



REVISTA DIGITAL ESA

Edição
Nº 01

ESA | OABRJ

Direito Administrativo



Brazilian Healthcare Fraud, FCPA Anti-Corruption Enforcement and Legal Compliance

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Introduction

Brazil is host to the world's sixth largest pharmaceutical (pharma) market and is an important strategic location for globally-oriented healthcare and life science companies. Top pharma companies in Brazil include Sanofi, Novartis, Roche, GSK, Johnson & Johnson, Pfizer, Bayer, MSD, Abbott, AstraZeneca and Merck. Other health industry key players such as 3M, GE Healthcare and Novo Nordisk also operate in Brazil and there has been considerable equity interest foreign capital investment in Brazilian hospitals and clinics.¹ Brand-name, generic and biosimilar drugs are integrally

part of Brazil's healthcare expenditure, now at 13% of its GDP,² and the pharmaceuticals market alone is expected to reach nearly USD 60 billion in 2020.³

Expressive U.S. Foreign Corrupt Practices Act (FCPA) anti-corruption enforcement⁴ took place in 2017 across a broad range of industries. Most noticeably concerning Brazil, the U.S. Department of Justice (DOJ) assessed USD 422 million in criminal penalties on Singapore-based Keppel Offshore & Marine Ltd. and its U.S. subsidiary Keppel Offshore & Marine USA Inc. for paying bribes to Petrobras officials and members of the then-governing

Partido dos Trabalhadores (PT) political party, yet another major case falling under the rubric of Operation Car Wash, the biggest corruption scandal in Brazilian history.⁵

Less prominently but no less significantly, 2017 FCPA enforcement also involved Brazil's healthcare arena, with regard to the foreign sales practices of U.S. publicly-traded medical device manufacturers Zimmer Biomet Holdings, Inc. and Orthofix International N.V.⁶ Later in the year, following their resolution, the DOJ announced a call for a concerted heightened scrutiny of healthcare company foreign

1. Law 13.097/2015, which entered into effect on January 20, 2015, amending Law 8.080/1990 (regulating the health sector in Brazil), expressly allows for the direct or indirect participation of foreign capital and companies in the sector, including by way of acquisition control and relative to the "installation, operation or exploration" of general and specialized hospitals and clinics. For example of how this opportunity has been seized upon see Sander Steverink, *The Brazilian Health Sector and Foreign Investments*, LinkedIn, (Jan. 20, 2017), <https://www.linkedin.com/pulse/brazilian-health-sector-foreign-investments-sander-steverink>.

2. *Brazil — A Must Win*, Healthcare & Life Sciences Review, PharmaBoardroom (Mar. 2018), https://pharmaboardroom.com/country_reports/brazil-pharma-report-2018/.

3. Ravikiran, *The Strong Growth of Pharma Markets in China, India, and Brazil*, MarketResearch.com (Market Research Blog) (Sept. 5, 2017), <https://blog.marketresearch.com/the-strong-growth-of-pharma-markets-in-china-india-and-brazil>.

4. For concise overview on the FCPA, which criminalizes government bribery and is criminally and civilly enforceable on company entities and individuals, see U.S. Dep't of Justice, *Foreign Corrupt Practices Act — An Overview*, <https://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act>, and U.S. Securities and Exchange Comm'n (SEC), *Foreign Corrupt Practices Act*, <https://www.sec.gov/spotlight/foreign-corrupt-practices-act.shtml>.

5. *United States of America v. Keppel Offshore & Marine Ltd., Deferred Prosecution Agreement, No. 17-CR-697 KAM* (E.D.N.Y. Dec. 22, 2017), available at <https://www.justice.gov/criminal-fraud/file/1021786/download>; see Press Release, U.S. Dep't of Justice, *Keppel Offshore & Marine Ltd. and U.S. Based Subsidiary Agree to Pay \$422 Million in Global Penalties to Resolve Foreign Bribery Case* (Dec. 22, 2017), available at <https://www.justice.gov/opa/pr/keppel-offshore-marine-ltd-and-us-based-subsidiary-agree-pay-422-million-global-penalties>.

6. This short article provides summary detail on their Brazil-related aspects and the resulting FCPA-charge DOJ and SEC investigation and settlement resolution.

practices, portending continued effective FCPA enforcement action in this area in Brazil as the wave for changing company behavior through legal compliance gains momentum and traction.

Zimmer Biomet Holdings, Inc.

As factually summarized in the relevant case documents,⁷ Biomet, Inc. (Biomet) was a U.S. publicly-traded⁸ orthopedic medical device manufacturer and seller incorporated in Indiana with its principal place of business in Warsaw, Indiana, U.S.A. In June 2015, Biomet's parent company LVB Acquisition, Inc. (LVB) was acquired by Zimmer Holdings, Inc., a publicly-traded⁹ designer, developer, manufacturer and seller of reconstructive orthopedic implants, also incorporated in Indiana and with its principal place of business in Warsaw, Indiana. As a result of the merger, Zimmer Holdings, Inc. changed its name to Zimmer Biomet Holdings, Inc. and LVB and Biomet became its wholly-owned subsidiaries.

Biomet sold its products into Brazil through its wholly-owned subsidiary Biomet International Corporation (Biomet International) and also into Argentina, China and elsewhere through other wholly-owned subsidiaries. Biomet's medical devices were sold in Brazil through distributors. From 2000 to 2008, Biomet, Biomet International and their related subsidiaries and employees paid approximately USD 1.1 million in cash incentives to doctors under the employ of Brazil's public Unified Health System (SUS) to facilitate the sale of Biomet products in Brazil's public hospitals. Through a Brazilian distributor, SUS doctors were bribed with payment of "commissions" or "scientific incentives" 10%-20% above the medical device purchase price.

On March 26, 2012, the DOJ Criminal Division Fraud Section filed an Information (criminal complaint) with the U.S. District Court of the District of Columbia against Biomet alleging violation

of the anti-bribery and books and records provisions of the FCPA. On that same date, acknowledging the filing of the Information and accepting responsibility for the misconduct it alleged, Biomet entered into a Deferred Prosecution Agreement (DPA).¹⁰ Taking into consideration that Biomet had investigated and voluntarily disclosed its own misconduct, was fully cooperative with the DOJ investigation and the contemporaneous SEC investigation,¹¹ undertook to implement an enhanced compliance program and other remedial measures (including the hiring of an independent monitor for eighteen months to assure DPA compliance)¹² and agreed to continue to cooperate with the DOJ, SEC and possible foreign authorities in any investigation regarding its conduct, it was agreed that Biomet would pay the monetary penalty of USD 17.28 million, a 20% reduction off the low-end of the U.S. Sentencing Guidelines fine range,¹³ to settle the criminal charges.¹⁴

7. *United States of America v. Zimmer Biomet Holdings, Inc., Deferred Prosecution Agreement, No. 12-CR-00080 RBW* (D.D.C. Jan. 13, 2017), available at <https://www.justice.gov/criminal-fraud/case/file/925831/download>; *In the Matter of Biomet, Inc., Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings and Imposing a Cease-and-Desist Order, Securities Exchange Act of 1934 Rel. No. 79780, Accounting and Auditing Enforcement Rel. No. 3843, Administrative Proceeding File No. 3-17771* (D.D.C. Jan. 12, 2017), available at <https://www.sec.gov/litigation/admin/2017/34-79780.pdf>.

