The Penumbra of the United States’ Foreign Corrupt Practices Act: Brazil’s Clean Companies Act and Implications for the Pharmaceutical Industry

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THE PENUMBRA OF THE UNITED STATES' FOREIGN CORRUPT PRACTICES ACT: BRAZIL'S CLEAN COMPANIES ACT AND IMPLICATIONS FOR THE PHARMACEUTICAL INDUSTRY

By: Beverley Earle* and Anita Cava**

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I. INTRODUCTION

The Foreign Corrupt Practices Act (FCPA), enacted in 1977, signaled a major philosophical shift in the United States regarding the

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acceptability of the common business practice of bribing foreign officials. Nonetheless, the reality of such business dealings worldwide did not change until very recently,2 when the consequences of ignoring the law became subject to enormous fines levied by the Department of Justice (DOJ).3 No doubt, the FCPA has inspired international efforts to eradicate corruption, national efforts to enshrine anti-bribery concepts in law, and serious efforts to enforce those laws. The Organization for Economic Cooperation and Development (OECD) Convention4 and the recent U.K. Anti-Bribery law5 reflect this trend, albeit with mixed success. Not surprisingly, many observers have remained cynical and doubt whether countries with an entrenched culture of corruption would ever change. This article examines Brazil’s surprising decision to enact its Clean Companies Law,6 thereby ending the country’s official tolerance of corruption and adding its name to the short list of countries that have taken major steps to change the business culture. It looks at this through the lens of the pharmaceutical industry, considering the preliminary groundwork for the law as established through industry and country codes. Finally this article concludes with some assessments of the efficacy of these efforts and recommendations for regulatory changes.

3 Id.
5 Bribery Act, 2010, c. 23 § 7 (Eng.).
II. FOREIGN CORRUPT PRACTICES ACT AND THE INTERNATIONAL RESPONSE

Passing the Foreign Corrupt Practices Act in the United States in 1977 was the bold act of a legislature not known for such activism for over a decade.\(^7\) In retrospect, it is interesting that neither gridlock nor partisan bickering obstructed this dramatic move. The statute criminalized the offering of something of value to a foreign official to obtain or retain business.\(^8\) It also required maintaining adequate books and records so failure to record a bribe could be actionable.\(^9\) No doubt, many expected other countries to follow suit and were disappointed: the community of nations not only failed to embrace this new view, many countries continued to condone the practice by allowing tax deductions for bribes.\(^10\)

A. Foreign Corrupt Practices Act

The 1977 law required issuers of securities defined by the law\(^11\) to “make and keep books, records, and accounts, accurately and fairly reflect the transactions . . .” as well as “. . . devise and maintain a system of internal accounting controls . . .”\(^12\) The standard was “reasonable detail” and “reasonable assurances.”\(^13\) Furthermore, Section 5 imposed a knowing standard: “No person shall knowingly circumvent or knowingly fail to implement a system of internal accounting controls or knowingly falsify . . .”\(^14\) This was an addition in 1988 and replaced the earlier “reason to know” standard.\(^15\) “Reason to know” was too vague and made business people uncomfortable with what might be imputed to them, whereas the knowing standard was more consistent with criminal standards.\(^16\)

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\(^7\) 15 U.S.C. § 78dd-1. Perhaps not since the Civil Rights Act of 1964 was there such an attempt to change the culture of business and society.

\(^8\) Id.


\(^12\) Id. at § 78m(b)(2)(A)–(B).

\(^13\) Id.; see also id. at § 78m(b)(7).

\(^14\) Id. § 78m(b)(5).


\(^16\) Statute requires both “corrupt” and willful intent for an individual. 15 U.S.C. § 78dd-1 states
Another section of the law makes it unlawful for an issuer of securities or domestic concern or any person . . . or officer, director, employee, or agent of such person . . . [to] . . . corruptly [ ] make use of the mails or any means or instrumentality of interstate commerce or to do any other act in furtherance of an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the payment . . . of anything of value to—
(1) any foreign official for purposes of—
(A) influencing any act or decision of such foreign official in his official capacity,
(ii) inducing such foreign official to do or omit to do any act . . . , or
(iii) securing any improper advantage; or
(B) Inducing such foreign official to use his influence . . . in order to assist such person in obtaining or retaining business for or with, or directing business to, any person.17

The statute also restricts influencing foreign political parties or candidates.18

The original FCPA included an exemption for functions that were “ministerial or clerical.”19 However, the 1988 version dropped that exemption for the clearer exemption of “routine governmental action,” which it defined as what could be “ordinarily and commonly performed.”20 A subsequent section clarifies that the law does not include specific actions connected to the decision making process “to award new business to or continue business with a particular party.”21

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Any officer, director or employee or agent of an issuer, or stockholder acting on behalf of such issuer, who willfully violates subsection (a) or (g) of section 78dd-f of the title shall be fined not more than $100,000 or imprisoned not more than 5 years or both. For discussion, see generally Don Zarin, The Foreign Payments Provisions, Doing Business Under the Foreign Corrupt Practices Act §§4–8, at 36 (2d ed. 2013).

17 FCPA, supra note 1, at §§ 78dd–3(a) (2012).
18 Id. at § 78dd–3(a)(2).
20 FCPA, supra note 1, at §§ 78dd–1(b)&(f)(3)(A) (2012) (listing obtaining permits or official documents allowing a person to do business in a foreign country, processing visas and work orders, police protection, inspections, phone service, loading and unloading cargo, or protecting perishable commodities or actions of a similar nature, as examples of ordinarily and commonly performed work).
21 Id. at § 78dd–1(f)(3)(B).
The Affirmative Defense sections allow a defense if the bribe was lawful in the country or it was a “reasonable and bona fide expenditure” including travel, promotion, or demonstration. A number of Department of Justice Opinions address the issue of whether underwriting travel for foreign officials and otherwise incurring expenses while promoting business relations constitute violations of the FCPA.

