* Part III.H.

the books and records and internal controls provisions of the FCPA, with an avenue to join DOJ in a parallel prosecution.<sup>54</sup> Indeed, healthcare companies must understand industry-specific vulnerabilities to the FCPA in order to prevent possible violations.

For example, many foreign governments have public healthcare systems, which pose unique risks to pharmaceutical, medical device, and other healthcare companies. Practices such as paying for a doctor to attend a conference with the understanding that the doctor will provide some benefit in return may violate the FCPA. Biomet faced an enforcement action when it paid traveling expenses for twenty government-employed surgeons and recorded them as “consulting fees.”<sup>55</sup> A substantial portion of the doctors’ visit included sightseeing and entertainment at Biomet’s expense.<sup>56</sup> The government found that Biomet’s intent was to encourage the purchase of Biomet products.<sup>57</sup>

Another notable aspect regarding the enforcement of the FCPA in the healthcare sector is that over half of the cases summarized above involve a government-employed healthcare professional as the recipient of a corrupt payment.<sup>58</sup> For example, Syncor provided cash, improper referral fees, personal loans, etc., to government doctors in return for referrals and sales of Syncor products.<sup>59</sup> Also, DePu made illegal commission payments to doctors and laboratory employees who controlled purchasing decisions at Chinese state-owned hospitals.<sup>60</sup> Other enforcement actions involve government-affiliated hospital executives with influence over purchasing decisions. For example, Schering’s donations to a nonprofit organization were deemed corrupt when the

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<sup>54</sup> Notably, while the corrupt payments in the enforcement actions described above were often recorded as travel, marketing, promotional expenses, or consulting fees, the Schering action was unique in that the SEC also found Schering guilty of books and records violations after it recorded payments to a bona-fide charity as “donations.”

<sup>55</sup> Deferred Prosecution Agreement at 20, *United States v. Biomet, Inc.*, No. 1:12-CR-00080-RBW (D.D.C. Mar. 6, 2012), available at <http://legaltimes.typepad.com/files/fraud.fcpa.biomet.dpa.pdf>.

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

<sup>57</sup> *Id.* at 16–18.

<sup>58</sup> The following cases involved payments to government-employed healthcare professionals: (1) Syncor, (2) Micrus, (3) Diagnostics, (4) AGA, (5) J&J, (6) S&N plc, (7) Biomet, and (8) Pfizer.

<sup>59</sup> Plea Agreement at 4–5, *United States v. Syncor Taiwan, Inc.*, No. 02-CR-1244-SVW (C.D. Cal. Dec. 9, 2002), available at <http://www.justice.gov/criminal/fraud/fcpa/cases/syncor-taiwan/12-03-02syncor-taiwan-plea-agree.pdf>.

<sup>60</sup> *Id.* at 2.

president of the nonprofit was also the director of a government health authority that had control over hospital purchasing decisions.<sup>61</sup>

For healthcare companies with an international business scope, it is especially important to convey to employees, agents, distributors, and affiliates the limits of gift-giving. A robust, well-executed, and up-to-date FCPA compliance program should be designed in light of the industry-specific risks discussed above. This is essential not only to decrease the liability of a healthcare company, but also to protect the end-users of their products—patients, who are often overlooked as the victims of FCPA violations.

#### IV. CONSEQUENCES FOR PATIENTS

Violators of the FCPA in the healthcare industry face the same harsh sanctions as in other industries such as: negative publicity, statutorily imposed penalties, significant legal costs, draining of resources, and possible negative impact on share price and profits.<sup>62</sup> The often overlooked consequence of violating the FCPA in the healthcare sphere is the adverse impact on patients who rely on medical services in the locations where the violations occur. In order to understand the harm to patients, it is important to reiterate that the pattern of FCPA enforcement actions in the healthcare industry demonstrates that FCPA violations fit into two broad categories. Healthcare entities or their agents provide “something of value” either (1) to an influential foreign official in order to secure access to an investment opportunity<sup>63</sup> or (2) to a healthcare professional in order to induce the professional to favor the company’s products.<sup>64</sup>

With regard to the first category, patients are disadvantaged because the bribes stifle competition in the market, preventing patients from

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<sup>61</sup> See *supra* Part III.B.