8. Its Common Stock was registered with the SEC and publicly traded on the NASDAQ stock market.

9. Its Common Stock was registered with the SEC and publicly traded on the New York Stock Exchange (NYSE).

10. For background on the use of DPAs by the U.S. federal government to resolve corporate investigations in lieu of civil or administrative settlement or criminal trial see U.S. Gov't. Accountability Office, GAO-09-636T, *Corporate Crime: Preliminary Observations on DOJ's Use and Oversight of Deferred Prosecution and Non-Prosecution Agreements* (Jun. 25, 2009), <http://www.gao.gov/assets/130/122853.pdf>.

11. The SEC filed its complaint with the District Court of the District of Columbia on the same date.

12. For insight on the use of monitors in DPAs see *Memorandum from Gary Grindler, Acting Deputy Att'y Gen., to Heads of Dep't Components and U.S. Attorneys, on Additional Guidance on the Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations* (May 25, 2010), <http://www.justice.gov/dag/dag-memo-guidance-monitors.pdf>.

13. For backdrop on the DOJ's enforcement policy as now implemented see United States Attorney's Manual (USAM) Insert § 9-47.120, <https://www.justice.gov/criminal-fraud/file/838416/download>.

14. In the related SEC action, under its Consent Agreement with the SEC Biomet consented to entry of a court order requiring a disgorgement payment of USD 4,432,998.00 and payment of USD 1,142,733.00 in prejudgment interest and similar to the DPA agreed to enhance compliance program implementation and independent monitor hire.

In October 2013, however, Biomet discovered ongoing (and further pre-DPA) misconduct regarding its Brazil and Mexico operations and following internal investigation disclosed its findings to the internal compliance monitor, the DOJ and SEC. Resultantly, the term of the independent compliance monitor appointment and the DPA's end date were extended.

On January 12, 2017, the DOJ filed a Superseding Information against Zimmer Biomet.¹⁵ The DOJ alleged that within the years 2009 to 2013 Biomet executives, ignoring internal audit recommendation and a company-wide requirement to the contrary, had continued to use a certain Brazilian distributor that had paid bribes to SUS doctors to sell its products, which use was disguised via the marketing of its products by one of the distributor's affiliated companies. Moreover, due to supposed improper recordkeeping, Biomet couldn't determine whether the bribe payment was ongoing. Biomet earned close to USD 3.2 million in profits from its sales in Brazil between 2009 and 2013 due to said continued distributor use.

On that same date, Zimmer Biomet entered into a three-year term Deferred Prosecution Agreement

(2017 DPA) acknowledging the filing of the Superseding Information that charged it with violating the internal controls provisions of the FCPA and accepting responsibility for the alleged conduct.¹⁶ Taking the mitigating factors of cooperation and voluntary remedial measures into account, it was agreed that a criminal monetary penalty of approximately USD 17.46 million would be paid. Further, an independent compliance monitor would be hired to report to the DOJ on the company's anti-corruption compliance for three years.

Also on January 12, 2017, the SEC initiated a related administrative proceeding for Zimmer Biomet to cease and desist FCPA violation, factually adding to what it mirrored of the 2017 DPA that Biomet had recorded the business transactions of its prohibited Brazilian distributor as being transactions with its authorized distributor. Zimmer Biomet was ordered to pay a total of close to USD 13.03 million (USD 5,820,100.00 disgorgement plus USD 702,705.00 prejudgment interest and USD 6.5 million in civil penalty). As in the DOJ's 2017 DPA, the SEC's administrative proceeding called for independent compliance monitor hire for a term of three years.

Orthofix International N.V.

As factually summarized in the relevant case documents,¹⁷ Orthofix International N.V. (Orthofix) is a U.S. publicly-traded¹⁸ limited liability global medical device company incorporated in Curaçao¹⁹ with its headquarters in Lewisville, Texas, U.S.A. Its product line consists of surgical and non-surgical medical equipment including for the Spine, Orthopedics and Sports Medicine market sectors. It directly distributes in the U.S., the United Kingdom, Italy, Germany, Switzerland, Austria, France, Belgium, Puerto Rico and Brazil, where Orthofix do Brasil Ltda. (Orthofix Brazil), its São Paulo-incorporated and headquartered wholly-owned Brazilian subsidiary, markets and sells its products to public and private hospitals, healthcare providers and patients.²⁰

On January 18, 2017, the SEC initiated an administrative proceeding for Orthofix to cease and desist violation of the FCPA books and records and internal controls provisions. The order instituting the cease and desist proceedings alleged that from 2011 to 2013 Orthofix Brazil accounted for approximately

15. As a result of the 2015 merger, Zimmer Biomet assumed Biomet's obligations under the DPA.

16. It admitted it was aware of the corruption relating to its distributor and knowingly and willfully failed to implement adequate internal accounting control.

17. *In the Matter of Orthofix International N.V., Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21 C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease & Desist Order, Securities Exchange Act Rel. No. 79828, Accounting and Auditing Enforcement Rel. No. 3851, Admin. Proc. File No. 3-17800* (Jan. 18, 2017), available at <https://www.sec.gov/litigation/admin/2017/34-79828.pdf>.

18. Its Common Stock is registered with the SEC and publicly traded on the NASDAQ stock market.

19. Curaçao is a former Lesser Antilles (Netherlands) island and now autonomous country.

20. It maintains a leased management, distribution and administrative facility there. See Orthofix International N.V., 2017 Annual Report (Feb. 26, 2018), available at <http://ir.orthofix.com/static-files/58b98dc6-52e6-4632-9601-a27303deb3c0>.

5-7% of Orthofix's consolidated net sales. Twelve point five percent of Orthofix Brazil sales were to public-sector customers such as SUS hospitals and its doctors. Third-party commercial representatives made two-thirds of Orthofix Brazil's direct sales and sixteen outside distributors were responsible for Orthofix Brazil's indirect sales.²¹

To quote from the Order, "Orthofix provided budgets, financial targets, and guidance to Orthofix Brazil and approved certain actions and expenditures. Orthofix also received regular updates from Orthofix Brazil on many details regarding sales opportunities, numbers, and business developments. Orthofix set internal sales targets and management imposed pressure on subsidiaries to meet those targets."

Under such pressure, Orthofix Brazil implemented an improper payment scheme whereby it would pay a commission of approximately 33-43% of the hospital-billed sales price to the commercial representative responsible for the sale. The commercial representative would in turn pay the doctors involved typically 20-25% of the sales price.