The statute has endured despite suggestions it hampered the United States’ business interests overseas.

B. OECD

Moral persuasion did not appear to be much of an incentive for countries to revise their laws in the years after 1977. However, two decades later, economic arguments began to grab the attention of the world community. The adverse impact of corruption on economic development became a topic of international conversation; outrage grew with respect to the common practice subverting economic assistance and development projects into mere camouflage for bribes. The OECD drafted a Convention on Combatting Bribery of Foreign Public Officials in International Business Transactions in 1997, which became effective in 1999. The Convention requires countries to have legislation that meets the standards in the Convention. The FCPA serves this purpose for the United States, and the U.S. ratified the Convention in 1998. The OECD has been instrumental in keeping interna-

22 Id. at § 78dd–1(c).
24 See, e.g., id. at 146.
27 OECD, supra note 4.
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tional attention on this issue and monitoring signatory countries for compliance.

The OECD monitors compliance by countries, and the reporting maintains pressure.\textsuperscript{28} However, one of the major pressures on countries to comply comes from the internet.\textsuperscript{29} This has reshaped the way information is shared and can bring additional pressure outside of both the electoral or normal enforcement process.

C. United Kingdom Bribery Act (UKBA)

The UKBA was adopted with fanfare in 2010, implemented in 2011, and touted as the “FCPA on steroids” because of its broader reach in terms of covering “private bribery,” which encompasses bribes between private businessmen.\textsuperscript{30} The UKBA covers any entity or person who does business in the U.K.—even if the acts took place outside the U.K.—and has a zero tolerance policy for facilitation payments, contrary to the FCPA.\textsuperscript{31} The statute includes an “adequate procedures defense,” which suggests that a good compliance program is going to allow a company to remain in good stead even if a rogue employee takes unauthorized action in violation of the law.\textsuperscript{32}

The Ministry of Justice issued \textit{Guidance} to clarify some of the ambiguity.\textsuperscript{33} However, there still is confusion about when promotional and entertainment expenses cross the line and become bribes. In December 2012, David Green, the head of the Serious Fraud Office, cla-


\textsuperscript{32} Bribery Act, supra note 5, at § 7(2).

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fied the illegality of facilitation payments.\(^{34}\) One group noted, “Where once enforcement of the U.K. Bribery Act seemed a paper tiger, we now see active prosecutions.”\(^{35}\)

**D. Other**

The philosophical shift in attitudes regarding bribing foreign officials — at least publically — is reflected in the drumbeat of organizations adopting anti-bribery agreements ten years after the FCPA. For example, the Organization of American States (OAS) enacted the Inter-American Convention Against Corruption in 1996.\(^{36}\) This required nations to criminalize bribery.\(^{37}\) It went into force in 1997, although the United States did not ratify until 2000.\(^{38}\) Interestingly, the Convention has a section addressing and prohibiting the “illicit enrichment” of officials.\(^{39}\) The section focuses on the personal profit that foreign officials routinely used their offices to secure. Public opinion is increasingly intolerant of such excess.\(^{40}\)

The United Nations Convention Against Corruption was enacted in 2003 and entered into force in 2005.\(^{41}\) A major aspect of the Convention is the requirement that countries have laws criminalizing many of the bribery offenses.\(^{42}\) As of November 29, 2013, 140 countries


\(^{37}\) Id. at art. VII.

\(^{38}\) See IACAC, *supra* note 36.

\(^{39}\) IACAC, *supra* note 36, at art. IX.


\(^{42}\) Id. at arts. 15–28.
signed on to the Convention. The number of signatories only broadens the base of consensus that countries and their citizens will no longer tolerate unofficial pillaging by their elected officials.

The World Bank’s efforts have also increased attention to the issue of bribery by the announcement in 2012 of Strengthening Governance, Tackling Corruption: The World Bank Group’s Updated Strategy and Implementation Plan. They have instituted Procurement Guidelines and have debarred firms for violations.

Other groups, including the International Monetary Fund (IMF), the African Development Bank, the Asian Development Bank, the Council of Europe, the African Union, and the Inter-American Development Bank, have also adopted rules and/or policies to penalize bribing officials while conducting business. This unity in condemning bribery and in tightening the noose of prohibition serves to send notice to business people who previously scoffed at the new-found seriousness towards rooting out this ancient evil.

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45 Don Zarin, Multilateral Efforts Concerning Transnational Bribery of Foreign Officials, Doing Business under the Foreign Corrupt Practices Act 13-11 (2d ed. 2013) (noting that “over 607 individuals and firms . . . have been debarred or cross-debarred).


47 See Noonan, supra note 25 (tracing the history of bribes throughout the centuries).
E. NGOs

Two NGOs are particularly important in the fight against corruption. First, Transparency International (“TI”), founded in 1993, states that its goal is “[a] world in which government, politics, business, civil society and the daily lives of people are free of corruption.” Its logo is an eye with the globe as the eyeball, symbolic of the world watching and the idea that transparency will help end the entrenched practice of corruption and bribery. TI uses surveys of Bribe Payers Index and Corruptions Perception Index to look at which countries are most likely to offer bribes and in which countries one may be most likely to be approached for bribes. Such surveys capture the phenomenon that although a country may have a relatively low tolerance for bribery within its borders, its business people are apt to resort to bribery when outside its borders. TI engages in research and strategies to engage civil society and find ways to combat corruption.