<sup>62</sup> See Barta & Chapman, *supra* note 16, at 855–56.

<sup>63</sup> See *supra* Part III. Illustrations include: (1) Schering making improper payments to a charitable foundation associated with a public official in order to induce the official’s influence over government funds; (2) HealthSouth making corrupt payments to a foundation’s director in order to secure HealthSouth’s staffing and management services at a hospital; and (3) Immucor paying cash to the director of a public hospital in order to influence his decision to award a contract.

<sup>64</sup> See *supra* Part III. Illustrations include: (1) Syncor providing improper payments to government doctors in return for referrals and sales of Syncor products; (2) Micrus paying government doctors in order to influence their purchase of Micrus embolic coils; and (3) DePu making illegal commission payments to doctors and laboratory employees who controlled purchasing decisions at government-owned hospitals.

receiving optimal medical goods and services at the best prices. With regard to the second category, patients receive inadequate care when bribes are paid to healthcare professionals that create a conflict of interest causing healthcare professionals to base clinical decisions on what is best for them or a third party rather than on what is best for the patient.

When healthcare markets are competitive, patients benefit from lower costs, better care, and more innovation.<sup>65</sup> When a healthcare company or its agents bribe foreign public officials, for example, in order to ensure that the officials select the company to supply pharmaceutical products or medical devices, the company effectively eliminates other competitors from the marketplace. Those competitors, however, may provide a better product or a lower cost. This ultimately deprives patients of the opportunity to have better and cheaper treatment options.<sup>66</sup>

Additionally, and of more direct harm to patients, bribes paid to healthcare professionals create a conflict of interest that impacts medical decision-making. In healthcare, conflicts of interest often arise out of financial arrangements, such as reimbursement incentives, investments in medical facilities, or gifts from third parties.<sup>67</sup> A small gift may be an

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<sup>65</sup> See *Value-Based Competition*, HARV. BUS. SCH., <http://www.hbs.edu/rhc/value.html> (“Healthy competition is competition to improve value for customers, or the quality of products or services relative to their price. . . . Health care competition must be transformed to a value-based competition on results. This is the best way, and the only way, to drive sustained improvements in quality and efficiency.”); see also Michael F. Cannon, Commentary, *Real Competition Is The Cure for Health Care*, CATO INSTITUTE (Oct. 1, 2005), <http://www.cato.org/publications/commentary/real-competition-is-cure-health-care> (“Where real market competition can be found in health care, it drives quality upward and prices downward.”).

<sup>66</sup> It is worth noting that since the FCPA’s enactment, some have perceived that the FCPA places American businesses at a disadvantage in the global marketplace because bribery is commonplace in many countries. Beverley H. Earle, *Foreign Corrupt Practices Act Amendments: The Omnibus Trade and Competitiveness Act’s Focus on Improving Investment Opportunities*, 37 CLEV. ST. L. REV. 549, 551 (1989). However, it would be erroneous, in the present day, to argue that companies prohibited from bribing foreign officials are at a competitive disadvantage in the global marketplace. Internationally, anti-bribery enforcement has developed a great deal. See Lauren Ann Ross, Note, *Using Foreign Relations Law to Limit Extraterritorial Application of the Foreign Corrupt Practices Act*, 62 DUKE L.J. 445, 460 (2012) (explaining that “[b]oth developed countries and emerging economic powers have adopted antibribery legislation prohibiting payments to foreign officials for the purpose of obtaining business”). DOJ and the SEC have also been proactively enforcing the FCPA, leading to increased prosecutions, penalties, and voluntary disclosures. See generally Margaret Ryznar & Samer Korkor, *Anti-Bribery Legislation in the United States and United Kingdom: A Comparative Analysis of Scope and Sentencing*, 76 MO. L. REV. 415 (2011).