Further, commercial representative-related companies would falsely invoice for services that were never rendered. These "administrative expenses" (approved by Orthofix Brazil's former general manager and instructed to be paid by its former finance director) would also be used to fund doctor payment. The doctor bank account direct deposit or in-person payment percentages, total amounts and instructions were openly discussed by Orthofix Brazil employees and the commercial representatives.

The Order also alleged that Orthofix Brazil would provide discounts of up to 70% to four third-party distributors who then used part of this discount to pay certain SUS doctors for use of Orthofix products (these discounts amounts were openly discussed with certain Orthofix Brazil employees). Similar to the scheme involving commercial representatives, Orthofix Brazil made "consulting for sales" payments on false invoices, which were inaccurately described in the company's books and records as being legitimate business expenses.

Despite the red flag of prior DOJ and SEC enforcement action

against it,²² Orthofix failed to devise and maintain an adequate system of internal accounting controls in Brazil until after discovery of the misconduct in late 2013. Acknowledging, however, that Orthofix had disclosed the Brazil allegations to the DOJ and the SEC as part of its self-reporting obligation relative to the Mexico misconduct settlement and that the remedial measures since taken by Orthofix and Orthofix Brazil have been considerable, such as customer representative and distributor termination, the development and implementation of new global accounting policies and internal and external (vendor) audit, expansion of Orthofix's compliance department and revision of employee compliance training, pursuant to the cease and desist order it was agreed that Orthofix would pay a civil money payment to the SEC of USD 2.928 million plus USD 2.928 million in disgorgement and USD 263,375.00 in prejudgment interest, as well as retain an independent compliance consultant for one year to test and review its compliance program.²³ The DOJ did not pursue the matter further.

21. Orthofix Brazil sold its products to the distributors who in turn resold the products.

22. In 2012, Orthofix entered into a DPA in which it admitted, accepted and acknowledged responsibility for USD 317,000.00 in "training and promotional expense"-related improper payment to Mexican government employees by its Mexican subsidiary, Promeca S.A. de C.V., and paid a USD 2.22 million criminal fine; under its civil injunction action settlement with the SEC Orthofix paid approximately USD 5.2 million in disgorgement and prejudgment interest. See *United States of America v. Orthofix International N.V., Deferred Prosecution Agreement, No. 12-CR-00150* (E.D. Tex. July. 10, 2012), available at <https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/08/15/2012-07-10-orthofix-dpa.pdf>. Additionally, Orthofix was ordered undertake certain FCPA compliance program remedial measures, including two-year self reporting to the SEC. See *Securities and Exchange Commission v. Orthofix International N.V., Consent of Defendant Orthofix International N.V., No. 12-CV-419* (E.D. Tex. Apr. 9, 2012), available at https://www.sec.gov/Archives/edgar/data/884624/000110465912048124/a12-16105_1ex99d1.htm.

23. Further, Orthofix agreed to pay USD 8.25 million and four Orthofix executives (a former accounting executive, its former corporate CFO and two former sales executives) also agreed to pay penalty under SEC orders to resolve accounting violations (as alleged by the SEC, Orthofix improperly recognized revenue on certain distributor and customer transactions for 2011 through the beginning of 2013). See *In the Matter of Orthofix International N.V., Order*

Heightened FCPA Healthcare Fraud Scrutiny

In her keynote address at the American Conference Institute's 8th Global Forum on Anti-Corruption in High Risk Markets on July 25, 2017, Sandra Moser, Acting Chief of the Fraud Section of the DOJ, made the observation²⁴ that:

We stand at a critical juncture in the fight against transnational corruption. And the importance of this fight cannot be overstated. The impact of corruption is unambiguous.

[...]

Here at home, foreign corruption puts American companies that are playing by the rules at a competitive disadvantage, resulting in significant and tangible harm to business, employees and shareholders.

[...]

On the international side, in recent years healthcare companies have come before the Fraud Section in connection with FCPA violations. Investigations

have revealed that healthcare companies operating overseas frequently interact with state-employed doctors and foreign public officials who work for government-owned hospitals and medical institutions. In addition, publicly funded and administered foreign health care programs are invariably run by government officials, which means that, to do business in these countries, a company must deal with government officials. As a result, we have seen a number of significant FCPA cases involving the payment of bribes and kickbacks by healthcare companies to foreign officials to obtain a wide variety of improper business advantages.

Stating that “we are taking additional steps to enhance our enforcement of the FCPA against both corporate and individual actors, and to promote transparency in doing so,” she announced that Corporate Fraud Strike Force of the Health Care Fraud Unit of the DOJ would begin to work “hand in hand” with FCPA prosecutors:

Together they will investigate and prosecute matters relating to health care bribery schemes,

both domestic and abroad. This increased coordination will ensure that companies, their executives, employees, and agents are held to account for the payment of bribes and kickbacks to foreign and domestic officials and actors regardless of the market. The reality is that the Fraud Section stands uniquely positioned to investigate and prosecute cases involving both domestic bribery and kickback schemes and FCPA anti-bribery violations in the healthcare industry and beyond.²⁵

The ongoing “Prosthetic Mafia” healthcare scam context to the Zimmer Biomet and Orthofix enforcement actions highlights that such global watchdog investigation and prosecution doubled efforts is undoubtedly warranted, and should prove to be effective, in Brazil.

Prosthetics Mafia Healthcare Scam Example

The Prosthetics Mafia healthcare scam first came to primetime public light on January 4, 2015 with the Brazilian Sunday-evening 60 Minutes-style television news program Fantástico story “A

Instituting Cease-and-Desist Proceedings Pursuant to Section 21 C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order, Securities Exchange Act of 1933 Rel. No. 79815, Securities Exchange Act of 1994 Rel. No. 79815, Accounting and Auditing Enforcement Rel. No. 3845, Admin. Proc. File No. 3-17791 (Jan. 18, 2017), available at <https://www.sec.gov/litigation/admin/2017/33-10281.pdf>; In the Matter of Jeffrey Hammel, CPA, Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21 C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order, Securities Exchange Act of 1933 Rel. No. 10282, Securities Exchange Act of 1934 Rel. No. 79817, Accounting and Auditing Enforcement Rel. No. 3846, Admin. Proc. File No. 3-17792 (Jan. 18, 2017), available at <https://www.sec.gov/litigation/admin/2017/33-10282.pdf>; In the Matter of Brian McCollum, Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21 C of the Securities Exchange Act of 1934, Making Findings, and Imposing Cease-and-Desist Orders, Securities Exchange Act of 1934 Rel. No. 79819, Accounting and Auditing Enforcement Rel. No. 3847, Admin. Proc. File No. 3-17793 (Jan. 18, 2017), <https://www.sec.gov/litigation/admin/2017/34-79819.pdf>; In the Matter of Kenneth Mack and Bryan McMillan, Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21 C of the Securities Exchange Act of 1934, Making Findings, and Imposing Cease-and-Desist Orders, Securities Exchange Act of 1934 Rel. No. 79820, Accounting and Auditing Enforcement Rel. No. 3848, Admin. Proc. File No. 3-17794 (Jan. 18, 2017), available at <https://www.sec.gov/litigation/admin/2017/34-79820.pdf>.