Another NGO, TRACE International, founded in 2001, helps support corporate compliance. TRACE International and TRACE Incorporated are distinct entities with a shared mission to increase commercial transparency for multinational companies and their commercial intermediaries by raising the standard of anti-bribery compliance. TRACE International is a non-profit membership organization that pools resources to provide members with anti-bribery compliance support, while TRACE Incorporated offers both members and non-members customizable risk-based due diligence, a comprehensive training package, and consulting ser-

49 Id. (referring to the graphic on the website).
51 Bribe Payers Index, supra note 50; Corruption Perceptions Index, supra note 50.
vices. Working together, TRACE International and TRACE Incorporated offer one complete, cost-effective, and practical solution for anti-bribery and third party compliance.54

ABOUT TRACE INTERNATIONAL

TRACE International was founded in 2001 by in-house anti-bribery compliance experts to achieve economies of scale and to set a common standard for two shared elements of anti-bribery compliance programs: due diligence reviews of commercial intermediaries and anti-bribery training for the global supply chain. TRACE International is a 501c (6) non-profit business association that leverages a shared-cost model to provide practical and cost-effective anti-bribery compliance services for multinational companies and their commercial intermediaries through a membership program.55

Although confusing because both have TI as acronyms, their functions are quite different, as the latter is an organization supporting compliance efforts and furthering industry education. While companies that compete do not collaborate in this arena, if competitors are united in complying with anti-bribery laws, all companies benefit. Companies pay dues to support the organization.56

This brief explanation of developments that occurred post-1977 shows the remarkable expansion globally of a common understanding of the economic consequences of bribery and a collective will expressed through law to change this practice.57

III. THE PHARMACEUTICAL INDUSTRY

As defined by the legal landscape outlined above, corruption in the pharmaceutical industry manifests itself in the manufacturing, promotion, and marketing of prescription drugs and medical devices writ large.58 Focusing specifically on the role of physicians in this pro-

54 Id.
55 Id.
57 SUSAN ROSE-ACKERMAN, CORRUPTION: A STUDY IN POLITICAL ECONOMY (1978).

Today, the goals of pharmaceutical policy and medical practice are often undermined due to institutional corruption — that is, widespread or systemic practices, usually legal, that undermine an institution’s objectives or integrity . . . .
cess, a major issue is that in many countries around the world—and especially in Latin America—doctors are employed by the government in some capacity. Accordingly, they function as public officials and are subject to the reach of anti-bribery legislation when they prescribe or make recommendations for adoption of specific pharmaceutical goods and services. As a result, the pharmaceutical industry has been under special scrutiny for influencing such decisions through gifts, hospitality, luxurious travel under the guise of educational opportunities or familiarization trips, and similar benefits offered to health care providers. The legal enforcement environment has been buttressed by industry efforts to police itself at every level—global, regional, and national—by adopting codes of conduct or ethics. This is certainly true in Brazil.

industry’s own purposes are often undermined. Moreover, certain practices have corrupted medical research, the production of medical knowledge, the practice of medicine, drug safety, and the Food and Drug Administration’s oversight of pharmaceutical marketing.

See Press Release, SEC, SEC Charges Stryker Corporation with FCPA Violations (Oct. 24, 2013), available at http://www.sec.gov/News/PressRelease/Detail/PressRelease/1370540044262#.U0v9e8e7nIU for a review of corruption in Latin America and the enforcement activity against pharmaceutical companies for improper development, promotion and sales reveals staggering sums assessed in fines. In 2013, Stryker was fined more than $13.2 million for improper bribes in five countries, including Mexico and Argentina. In a review of FCPA enforcement actions in Latin America in 2012, three of the six major defendants were pharmaceutical companies that were fined a total of $59.9 million (Biomet: $22.8 million; Orthofix: $7.7 million; Eli Lilly: $29.4 million). See also Matt Ellis, FCPA in Latin America: 2012 in Review, LACCA net (Feb. 15, 2013), available at http://www.millerchevalier.com/portalresource/lookup/poid/Z1tOl9NPl0LTynMQZ56TfzcRVMQiLsSwampDm83/document.name=/FCPA%20in%20Latin%20America.pdf.


60 See Breuer, supra note 59, at 2 (“The depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates a significant risk that corrupt payments will infect the process. The Criminal Division stands ready to ferret out this illegal conduct and we are uniquely situated to do so.”).

61 Jeffrey Francer et al., Ethical Pharmaceutical Promotion and Communications Worldwide: Codes and Regulations, PHIL. ETHICS & HUMAN. IN MED. 7 (2014), available at http://www.peh-med.com/content/pdf/1747-5341-9-7.pdf (offering tables summarizing the many strands of industry self-regulatory organizations); see also GlaxoSmithKline’s (GSK) helpful inventory of all pharmaceutical, vaccine, and consumer product trade associations in existence in 2013, organized by global, regional, and country status. Main Pharmaceutical, Vaccine and Consumer Prod-
A. Industry Codes

Throughout Latin America, the medical establishment has long worked with the pharmaceutical industry to create robust codes of conduct. The Argentine Chamber of Medical Specialities (CAEMe) is credited with launching the first such effort in 1925, while the respected Latin American regional industry organization, the Federation of Pharmaceutical Industries (FIFARMA), organized itself in 1962. Today, the pharmaceutical industries in many countries in the region have agreed to governance by the principles put forward by the European-based International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), widely viewed to be the gold standard. The IFPMA Code of Practice, which was adopted in 1981 and significantly updated in 2012, has been explicitly embraced by the...
industry associations of various Latin American countries, including: Argentina, Brazil, Chile, Colombia, Ecuador, Guatemala, Mexico, and Peru. Each of these trade associations is known by its own acronym and provides information about the Code of Practice on its individual website.

In Brazil, two trade associations represent the large sector in question: Abimed, the umbrella for technology and medical device manufacturers, and Interfarma, which includes pharmaceutical companies. Both have adopted codes to govern the competitive environment of their respective sector, which in many respects parallel each other.