<sup>67</sup> See generally BERNARD LO, *RESOLVING ETHICAL DILEMMAS: A GUIDE FOR CLINICIANS* (Lippincott Williams & Wilkins eds., 3d ed. 2005).

appropriate and permissible way for business people to demonstrate their respect or appreciation for each other, so long as the gift does not improperly influence the recipient.<sup>68</sup> Gifts of nominal value may include company promotional items, and reasonable meals and entertainment expenses. Such gifts should be given openly and the recipient must properly record the gift. Importantly, a large gift (or several small gifts) is more likely to be given with improper purpose as part of a bribe, and is therefore impermissible under the FCPA.<sup>69</sup>

As a general matter, healthcare professionals must avoid accepting improper gifts because they give rise to unnecessary conflicts of interest, which may lead to bad outcomes for patients. This is because, first, patients and the public may be directly harmed if physicians base clinical decisions on what is best for them or a third party rather than on what is best for the patient. Second, patients need to rely on the recommendations of healthcare professionals because patients lack medical expertise—if patients fear that healthcare professionals are not acting on their behalf, patients may worry or fail to follow recommendations. Finally, the public may be harmed because of an increased likelihood that when healthcare professionals make decisions based on their own interest, in the aggregate, such medical decisions will harm entire populations. While doctors may be able to avoid conflicts of interest by taking precautions such as properly disclosing their financial

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<sup>68</sup> CRIMINAL DIVISION, U.S. DEP'T OF JUSTICE & ENFORCEMENT DIVISION, U.S. SEC. & EXCH. COMM'N, A RESOURCE GUIDE TO THE U.S. FOREIGN CORRUPT PRACTICES ACT 15 (2012), <http://www.justice.gov/iso/opa/resources/29520121114101438198031.pdf>.

<sup>69</sup> *Id.* In the United States, in order to avoid crossing the fine line between gifts and bribes, several pharmaceutical companies have voluntarily implemented strict corporate guidelines to regulate their marketing activities. See Natasha Singer, *No Mug? Drug Makers Cut Out Goodies for Doctors*, N.Y. TIMES, Dec. 30, 2008, at A1, available at [http://www.nytimes.com/2008/12/31/business/31drug.html?\\_r=1&](http://www.nytimes.com/2008/12/31/business/31drug.html?_r=1&). Such guidelines may require meals provided in connection with informational presentations or discussions to be modest, unrelated to entertainment or recreation, and conducive to informational communication in office or hospital settings. PHARMA, CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 4 (2008), available at [http://www.phrma.org/sites/default/files/108/phrma\\_marketing\\_code\\_2008.pdf](http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf). They may also prohibit entertainment and recreational expenses, and non-educational items of minimal value, such as pens, notepads, and mugs. *Id.* at 11. Some suggest that government regulation, in addition to self-regulation, is necessary to reduce the improper influence of gifts in the pharmaceutical industry. David Grande, *Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention?*, J. GEN. INTERNAL MED., Jan. 2010, at 79, 79–83, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811591/>. Such self-regulation may include disclosure requirements, limits on the sale of physician-prescribing data for marketing purposes, licensure of pharmaceutical sales representatives, or an outright ban on gifts. *Id.*

relationships with a third party, healthcare professionals should conduct their affairs to avoid undue conflicts of interest in order to prioritize their patients' best interests.<sup>70</sup>

## V. CONCLUSION

Violations of the FCPA in the healthcare sphere lead to an ironic result. The industry that profits when it improves medical solutions, in effect, harms those it seeks to help by depriving patients of optimal care at competitive prices and by creating conflicts of interest that impede the judgment of healthcare professionals. All companies operating in international markets, especially in the healthcare industry, stand to gain a great deal from a strong FCPA compliance program for their employees, agents, distributors, and other business affiliates.

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<sup>70</sup>The OECD recommendations suggest that:

[A] modern Conflict of Interest policy should seek to strike a balance, by identifying risks to the integrity of public organisations and public officials, prohibiting unacceptable forms of conflict, managing conflict situations appropriately, making public organisations and individual officials aware of the incidence of such conflicts, ensuring effective procedures are deployed for the identification, disclosure, management, and promotion of the appropriate resolution of conflict of interest situations.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, RECOMMENDATION OF THE COUNCIL ON GUIDELINES FOR MANAGING CONFLICT OF INTEREST IN THE PUBLIC SERVICE 3 (2003), <http://www.oecd.org/gov/ethics/2957360.pdf>.