24. Sandra Moser, speech (Keynote Address, 8th Global Forum on Anti-Corruption Compliance in High Risk Markets, Jul. 25, 2017), American Conference Institute (ACI), available at <https://pt.scribd.com/document/355621572/Sandra-Moser-Remarks>.

25. *Id.*

Prosthetics Mafia Puts Lives at Risk with Unnecessary Surgery.”²⁶ The undercover investigative reporting in the States of Rio de Janeiro, São Paulo, Minas Gerais, Rio Grande do Sul and Santa Catarina revealed, among other things, orthopedic and implant device distributors offering cash commission for product prescription and fraud related to systematic unnecessary replacement surgery in hospitals.²⁷

On September 20, 2016, the Criminal Justice Defense of Health Services Users (PRÓVIDA) and Health Defense (PROSUS) divisions of the Federal Public Prosecutor’s Office filed the first complaint to the Federal District Civil Police and Federal Public Prosecutor’s

Office “Operation Mr. Hyde” Prosthetics Mafia investigation.²⁸ According to the complaint, doctors involved in the scheme²⁹ directed patients via fraudulent medical declarations and falsified documents principally to Home Hospital Ortopédico e Medicina Especializada in Asa Sul, Brasília, for unnecessary surgery involving the insertion of prosthetics and stents supplied by a TM Medical hospital products supplier representative, which material was either non-conforming with what was stated in the insurance claims³⁰ or out of date for use.³¹

On November 28, December 13 and December 14, 2016 respectively, the private group health insurer association ABRAMGE (Brazilian Association of Group Medicine)

filed three U.S. civil fraud and conspiracy lawsuits against five U.S. medical group defendants, one of which was Zimmer Biomet.³² ABRAMGE alleged that fraudulent improper payments or kickbacks were paid to SUS doctors for unnecessary purchase of their devices, that unnecessary medical procedures (justified on the basis of falsified medical reports and sometimes using expired or damaged devices) were conducted and that via this fraud on the Brazilian medical device market insurers were resultantly overbilled for the products and procedures. According to the complaints, this is standard operating procedure for medical device companies selling products in Brazil.

On May 15, 2017, as a result of “Operation Exposed Invoice”

26. Investigative journalism in Brazil, however political and ideological the media tends to be, does play a very useful muckraking role.

27. According to the report, the prosthetics market turnover is BRL 12 billion annually and, as stated by one witness interviewed, the orthopedics, neurology and cardiology areas to it are the most lucrative targets for bribery and fraud. To watch the actual broadcast in its entirety see Fantástico, TV Globo, *Máfia das Próteses Coloca Vidas em Risco com Cirurgias Desnecessárias* [A Prosthetics Mafia Puts Lives at Risk with Unnecessary Surgery] (Jan. 4, 2018), <http://g1.globo.com/fantastico/noticia/2015/01/mafia-das-protese-coloca-vidas-em-risco-com-cirurgias-desnecessarias.html>, which contains a video of the transmission as well as its partial transcript.

28. Complaint, *Federal Public Prosecutor’s Office Investigative Proceeding No. 2016.01.1.098809-5*, 2nd Criminal Court of Brasília, filed Sept. 20, 2016, available at http://www.mpdf.mp.br/portal/pdf/noticias/setembro_2016/denuncia_mr_hyde.pdf. The Federal Public Prosecutor’s Office (MPF) and the Federal Police (DFP) are the two principal crime-investigating institutions in Brazil and frequently work together. The MPF can also conduct civil investigation, which can sometimes inform criminal investigation (and administrative investigation by the National Disciplinary Board (CRG) of the Office of the Comptroller General (CGU)) due to factual overlap. See footnote 55, *infra*, for example of such joint effort.

29. According to the complaint, the doctors received 30% of the total of each surgery, which was divided up amongst them.

30. Cassi, Bradesco, Geap, Unimed, Assefaz, Gama and Caps-Saúde were identified as some of the insurance companies falling victim to the scheme.

31. TM Medical oriented the doctors as to the filling out of surgery-related documentation, which reports always indicated the necessity of medical equipment and devices and at the highest price. In the second phase of the Operation, intercepted telephone conversations revealed the cost of the surgeries to be 400 to 1000% above normal. See Public Prosecutor’s Office of the Federal District and Territories, *Operação Mr. Hyde: Segunda Fase Cumpre Cinco Mandados de Busca e Apreensão e de Condução Coercitiva* [Five Search and Seizures and Arrests in the Second Phase to Operation Mr. Hyde] (Oct. 6, 2016), <http://www.mpdf.mp.br/portal/index.php/comunicacao-menu/noticias/noticias-2016/noticias-2016-lista/8783-operacao-mr-hyde-segunda-fase-cumprir-cinco-mandados-busca-e-apreensao-e-de-conducao-coercitiva>.

32. Complaint, *Associação Brasileira de Medicina de Grupo d/b/a Abramge v. Stryker Corp.*, No. 1:16-cv-1366 (W.D. Mich. Nov. 28, 2016), Complaint, *Associação Brasileira de Medicina de Grupo d/b/a Abramge v. Abbott Laboratories, Inc.*, No. 1:16-cv-11326 (N.D. Ill. Dec. 13, 2016), available at https://globalinvestigationsreview.com/digital_assets/9d256d5e-e022-4f54-bb49-8f89f6d64e86/abbottcomplaint_abramge.pdf and Complaint, *Associação Brasileira de Medicina de Grupo d/b/a Abramge v. Boston Scientific, Arthrex, Inc. and Zimmer Biomet Holdings, Inc.*, No. 1:16-cv-01184-GMS (D. Del. Dec. 14, 2016), available at <https://www.courthousenews.com/wp-content/uploads/2016/12/Boston-Scientific.pdf>.

investigation,³³ the Anti-corruption Nucleus — Car Wash Task Force of the Federal Public Prosecutor's Office in Rio de Janeiro filed a complaint with the 7th Federal Criminal Court of Rio de Janeiro against former state governor Sérgio Cabral, former state health secretary Sérgio Côrtes and others³⁴ charging them with corruption, cartel forming and bidding fraud relative to the employment of an “international bidding club” cartel of foreign companies³⁵ organized by Miguel Iskin, president of Brazilian medical device distributor Oscar Iskin, from which winners were

pre-selected for public tenders of medical equipment and prosthetics purchased by the National Institute of Traumatology and Orthopedia (INTO) and the Secretary of Health and Civil Defense (SESDEC) of Rio de Janeiro.³⁶

The scheme was allegedly first implemented in 2004, when Côrtes was Director General of INTO³⁷ and continued after 2007, when Cabral was elected governor and Côrtes was named secretary of health by him. According to the complaint, between January 1, 2007 and December 28, 2014

at least BRL 16.2 million was paid out in thirty five monthly bribe payments.³⁸

Brazilian Congressional and Senate Parliamentary Investigating Committee Recommendation