A close review of Interfarma’s Code of Practice reflects its aim to establish high standards for the industry and to offer innovative guidance for clean competition in a lucrative environment. The Preface provides:


The respective associations of each nation are: Argentina – Federación Latinoamericana de la Industria Farmacéutica (FIFARMA) and Cámara Argentina de Especialidades Medicinales (CAEMe); Brazil – Associação da Indústria Farmacêutica de Pesquisa (Interfarma); Chile – Cámara de la Innovación Farmacéutica de Chile (CIF); Colombia – La Asociación de Laboratorios Farmacéuticos de Investigación (AFIDRO); Ecuador – Industria Farmacéutica de Investigación e Innovación (IFI); Guatemala – La Federación Centroamericana de Laboratorios Farmacéuticos (Fedefarma); Mexico – Asociación Mexicana de Industrias de Investigación Farmacéutica, A.C (AMIIF); and Peru – Asociación Nacional de Laboratorios Farmacéuticos (ALAFARPE). Id.


For us at Interfarma, the Code of Conduct is more than just a text. It is a document that governs our daily practice and our greater commitment with society and with the country: act ethically. Thus, only those companies that respect and follow the Code can become members of our entity. And, in the event of noncompliance with the rules, the Code itself establishes the mechanisms that lead to punishment.

With this initiative, we hope to help patients, doctors, authorities and professionals transform public health and the relations that exist therein in our Country in areas of clarity, transparency, respect for laws and ethics.70

The document is divided into four sections, each of which addresses in detail the following concerns: general rules, prescription drugs, over-the-counter (OTC) drugs, and guidance for dispute resolution.71 Under its umbrella of general rules, Interfarma sets out ten guidelines that cover industry relationships with public officials and government agents and patient groups, specifically addressing longstanding areas of concern with respect to corruption in the industry: inappropriate support of physicians to attend or lecture at meetings and lavish gifts intended influence purchasing decisions.

Accordingly, Interfarma’s Code limits a physician’s ability to attend medical meetings at a pharmaceutical company’s expense. Although support for both national and international travel expenses, meals, and hospitality is permitted, it “may not be conditional on the prescription, distribution, and/or advertisement or promotion of any kind of medicine.”72 Further, any support must be disclosed for lectures or presentations, as well as any conflict of interest that might exist, and gifts other than items directly related to medical services and of minimal value are prohibited.73

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70 Theo Van der Loo & Antônio Britto, Preface to INTERFARMA, CODE OF CONDUCT, supra note 69, at 3.
71 INTERFARMA, supra note 69, at 10.
73 Section 10.1 of the Code regarding The Offer of Gifts specifically provides:

The Companies bound to this Code of Conduct may offer gifts to Healthcare Professionals, provided the all the following conditions are complied with:

i) the gifts shall be objects related to medical practice and/or strictly educational, such as, but not limited to publications,
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Similar restrictions apply to the marketing of drugs to physicians: incentives are forbidden, meals must be for educational purposes only, and neither companions nor health care professionals who are not licensed to prescribe may be offered hospitality.74 The final chapter of the Code includes provisions for an independent Ethics Committee as well as a list of penalties for violation of the rules, which provide that fines shall be donated to selected non-profit entities.75

Abimed’s Code of Practice, an updated version of which was promulgated in 2012, sets forth “four basic principles [to] serve as a guide to . . . [the] Code of Ethics – Separation, Transparency, Equivalence, and Documentation. . .”76 These specifically address the concerns that permeate the industry: the ability of health care professionals working in their official capacity to affect purchasing decisions; the need for all interactions with health care professionals to be clearly documented; the notion that any support be in proportion to the work done in exchange; and, finally, that all transactions be in writing.77 Interestingly, in the very next paragraph following articulation of its basic principles, the document specifically incorporates by reference the requirements of the FCPA as it applies to its “associate companies.”78

As noted above, Interfarma and Abimed are but two of a number of industry organizations operating in Latin America, but they have earned a degree of respect for leadership in addressing the temptations presented to those involved in the sale and purchase of

stand-alone issues of scientific periodicals (except subscriptions), and anatomic models;

ii) the gifts shall be objects of a merely symbolic value, i.e., objects whose individual value is not higher than one third (1/3) of the national minimum wage at the time of their acquisitions, and may or may not have the Company’s logo; and

iii) the offers of gifts are limited to three (3) events per year for each Healthcare Professional.

Section 10.2 provides:

Products used in the administrative routine of clinics, including, but not limited to pens, pencil holders, and notepads shall not be considered objects related to medical practice and, therefore, shall not be distributed as gifts. The prohibition set forth in this item does not include the offer of pens and notepads used as support material by participants in congresses, seminars or scientific lectures held outside the medical clinic environment.

Id. at 27–28 (footnotes omitted).

74 Id. at 31–32.

75 Id. at 41–42.

76 See ABIMED, supra note 68, at 5–6.

77 Id. at 6.

78 Id.
medicines and medical devices. Indeed, Interfarma in particular is seen to be working closely with the government in drafting legislation designed to promote its goals.\footnote{In a recent interview, Edvard Philipson, Vice President of Ferring Pharmaceuticals in Latin America, stated: The industry association in Brazil, INTERFARMA, participates very actively in developing [pharma industry] regulations and ensuring their success. There are already very specific guidelines on what type of promotional materials can be given to physicians, the cost and size of samples provided, and so on. Brazil, followed by Chile, Mexico and Columbia are at the forefront – these are countries where the government is fundamentally the payer, and has more of a say in how things are done. However there are other countries where regulations there are not so strict or so well-enforced – countries such as Bolivia, Peru, Venezuela, even Argentina. Ben Steele, \textit{Global Ethics Codes and the Latin American Pharma Market}, EYE FOR PHARMA, June 6, 2013, http://social.eyeforpharma.com/market-access/global-ethics-codes-and-latin-american-pharma-market.}