The systematic corruption in the Brazilian healthcare area having to do with prosthetic and other medical devices resulted in a special Congressional Parliamentary Investigating Committee (CPI) being formed in 2015³⁹ that in its final report⁴⁰ listed fifteen companies that it

33. This Operation was a result of the Calicut and Efficiency Operations, which investigations resulted in Sérgio Cabral's arrest and imprisonment. As was alleged under Operation Calicut, the construction company Andrade Gutierrez paid bribes for construction in the state of Rio de Janeiro, including subway line expansion and the modernizing of the Maracanã stadium for the World Cup and Olympics, which bribes were laundered through the purchase of expensive jewelry and the law firm of Cabral's wife. Complaint, *Federal Public Prosecutor's Office Investigative Proceeding No. 0509503-57.2016.4.02.5101*, 7th Criminal Court of Rio de Janeiro, filed Dec. 5, 2016, available (in part) at <http://politica.estadao.com.br/blogs/fausto-macedo/wp-content/uploads/sites/41/2016/12/denuncia1.pdf>. Operation Efficiency investigated the alleged payment of BRL 16.5 million in bribes by Eike Batista to Sérgio Cabral involving transfers into offshore accounts, one of them being named “Efficiency.” Complaint, *Federal Public Prosecutor's Office Investigative Proceeding No. 0501634-09.2017.4.02.5101*, 7th Criminal Court of Rio de Janeiro, filed Feb. 10, 2017, available at <http://www.mpf.mp.br/rj/sala-de-imprensa/docs/pr-rj/denuncia-operacao-eficacia>.

34. Complaint, *Federal Public Prosecutor's Office Investigative Proceeding No. 0503435-57.2017.4.02.5101*, 7th Criminal Court of Rio de Janeiro, filed May 15, 2017, available at <http://www.mpf.mp.br/rj/sala-de-imprensa/docs/pr-rj/denuncia-fatura-exposta>.

35. Rizzi, M.D. Internacional, AKA Trade, Indumed, Per Prima, Comercial Médica, Philips Medical Systems Nederland B.V., DBS3 Comercial Científica, Drager, Helo Med, Maquet, Dixtal, New Service, Ultra Imagem, M&M Lopes, Stryker, Macromed, Multimedic, AGA Med and Siemens.

36. Under Article 42 § 4 of the Law 8.666/1993 (Brazil's Public Tender Law), foreign bidder bid proposals must include the same tax amounts imposed exclusively on Brazilian bidders. The companies were directed to include tax charges on their invoices, which invoices were approved and paid by INTO and SESDEC at inflated amounts and included tax, despite INTO and SESDEC being exempt from paying the tax. It is alleged that the companies decided the price of the winning bid among themselves.

37. Sérgio Côrtes was Director General of INTO from 2002-2006, where Cesar Romero, his right-hand man in facilitating the scheme at INTO was head of its legal department. In 2007, Sérgio Cabral was elected governor of the State of Rio de Janeiro naming Sérgio Côrtes as SESDEC secretary and Romero as executive sub secretary. Romero's statements under a plea bargain arrangement with the prosecutors greatly assisted the investigation.

38. According to the complaint, 40% of the winning bid price (equivalent to the tax amount that was stated) went directly to Miguel Iskin and Côrtes via payments made abroad under a letter of credit with a Miguel Iskin company as beneficiary for playing an intermediary role in the importation, which amounts were received in a Bank of America account held by Miguel Iskin in the United States. An additional 10% of the total winning bid price would be paid out as follows: Cabral receiving 5% (his standard take as per the “rules of the game”), Côrtes receiving 2%, Romero 1%, “someone” in the Rio de Janeiro State Court of Accounts (TCE-RJ) receiving 1% and 1% going to the scheme's general pool, which payments would be paid out by financial operators Carlos Miranda and Carlos Bezerra under various codenames, as their handwritten notes revealed.

39. Comissão Parlamentar de Inquérito Destinada a Investigar a Cartelização na Fixação de Preços e Distribuição de Órteses e Próteses, inclusive, com a Criação de Artificial Direcionamento da Demanda e Captura dos Serviços Médicos por Interesses Privados — Máfia das Órteses e Próteses no Brasil [The Congressional Parliamentary Investigating Committee to Investigate the Cartel to Prosthetic and Stent Price Fixing and Distribution Including by Way of Artificial Channeling of Demand and the Capture of Medical Services by Private Interests — the Prosthetics and Stent Mafia in Brazil] (CPIORTES). Brazil's legislature, the National Congress (Congresso Nacional), is comprised of the Federal Senate (Senado Federal) and the Chamber of Deputies (Câmara dos Deputados). Chamber of Deputies is substituted by Congress throughout this article for ease of reference.

40. Final Report REL 2/2015 CPIORTES, presented on Jul. 15, 2015, available at http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra?codteor=1362241&filename=REL+2/. The report was based on hearing testimony and the providing of information by the Brazilian Ministry of Health, the Brazilian Federal Council of Medicine (CFM), the Brazilian Association of Medicine (AMB), the National Council of Health Secretaries (CONASS) the National Council of Municipal Health Secretaries (CONASEMS) as well as on the testimony of Brazilian HMO representatives, doctors and lawyers and relied on Federal Police investigation results.

would notify the Federal Public Prosecutor's Office to continue to investigate.⁴¹ The report also proposed four draft bills to aid in barring abusive commercial practice.⁴² The first bill, PL 2451/2015,⁴³ proposed that court orders for urgent medication prescription or medical treatment involving medical devices should necessarily be based in part on SUS and health plan input. The second bill, PL 2452/2015,⁴⁴ proposed modifying the Brazilian Consumer Defense Code (Law 8.078/1990) to typify the gaining of undue advantage in the commercialization of medication, prosthetics, stents or implants of any nature, and altering the Brazilian Penal Code (Decree-Law n.2.848/1940) and Heinous Crimes legislation (Law 8.072/1990) to

criminalize medical fraud (up to six years imprisonment),⁴⁵ medical corruption (up to six years imprisonment and fine), the reuse of implant devices without due authorization (up to four years imprisonment) and the promoting of unnecessary surgery via court orders for medical treatment (up to six years imprisonment and fine). The third bill, PL 2453/2015,⁴⁶ proposed modifying Law 8.080/1990 (which created Brazil's Unified Health System (SUS)) to create a SUS-related Education in Medical Devices and Technology System to discourage sales representative interaction with healthcare professionals. Lastly, the fourth bill, PL 2454/2015,⁴⁷ suggested standardized public listing of medical device prices.

The Brazilian Senate also formed a parliamentary investigating committee on prosthetic device fraud and abuse (Senate CPI das Próteses or CPIDPRO).⁴⁸ The Senate Committee held twelve hearings over the course of a year,⁴⁹ five of which were public and were of presentations, including that of the Ministry of Health, which among other things informed that 90% of the BRL 20 billion medical device market in Brazil is comprised of small to mid-sized companies and that nearly all implantable medical device purchase is financed by HMOs or SUS.

Similar to the Congressional Parliamentary Investigating Committee, the Senate Parliamentary Investigating Committee suggested relay of

41. The report states that the CPI was formed to specifically investigate the bribe payments made by distributors to doctors that were revealed in the Fantástico broadcast in the beginning of 2015. The companies named in the report are: Oscar Iskin, Totalmedic, Life X, Orcime, IOL, Brumed, Strehl, Intelimed, Prohosp, Tellus Rio Comércio e Importação e Exportação Ltda., Osteocare Serviços Médicos, Locação e Representação Ltda., Signus do Brasil Comércio de Materiais Hospitalares Ltda., Biotronik Comercial Médica Ltda., Biomet and Intraview.

42. The Brazilian Constitution of 1988 allows for the formation of Congressional and Senate Parliamentary Investigating Committees, which, similar to the Brazilian judiciary, can hear witnesses, make document requests and access bank and tax information. Their findings are outlined in a final report, which can direct the Federal Public Prosecutor's Office to take further action and can also suggest draft legislation.

43. First presented on Jul. 17, 2015, PL 2451/2015 was initially approved in modified draft form on Jun. 16, 2016 by the Family and Social Security Commission of the Brazilian Congress (CSSF). Slight alterations have been made by Constitution and Justice and Citizenship Commission (CCLC) of the Brazilian Congress to the text, redrafted as of May 16, 2018. Brazilian Congress, *PL 2451/2015*, <http://www.camara.gov.br/proposicoesweb/fichadetramitacao?idproposicao=1594343>.

44. First presented on Jul. 17, 2015, PL 2452/2015 was received on Dec. 1, 2015 by the CSSF, which modified its text (some of the changes being indicated here) and joined the draft bill to PL 221/2015 (presented on Feb. 5, 2015 by Congresswoman Maria do Socorro Jô Moraes), which also proposes modifying the Brazilian Consumer Defense Code to typify the gaining of undue advantage in the commercialization of medication, prosthetics, stents or implants of any nature. No further action appears to have been taken. Brazilian Congress, *PL 2452/2015*, <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=1594345> and *PL 221/2015*, <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=946065>.

45. Up to fifteen years in the case of death (as a heinous crime).

46. First presented on Jul. 17, 2015, PL 2453/2015 has been with the CSSF since Jul. 6, 2016 and no further action appears to have been taken. Brazilian Congress, *PL 2453/2015*, <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=1594348>.

47. First presented on Jul. 17, 2015, PL 2454/2015 was received on May 30, 2017 by the CSSF, which joined the draft bill to PL 380/2015 (presented on Feb. 12, 2015 by Congressman Fabio Cruz Mitidieri), both suggesting modifying Law 10.742/2003, which establishes the guidelines for the economic price regulation policy and creates the Brazilian Drugs Market Regulation Chamber (CMED), to also relate to the prosthetics, stents and health markets sector. Brazilian Congress, *PL 2454/2015*, <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=1594350> and *PL 380/2015*, <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=946750>. No further action appears to have been taken.

48. Brazilian Senate, *Atividade Legislativa, CPIDPRO, CPI dos Próteses*, <https://legis.senado.leg.br/comissoes/comissao;jsessionid=5999844AE0FBBEEC75DF8403692BCD2E70&codcol=1900>. The commission was formed under Requerimento RQS 93 [Request No. 93] on May 31, 2015.

49. The deadline for its conclusion and submission of its final report was Sept. 28, 2015. The commission hearing actually concluded on Aug. 15, 2016, without an approved final report. *Id. See also note 50, infra*.

Federal Police investigation results to the Federal Public Prosecutor's Office for possible criminal prosecution purposes. The Senate Parliamentary Investigating Committee also recommended that the Ministry of Health form and operate an implantable device database and that it establish norms and protocols for SUS professionals to follow relative to the acquisition and use of implantable medical devices. It suggested that the Brazilian Health Regulatory Agency (ANVISA) establish nomenclature and communication means relative to medical devices in keeping with international standards. And lastly it recommended to the Federal Counsel of Medicine (FCM) and the Federal Counsel of Odontology (FCO) that they be

more vigilant in their oversight of implantable medical device purchase and use and look beyond patient complaints to information provided by the medical insurance providers and SUS as well as the database to be created. A draft bill was proposed incorporating some of the recommendations made, as well as criminalizing the offering or receiving of a commission in the prescription of medical devices.⁵⁰

Conclusion

"Le Brésil n'est pas un pays sérieux" is the phrase commonly attributed to Charles de Gaulle from the 1960s. In spite of the changing world events since the time of the "Lobster War" between France and Brazil, this critical sarcasm still resonates today with ongoing

pronouncements of Brazil being plagued with chronic and endemic corruption and fraud⁵¹ and that the country "needs to reform its political system and ensure that existing laws are implemented and enforced."⁵²

Total medical device import in Brazil for year 2017 was USD 8.6 billion, a 5.4% increase over 2016.⁵³ Two point three million prosthetics were used in SUS surgeries in 2017, at a cost of BRL 1.25 billion in Brazilian taxpayer spending.⁵⁴ It appears that the considerable healthcare market in this area similar to any other in Brazil is not immune to criminal corruption.⁵⁵ The effectiveness of Federal Police, Civil Police and Federal Public Prosecutor's Office investigation in obtaining

50. The final report of the Senate CPI was that of Senator Humberto Costa, which report was submitted on Aug. 15, 2016. Brazilian Senate, *Relatório do Senador Humberto Costa*, <http://legis.senado.leg.br/sdleg-getter/documento?dm=4001079&disposition=inline>. The Senate CPI was concluded, however, without the report having been approved. Brazilian Senate, Ofício No. 178/2016 — CPIDPRO, *Encerramento dos Trabalhos da CPI das Próteses [Senate CPI Termination]*, <http://legis.senado.leg.br/sdleg-getter/documento?dm=4001079&disposition=inlin>.

51. See Transparency International, *Corruption Perceptions Index 2017* (Feb. 21, 2018), https://www.transparency.org/news/feature/corruption_perceptions_index_2017, which ranks Brazil in 96th place (out of 180 countries and territories), together with Columbia, Indonesia, Panama, Peru, Thailand and Zambia, on the basis of expert and businesspeople perception of public sector corruption.

52. *Id.*, *Brazil: Overview of Corruption and Anti-corruption* (Dec. 16, 2014), <https://knowledgehub.transparency.org/helpdesk/brazil-overview-of-corruption-and-anti-corruption>. "[T]he country's systemic failures [...] open opportunities to mismanagement and corruption. Such opportunities come from the political finance environment, the politicization of key government positions and weak oversight mechanisms which, combined with a rather ineffective judiciary, contributes to fueling the culture of impunity that permeates the country."