\section*{B. Country Code}

Brazil has been the focus of regional scrutiny with respect to its evolving regulation of the pharmaceutical and medical device industry as a whole. The regulatory scheme for the pharmaceutical industry is complex. The federal government plays a role in establishing the right to advertise and fairly compete,\footnote{See Flesch et al, \textit{supra} note 72, at 3–6.} but with respect to the regulation and marketing of drugs and medical devices, the government’s Ministry of Health is “responsible for public health in Brazil [and] oversees Brazil’s national health system.\footnote{Jennifer Bragg et al., \textit{Ensuring FCPA Compliance While Transacting Business in Brazil}, FDLI 8, 9 (May/June 2012), https://www.skadden.com/sites/default/files/publications/Loucks_Bragg_Ensuring%20FCPA_MayJune2012.pdf.} The Ministry operates under a management contract with the National Health Surveillance Agency (ANVISA), which is essentially independent and financially autonomous\footnote{\textit{Id. at 10. (“Anvisa is responsible for regulating, controlling, and inspecting products and services that have the potential to pose risks to public health. Among other things, Anvisa monitors and regulates drugs, medical devices and controls, and smoking products, and provides technical support in the grant of patents.”).} and is referred to as “Brazil’s FDA-equivalent.”\footnote{\textit{Id.}}

ANVISA wields great power over the global pharmaceutical and medical device companies under its jurisdiction. In order to do business in Brazil, a pharmaceutical firm must register all products, which must also pass clinical tests within the country—even if the...
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United States Food and Drug Administration (FDA) has approved it.\textsuperscript{84} In addition, “a foreign company seeking to market a pharmaceutical product must have a domestic partner, given the Latin American business culture’s reliance on personal relationships.”\textsuperscript{85}

Further, since its creation in 1999, ANVISA “has increased the level of surveillance in the sector,”\textsuperscript{86} issuing a number of regulations, known as rulings, that address concerns surrounding corruption and compliance in the pharmaceutical industry. For example, in June of 2009, ANVISA issued Resolution RDC 96/08, which imposed significantly more restrictions on advertisements for medicine and drugs than did its earlier standard.\textsuperscript{87} Although these only apply to the promotion of pharmaceuticals to private practice physicians, they set a best practices standard for the entire healthcare industry.\textsuperscript{88}

Resolution 96/08 addresses gifts to physicians who can prescribe medications\textsuperscript{89} as well as hospitality and entertainment for healthcare professionals to attend educational conferences,\textsuperscript{90} “but does not provide the level of education and entertainment that is considered acceptable.”\textsuperscript{91} The resolution also addresses other areas of concern in

\textsuperscript{84} Id.
\textsuperscript{85} Id.
\textsuperscript{86} See Flesch et al, supra note 72, at 3.
\textsuperscript{87} Id. at 5. Note that the General Attorney of the Brazilian Government has questioned the validity of these restrictions on jurisdictional grounds, which ANVISA has ignored. Id.
\textsuperscript{88} Id. at 6. It is important to note that the rules outlined below are applicable to private practice doctors only, as dealings with governmental officials involve another set of regulations. However, the issue of a physician’s possible public function is a broad concept which is not fully defined in Brazilian law. The main consideration is that a physician who works for a governmental or a public funded entity should not have any decision-making powers. This includes holding administrative/managerial functions within the institution or participating in the elaboration of technical specifications for public bids/tenders. Id.
\textsuperscript{89} Id. at 7. ANVISA Resolution RDC 96/08, Article 5 provides that pharmaceutical companies cannot offer gifts, benefits or anything else of value to physicians who can prescribe medicines, whether or not the intent was quid pro quo. “However, low-value gifts (pens, notebooks, etc.) are still authorized. Prescription pads cannot contain the company logo or promote a drug. Materials containing scientific information such as magazines and medical journals can be freely distributed.” Id.
\textsuperscript{90} Id. at 7–8. As seems to be the emerging custom, travel support to educational opportunities is permitted by Brazilian law, but it must be free of any conditions and any relationship between the healthcare provider and the company must be disclosed in all appropriate ways. Further, the conference must be genuinely educational in nature, not a subterfuge for luxury travel.
\textsuperscript{91} Id. at 8.
the global enforcement environment, including off-label promotion of drugs, distribution of free samples, and comparison advertising.92

Note that ANVISA has both civil and criminal sanctions at its disposal and it has increased its enforcement activity in the past five years, imposing four times the amount of money in fines between 2008 and 2010.93 Obviously, it is difficult to explore the full dimensions of the legal landscape governing pharmaceutical and medical devices promotion and sales in Brazil,94 but suffice it to say that the issue has been the topic of no less than eighteen educational conferences between January, 2012 and March, 2014.95 No doubt this is in large measure due to the reality of the marketplace, which is rife with temptation.

C. Reality

Today, with its robust economy, Brazil is a very attractive place to do business. In 2012, it ranked as the top recipient of foreign direct investment in Latin America, receiving $65.272 billion in foreign investment in 2012 alone.96 It is the world’s ninth largest market for pharmaceuticals and drugs, worth nearly $15.5 billion.97 Estimates for 2014 place that number at closer to $25 billion annually.98 A survey of managers in the pharmaceutical and healthcare sectors sug-

92 Id. at 8–9. These topics are interesting, but outside the corruption under consideration in this article.
93 Id. at 11.
97 Bragg et al, supra note 81, at 8–9.
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gests that Brazil is the favored emerging market for 2012-2017 by a wide margin.\textsuperscript{99}

At the same time, the 2013 Transparency International Corruption Index ranked Brazil 72nd out of 177 countries and territories surveyed,\textsuperscript{100} underlining an environment where the potential for abuse threads throughout the healthcare system. There is general agreement that with increased investments in emerging markets comes increased risk of corruption. According to Robert Barrington, TI’s Director of External Affairs, “[t]here are a number of classic red flags for bribery that indicate the pharma sector is particularly vulnerable . . . . These include a tradition of gifts and hospitality, a lack of transparency in pricing and the need for regulatory approval in everything.”\textsuperscript{101}

One area of concern is the process in place for purchasing medical goods and services for the government’s healthcare system. In Brazil, private entities submit bids in a public procurement mechanism that is not centralized in a single national entity, so federal, state, and municipal authorities organize tenders,\textsuperscript{102} or requests for proposals. The system involves multiple points of access to decision makers, which leads to serious corruption risk because would-be bribers can use multiple avenues to encourage or influence corrupt conduct of decision makers, including health authorities responsible for budgets or procurement decisions.\textsuperscript{103} Another area of concern is, of course, any interaction with health care providers who might influence the choice of products and devices for the system.\textsuperscript{104} These realities, coupled together with general perceptions of corruption in the country,\textsuperscript{105} no doubt provided the basis for the decision of the Brazilian government to take dramatic action.