53. See Brazilian Alliance for an Innovative Health Industry (ABIIS), Economic Bulletin No. 21 (March 2018), *Setor de Dispositivos Médicos (DMAs) no Brasil, Desempenho do Setor [The Brazilian Medical Devices (DMAs) Sector, Sector Performance]*, https://abiis.org.br/wp-content/themes/mxp_base_theme/mxp_theme/assets/abiis_boletim-21_-jan-dez-17b.pdf.

54. See the press conference presentation of Health Minister Ricardo Barros at Barros, Ricardo, *Ministério da Saúde Lança Licitação para Registro de Preços de Órteses e Próteses [The Ministry of Health Calls a Prosthetic and Stent Pricing Registration Bid]* (Ministry of Health press conference PowerPoint presentation, Feb. 1, 2018), <http://portalarquivos2.saude.gov.br/images/pdf/2018/fevereiro/01/Coletiva-Ortese-e-Protese.pdf>.

55. As continuing example, on July 4, 2018, the Anti-corruption Nucleus — Car Wash Task Force of the Federal Public Prosecutor's Office in Rio de Janeiro announced in a press conference that, together with the Brazilian Administrative Counsel for Economic Defense (CADE), the Federal Police (DFP), the Federal Court of Accounts (TCU), the Office of the Comptroller General (CGU) and the Brazilian Revenue Service (RF), a new operation, "Operation Resonance," was now being launched to further the "Operation Exposed Invoice" investigations and that twenty two warrants for arrest had been issued. These warrants include that of Frederik Knudsen, Philips Healthcare Patient Care and Monitoring Solutions (PSMS) Product [Sales] Manager at the time in question, as well as Daurio Speranzini Júnior, Philips Healthcare Senior Vice President and head of Philips Medical Systems in Brazil at the time in question and currently President and CEO Latin America of GE. See Prosecutor's Office of the Federal District and Territories, *Operação Ressonância: MPF aprofunda investigação sobre fraudes no Into* [Operation Resonance: MPF Furthers Investigation of Fraud within INTO] (July. 4, 2018), <http://www.mpf.mp.br/rj/sala-de-imprensa/noticias-rj/operacao-ressonancia-mpf-rj-aprofunda-investigacao-sobre-fraudes-no-into>. For background on the Operation Exposed Invoice investigation see footnotes 33-38, *supra*, and accompanying text, as well the implicating exposé of facts justifying the request for warrant for arrest contained in Request for Warrant for Arrest, *Anti-corruption Nucleus — Car Wash Task Force of the Federal Public Prosecutor's Office in Rio de Janeiro, Concerning Federal Public Prosecutor's Office Investigative Proceeding No. 0501634-09.2017.4.02.5101*, 7th Criminal Court of Rio de Janeiro, filed Jun. 15, 2018, available at <http://www.mpf.mp.br/rj/sala-de-imprensa/docs/pr-rj/prisao-ressonancia>.

evidence⁵⁶ goes some way in implicating companies⁵⁷ and even a few prominent politicians, and the earnest application of anti-corruption preventative measures such as proposed under Congressional and Senate Parliamentary Investigating Committee recommendation as well as of Law No. 12.846/2013

(The Clean Company Act) could have an impact on prioritizing compliance within this area.⁵⁸ However, “[i]t is one thing for laws to be in place, but it is quite another for them to be respected.”⁵⁹

As is readily evident via international news coverage of its more high-profile scandals, Brazil’s politicians

regularly obstruct justice and avoid prosecution on corruption charges, many serving time under mere house arrest, if at all.⁶⁰ And, as can be clearly seen in cases as large as those involving Operation Car Wash to smaller instances such as those of Zimmer Biomet and Orthofix,⁶¹ the business culture is also prone to mimicking political reality in

56. There has also been a medical device manufacturer cartel investigation conducted by the Brazilian Administrative Counsel for Economic Defense (CADE) based on apparent public bid collusion. The “Operation Merchant of Venice” investigation, supported by information supplied by the Federal Police, was also supported by data from the Federal Court of Accounts (TCU), which has as its institutional directive the promotion of public sector integrity. See Notícias [Press Release], CADE, *Cade Conducts Dawn Raid to Investigate Alleged Cartel in the Market of Orthoses and Prostheses* (Dec. 2, 2015, updated Apr. 11, 2016), <http://en.cade.gov.br/press-releases/cade-conducts-dawn-raid-to-investigate-alleged-cartel-in-the-market-of-orthoses-and-prostheses> and see Tribunal das Contas da União (TCU), *The Federal Courts of Accounts (TCU — Brazil)*, <https://portal.tcu.gov.br/english-2/>. Two CADE administrative proceedings, initiated Jun. 20, 2017, have resulted from Administrative Inquiry No. 08001.00000/2015/29, one involving four companies, 29 individuals and the industry associations Brazilian Medical Devices Manufacturers Association (ABIMO) and the Brazilian Association of Importers of Medical Equipment and Devices (ABIMED) relative to collusive activity having allegedly occurred between 2004 and 2015, and the other involving 46 companies, 80 individuals and the Brazilian Digital Agencies Association (ABRADI). See Notícias [Press Release], CADE, *General Superintendence Initiates Administrative Proceeding to Investigate a Cartel in the Market of Orthoses, Prostheses and Special Medical Supplies* (Jun. 22, 2017, updated Aug. 4, 2017), <http://en.cade.gov.br/press-releases/cade2019s-general-superintendence-initiates-administrative-proceeding-to-investigate-a-cartel-in-the-market-of-orthoses-prostheses-and-special-medical-supplies>.

57. This includes internationally. The International Cooperation Unit of the MPF has been lauded for the assistance it rendered to the DOJ and SEC (as well as the FBI) relative to Operation Car Wash and the 2016 Odebrecht S.A. and Braskem S.A. enforcement actions. See SEC, *Odebrecht and Braskem Plead Guilty and Agree to Pay at Least \$3.5 Billion in Global Penalties to Resolve Largest Foreign Bribery Case in History*, <https://www.justice.gov/opa/pr/odebrecht-and-braskem-plead-guilty-and-agree-pay-least-35-billion-global-penalties-resolve> (quoting former United States Attorney for the Eastern District of New York Robert L. Capers: “These resolutions are the result of an extraordinary multinational effort to identify, investigate and prosecute a highly complex and long-lasting corruption scheme that resulted in the payment by the defendant companies of close to a billion dollars in bribes to officials at all levels of government in many countries.”).