\textsuperscript{103} Korenchuk et al., supra note 98.

\textsuperscript{104} Id.

\textsuperscript{105} See generally Stuart Vincent Campbell, Note, Perception is Not Reality: The FCPA, Brazil, and the Mismanagement of Corruption, 22 MINN. J. INTL. LAW 247 (2013).
IV. BRAZIL’S CLEAN COMPANIES ACT

A. Analysis

The sheer scale of preparing for both the soccer (known as football outside of the United Stated of America) World Cup in 2014 and the Summer Olympics in 2016 may have alerted the Brazilian legislators that “business as usual” would not be an appropriate way to showcase the country to the world audience.106 No doubt this sentiment was highlighted by the events of the 2013 “Brazil Spring” when an increase in bus fares drove protesters to the streets, where they tapped into deep discontent about the country's economy and its massive spending to prepare for both events.107 Brazil’s history of corruption is legendary; recent examples include the Siemens case,108 the incarceration of officials from the “Mensalao” prosecutions,109 the Bridgestone


107 Girish Gupta, Brazil’s Protests: Social Inequality and World Cup Spending Fuel Mass Unrest, Time (June 18, 2013), http://world.time.com/2013/06/18/brazil-protests-social-inequality-and-world-cup-spending-fuel-mass-unrest/ (noting that “[protestors] decry a culture marked by corruption, a general lack of return on high taxes, and point to inadequate government upkeep and spending on infrastructure, education and healthcare.”); see also Brazil’s New Anti-Bribery Act Goes Into Effect in January 2014—Is Your Company Ready? BLANK ROME LLP (Dec. 2013), https://www.blankrome.com/index.cfm?contentID=37&itemID=3224 [hereinafter Brazil’s New Anti Bribery Act (“Commentators have noted that the Brazilian Congress finally passed the Act in response to widespread protests against official corruption and government spending in connection with the 2014 FIFA World Cup and the 2016 Olympics, both of which will be held in Brazil.”]). But see, Jones Day & Mattos Nuriel Kestener Advogados, Brazil's Clean Company Law: New Risks for Companies Doing Business in Brazil, JONES DAY 1 (Aug. 2013), available at http://www.jonesday.com/files/Publication/3c9b0192-a812-4849-b9fb-96fc1e520f70/Presentation/PublicationAttachment/ec9bf444-80c0-4892-af4a-9731b3d3e57c/Brazil%20Clean%20Company%20Law.pdf (noting that “[t]he adoption of the Law caps a three-year process that mostly predates the recent public outcry against corruption” and likening it to the OECD compliance issue).


investigations and plea, and the Brazilian subsidiary of Eli Lilly pharmaceutical’s problems with bribery involving the sale of drugs. In November 2013, the first Brazilian officials convicted in the “Men-salao” or “big monthly allowance” scheme started serving their jail sentences. This fact alone sends an alert to the business community – punishment for common corruption, once thought to be impossible, was in fact imposed. A several million dollar fine, which amounts to a mere slap on the wrist in many situations, may be considered an acceptable cost of doing business, but incarceration along with even larger fines will begin to deter criminal behavior.

The Brazilian Clean Companies Act was passed August 1, 2013 and became effective January 29, 2014. The law is divided into seven chapters. Initially, the law provides for “strict administrative and civil liability of a legal person for engaging in acts against the public administration, national or foreign.” It applies to “companies . . . with personhood or not, regardless of the form.” The law does not preclude individuals’ liability as well. The definition of what is prohibited mirrors the FCPA by making it illegal “[t]o promote, offer, or give, directly or indirectly, an improper benefit to a public agent or to a third person related to him.” Interestingly, the law also outlaws “sponsoring” the illegal acts of or “hid[ing] or cover[ing] up” the “real

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110 In 2011, Bridgestone agreed to pay $28 million to the DOJ for “violating the FCPA through bid rigging and corrupt payments to government officials in a number of countries, including Brazil.” Brazil’s New Anti-Bribery Act, supra note 107, n. 3; see also Press Release, Dept’ of Justice, Bridgestone Corporation Agrees to Plead Guilty to Participating in Conspiracies to Rig Bids and Bribe Foreign Government Officials (Sept. 15, 2011), available at www.justice.gov/opa/pr/2011/September/11-crm-1193.html.


112 Ex-Government Leaders, supra note 109 (discussing the Supreme Court ordering twelve men to begin serving sentences immediately, including former President Lula Da Silva’s former chief of staff).


114 Id., ch. I, art. 1.

115 Id.

116 Id.
interests or the identities of the beneficiaries.”

The Clean Companies Act specifies that engaging in fraud in the public bid process or hindering investigations would also violate the law. It also extends a very broad definition of “public agent” and can include someone who is not paid. What this means, however, has yet to be determined.

Rather than requiring criminal intent, the new Act states that “the legal persons shall be held strictly liable . . . for the injurious acts stipulated herein.” This may be akin to the earlier version of the FCPA, which had the “reason to know” standard rather than the “knowing” standard. Note, however, that Brazil’s position seems to run counter to the trend reflected in the more recent UKBA, which allows an “adequate procedures defense.” Perhaps Brazil’s first step reflects an effort to enact tough legislation, but in reality what may be needed instead is an articulated bright line that has clear, consistent consequences once crossed.

Liability, set out in Chapter III, “shall include a fine of from .1% to 20% of gross billings of the fiscal year prior . . . which shall never be less than the benefit gained . . .” If gross billings cannot be estimated, the fine should be from R$6,000 to R$60,000,000. The factors considered include the seriousness of the offense, the benefit gained, negative effects, the position of the violator, cooperation, and the existence of an international compliance program.

Chapter IV highlights the “Administrative Proceeding for Liability,” which surprisingly allows many agencies to take control of these proceedings, noting, “[t]he institution and judgment of an administrative proceeding to ascertain the liability of a legal person appertains to the supreme authority of each body or entity of the Executive, Legislative and judicial branches . . .” Each authority shall have a committee by “[two] or more permanent civil servants.” This is the most serious defect in the law: a system of myriad committees with many different quasi-judges reduces accountability while increasing the potential to use accusations in and of themselves as a

117 Id., ch. II, art. 5.
118 Id.
119 Id.
120 Id., ch. I, art. 2.
121 See Shearman & Sterling, supra note 3; OECD, supra note 4.
123 Id., ch. III, art. 6.
124 Id.
125 Id. at ch. III, art. 7.
126 Id. at ch. IV, art. 8.
127 Id. at ch. IV, art. 10.
means of shakedown. The Comptroller General handles matters dealing with a “foreign public administration.”

Chapter V, “Leniency Agreement,” officially recognizes the benefits of cooperating with the investigation. This is akin to non-prosecution agreements that have been used so effectively in the United States.

Chapter VI, “Judicial Liability,” notes that even if the entity is found liable, it could face additional penalties, including “suspension or partial prohibition of its operations” or “compulsory dissolution of the legal person.” Further, there may be “freezing of assets,” although nothing explains what this means or how it will apply. Unlike the possibility of using the British Serious Fraud Office’s budget as an indicator of enforcement intent, Brazil’s decentralized investigation and prosecution process makes it impossible to view funds allocated for these procedures as a proxy for the seriousness of Brazil’s plans for enforcement.

Chapter VII, “Final Provisions,” announces the National Registry of Punished Companies, which will publish penalties imposed by all branches of government. The Registry will also publish Leniency Agreements. This measure demonstrates cognizance of the problem of decentralized enforcement and offers a way to centralize reporting, thereby partially curing the defect; however, the Registry’s effectiveness remains to be seen.

There are interesting comparisons to be made with the FCPA, U.K. Bribery Act, and the Brazilian Clean Companies Act. Many law firms have issued advisories to their clients on how to comply with this

128 Id. at ch. IV, art. 9.
129 Id. at ch. V, art. 16.
130 See Gibson Dunn, 2013 Mid-Year Update on Corporate Deferred Prosecution Agreements (DPAs) and Non-Prosecution Agreements (NPAs) 1, 1(2013), http://www.gibsondunn.com/publications/Documents/2013-Mid-Year-Update-Corporate-Deferred-Prosecution-Agreements-and-Non-Prosecution-Agreements.pdf (comparing the use of deferred prosecution agreements and non-prosecution agreements in the US with recent developments in the UK regarding their approach to such agreements).
132 Id.
new regulatory effort. One cannot overstate the importance of Brazil’s first step, particularly in the context of the significant financial outlays for the World Cup and the Olympics. This is an important and laudable initial attempt to level the playing fields for the countries’ whose companies do not fall within the reach of the FCPA or the U.K. Bribery Act. For example, Chinese companies that do not have a presence in the U.K. or U.S. will begin to feel the potential consequence of this law. This is significant because companies from countries that could ignore external constraints up to now may become ensnared in embarrassing prosecutions.

There is no criminal liability for entities, which is an important distinction. Yet, theoretically, the company could be barred or could also be dissolved, which—if used—is a powerful incentive to adopt appropriate business practices.

Similar to the U.K. Bribery Act, Brazil’s law does not permit the facilitation exception that exists in the FCPA, however, it is not clear how this will be enforced. If everything is a violation of the law, then companies may find it easier to ignore. The experience of the United States is perhaps instructive: Congress amended the FCPA to allow facilitation payments for “routine government action.” In so doing, it addressed the realities of business by drawing a clearer line between what was de minimis and necessary to accomplish things in certain environments and what was corrupt and unlawful. Perhaps Brazil will see a revision is eventually necessary.

B. Commentary

The passage of the Clean Companies Act ushers in a new era of possible change in the Brazilian business climate. As one commentator highlighted, between 2001 and 2013, at which time Brazil ratified the OECD Anti-Bribery Convention, there was only one prosecution for bribery of foreign public officials. However, during this time, the police “conducted 289 domestic bribery investigations . . . resulting in


137 Covington and Burling, Advisory – Anti-Corruption: New Brazilian Anti-Bribery Statute 1, 3 (2013), http://www.cov.com/files/Publication/83260639-b097-4908-843c-1434efafca9e/Presentation/PublicationAttachment/8c7a9c35-5f0c-4e2f-9e12-168b79085722/New_Brazilian_Anti-Bribery Statute.pdf (analyzing the statute and suggesting that companies need to develop policies and procedures to deal with both domestic and foreign bribery).
1,600 arrests – including the arrest of more than 100 public officials."\(^{138}\)

Regulations are expected to be promulgated, but have not as of this writing.

What is not in the law is interesting as well. One commentator has focused not on the law’s provisions, but rather on the three sections of the law vetoed by President Rousseff.\(^{139}\) One removed a lower ceiling on company fines, and another addressed factoring conduct of public official and the last required proof of willful misconduct.\(^{140}\) The impact of these vetoes made the law more stringent,\(^{141}\) yet one of the parts that weakened the law—the diffused enforcement—was not addressed.