58. Brazil is a signatory to the Convention on Combating Bribery of Foreign Officials in International Business Transactions of the Organisation for Economic Co-operation and Development (OECD), the U.N. Convention against Corruption (UNCAC) and the Inter-American Convention against Corruption (IACAC). A number of its laws penalize acts of malfeasance involving public officials, such as the Brazilian Penal Code (Decree-Law n. 2.848/1940), Law 12.850/2013 (the Organized Crime law), Law 9.613/1998 (amended by Law 12.683/2012, criminalizing money laundering), the Public Tender Law (Law 8.666/1993) Federal Court of Accounts Law 8.443/1992), Law 8.112/1990 (the Federal Public Servants Regimen) and Law 8.429/1992 (which applies civil penalty for severe administrative misconduct). The Clean Company Act was enacted to specifically counter public and private sector corruption and imposes strict liability on companies operating in Brazil for domestic and foreign bribery committed by their employees, applying civil and administrative fines of up to 20% of a company’s prior year gross revenue or suspension or dissolution. Leniency is possible for investigation cooperation and violation self-disclosure and fine reduction is possible depending on the quality of the company’s compliance program. See Lei No. 12.846 de 1º de Agosto de 2013 [Law No. 12.846 of Aug. 1 2013], http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2013/lei/l12846.htm. In its respect, borrowing the words of Moser, “[o]ne need look no further than Brazil to see how far and how fast a country can come in confronting corruption head on,” who cites Brazil as one of the countries that have “watched” the United States, “[...] have worked with us, [...] have learned from us, and [...] are now following the example we set [...]” See note 24, *supra*. See also Zachary B. Tobolowsky, *Brazil Finally Cleans Up Its Act with the Clean Company Act: The Story of a Nation’s Long-Overdue Fight against Corruption*, 22 *Law & Bus. Rev. Am.* 383 (2016), available at <http://scholar.smu.edu/lbra/vol22/iss4/5> (“Make no mistake, Brazil’s passage of such a punitive and extensive anti-corruption law was an improbable achievement, and this unprecedented opportunity is one that the people of Brazil simply cannot afford to waste.”).

59. Tobolowsky, *Id.* “[F]or Brazil to effectively sever the grip of corruption, it will require more than political will and legislative measures.” *Id.*

60. See Samoa Observer, *Massive Graft Probe in Brazil Powers Electronic Bracelets* (May 31, 2018), http://www.samoobserver.ws/en/27_08_2017/technology/23642/Massive-graft-probe-in-Brazil-powers-electronic-bracelets.htm (“Wealthy businessmen or politicians caught up in the massive ‘Car Wash’ investigation are often serving time at home, either by reaching plea bargains or appealing.”). See also Folha de São Paulo International, *Brazil Supreme Court Unanimously Convicts First Congressman in Operation Lava Jato* (May 30, 2018), <http://www1.folha.uol.com.br/internacional/en/brazil/2018/05/1970423-brazil-supreme-court-unanimously-convicts-first-congressman-in-operation-lava-jato.shtml>. Nelson Meurer is the first Brazilian congressman to be convicted by the Brazilian Supreme court relative to Operation Car Wash. Accused of having solicited and received BRL 29.7 million in 99 monthly bribe payments of BRL 300,000.00 each, Meurer was sentenced to close to fourteen years in prison for corruption and money laundering but will only begin to service his sentence once decision is rendered on his appeals, certain to be filed. His two sons were also implicated for receiving kickbacks. One faces close to five years but under house arrest. His other son will not be serving any time as supposedly the statute of limitations had run out on the charge against him.

61. See text and accompanying notes, *supra*, pages 2-5.

the making of corrupt payments or otherwise evading of legal rules and regulation with relative impunity. Despite the greater gains to be achieved from building long-term business goals with propriety, integrity and transparency⁶² — first and foremost reputationally — companies and their executives, so inclined, ignore this potential and perpetuate the status quo. Fundamentally problematic is that without true answerability they are ill-disposed to change this approach.

The extra-territorial reaching of a now-empowered FCPA, with the actual accountability through aggressive application of fines, threat of individual prison sentencing in the United States and compulsory appointment of internal monitors to scrutinize and dissuade should efficaciously curb the temptation of SEC-registered companies operating in Brazil not to “play by the rules of the game”⁶³ of corrupt payment and fraudulent scheming but to “play by the rules”⁶⁴ of maintaining best practices involving Brazil’s public healthcare system in the near and short term,⁶⁵ and we gladly await its results relative to this year 2018 and onwards.

Its path is not an easy one. Take the recidivism of Biomet as an example. But the FCPA’s particularly effective level of enforcement in preventing the willful misconduct of bribery and books and records and internal controls evasion abroad is a most needed and anticipated catalyst to bringing about change here, nationally, in this context.

This having been said, systematic change must come about from within. By “within” is meant at the specific company level, where it is essential that those individuals concerned — starting at upper management — necessarily have the gravitas to implement correct action.

There has been a building groundswell of enthusiasm in Brazil towards the improved application of company compliance measures, which has been achieved by Brazilian law. As recent important examples, Federal District Law 6.112/18 and Rio de Janeiro State Law 7.753/17, both effective as of the beginning of this year, mandate companies supplying products or providing services to their jurisdictions by means of public contracting, consortiums, conventions,

concessions or public-private partnerships to have viable compliance programs in place.⁶⁶ Concomitantly, there has been an increased sophistication in the compliance-related service rendering of outside counsel⁶⁷ as they work with internal counsel in playing an ever more central role in imposing internal control.

On the topic of corporate business lawyers, a quotation of J.P. Morgan is that “[w]ell, I don’t know as I want a lawyer to tell me what I cannot do. I hire him to tell me how to do what I want to do.” It is this business-oriented legal input⁶⁸ in company decision-making that is often the crux of the problem. It is entering the dangerous zone between legitimately utilizing valid exemptions and loopholes in stated law and deliberately negating the law for business gain and advantage.

Successful business practice in this modern high-risk environment is not solely about following legally-enforced discouragement and prevention methods as much as establishing a culture of good business and legal ethics in which to work. Transparent and enforced legal and business ethics — here in Brazil as everywhere — are what will steer the correct course and prevail in the long run.

62. See OECD, OECD/LEGAL/0383, *Declaration on Propriety, Integrity and Transparency in the Conduct of International Business and Finance* (adopted May 27, 2010), <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0383>, as the source of this phrase.

63. See note 38, *supra*.

64. See note 24, *supra*, and accompanying text.

65. “[C]orruption can’t be rooted out in one big sweep. Rather, fighting it is a step-by-step, project-by-project process.” Transparency International, *What is Corruption?, What Do You Do to Fight Corruption?*, <https://www.transparency.org/what-is-corruption#fight-corruption>.

66. Both laws cite the objective behind this as being administrative protection from the financial harm resulting from fraudulent contracting. See Art. 3, I to IV, Law 6.112/2018 and Art. 2, I to IV, Law 7.753/2017. There are a number of bills pending of various jurisdictions along similar lines: Goiás (PL 659/2018), Paraíba (PL 1.718/2018), Bahia (PL 22.614/2017), Joinville (PL 15/2018 and PL 431/2017), São Paulo (723/2017) and Mato Grosso (PL 384/2016). Federal Congress bill PL 7.149/2017 is presently pending as well.

67. Brazilian corporate lawyers specializing in this area are proving to be well versed in providing invaluable assistance to their clients in conducting due diligence and internal investigation, assessing risk and reviewing and designing company compliance programs.

68. Lawyers have professional license-regulated fiduciary duty to their clients and moral obligation.