The risk of multijurisdictional action is highlighted.\(^{142}\) For example, commentator Gwendolyn Hassan notes four trends that are changing the playing field: 1) more stringent (compared to the FCPA) new national laws; 2) updates and strengthening of existing laws; 3) new enforcement efforts (citing Canada, Korea, Switzerland, and Algeria); and 4) increasing cross border dual prosecutions thereby increasing potential penalties.\(^{143}\) This is in the international context of the G-20 adopting “The Guiding Principles on Enforcement of the Foreign Bribery Offense” and “Guiding Principles to Combat Solicitation” in the fall of 2013\(^{144}\) and also issuing a related Declaration.\(^{145}\) Heather Lowe, legal counsel of Global Financial Integrity, noted:

\(^{138}\) Id. at 3, n. 9.
\(^{139}\) JONES, supra note 107, at 4.
\(^{140}\) Id.
\(^{141}\) Accord. SCHUMPETER, Brazil’s New Anti-Corruption Law: Hard to Read, ECONOMIST (Jan. 29, 2014, 9:40 PM), http://www.economist.com/blogs/schumpeter/2014/01/brazil-s-new-anti-corruption-law (but noting that how the regulations are implemented will make a great difference and highlighting the problem of decentralized enforcement).
\(^{143}\) Id.
Four or five years ago, the idea of automatically exchanging tax information wasn’t even on the table. . . . Now the 20 largest economies in the world have announced that they will begin sharing information automatically within two to three years. This is really a sea change.146

While this is a significant change, the implementation will have to be watched. Ironically, although Russia exerted significant leadership in the 2013 G-20 process in anticipation of the 2014 Winter Olympics in Sochi in 2014, it exerted brute force in annexing Crimea in March of 2014 and has been shunned by the community of nations. Accordingly, it is certain that Russia will not be leading this effort and may not even participate in it.147 Obviously, it will be an ongoing problem if Russian companies continue to bribe with impunity in their home country, and Russia is a safe haven for corrupt officials and their booty. Indeed, Russia has offered a safe haven to the ousted leader of the Ukraine, Victor Yanukovich, whose extensive corruption is evident from his opulent home and galleon-shaped banquet hall—collectively referred to as “the museum of corruption.”148 These developments are deeply troubling and will no doubt set back Russia’s efforts to address corruption, however minimal those measures have been.

As Transparency International has made clear with its Bribe Payers Index, if offering the bribe continues, the corruption cycle keeps moving. If countries simultaneously crack down on corruption, it will dry up both the offers and the offerees. So, if Chinese companies become concerned, then that could be significant change. If Russia is no longer an active member of the G-7 or G-20, and there is a European-Russian split brought on by the tension in Ukraine and the annexation of Crimea, there will be a ripple effect all over the world, including Brazil, in terms of progress on international and national anti-corruption measures.

146 Rubenfeld, supra note 145.
C. Impact

Companies will have to be prepared for enforcement efforts in Brazil. Whether they materialize is another question. Companies will need a compliance program that is thought out beyond just compliance with the FCPA, because as the earlier sections illustrated, that will not be sufficient. One Brazilian compliance consultant commented, “[G]iven the lack of enforcement to date, coupled with the high levels of bureaucracy, Brazil presents a high level of compliance risk for most companies.”149

The replacement enforcer for Lanny Breuer in the United States Department of Justice, Associate Attorney General, Mythili Raman, noted the SEC was using Nonprosecution Agreements in an FCPA case.150 Furthermore, parallel prosecution will have a dramatic impact:

>[A]nother major trend in FCPA enforcement is the use of parallel or “carbon copy” prosecutions. With many countries passing their own anti-bribery statutes or choosing to aggressively enforce statutes already on the books, multi-national corporations are increasingly required to navigate and interact with multiple regulatory regimes while conducting business abroad. When companies violate these laws they face prosecution by multiple countries for the same set of alleged bad acts. Moreover, where one country begins an investigation into alleged bribery, this investigation may in and of itself catalyze other countries’ investigations or the commencement of their legal proceedings against the company.151

How this will translate into numbers of investigations and convictions for corruption and bribery in Brazil or in other countries for activities in Brazil will have to be watched carefully in 2014 and 2015.

V. SUGGESTIONS FOR CHANGE AND IMPLICATIONS FOR THE PHARMACEUTICAL INDUSTRY

Pharmaceutical companies no doubt have their collective eye on Brazil, welcoming this new Clean Companies Act with a mixture of anxiety and relief. On the one hand, the multinational entities have long participated in local, regional, and global efforts to self-regulate, thereby meeting and even exceeding the long-standing requirements of the FCPA. More recently, compliance officers have devoted serious

150 BakerHostetler, supra note 111, at 1.
151 Id. at 2.
attention to the stricter UKBA, particularly with its reach to purely private business entities and its zero-tolerance for facilitation payments.

Always mindful of these rules, multinational pharmaceutical companies have had to compete with local and international firms not necessarily willing to be subject to them. Accordingly, despite Brazil’s having embraced the standards of the IFPMA, which promotes best practices in the pharmaceutical industry globally, their efforts to do business in Brazil have been hampered. No doubt this national effort to level the business playing field is welcome.

Nonetheless, the threat of large fines and imprisonment certainly is a harbinger of a more difficult business environment on the ground in Brazil. Just as the pace of anti-bribery enforcement in the United States has quickened and has seemingly targeted the pharmaceutical sector, the same might well prove to be true for the industry in Brazil. A sea change is evident by the mere signing of this Act into law. It is not surprising that a cottage industry of another sort has arisen to assist in navigating this unexpectedly new and potentially turbulent environment: the plethora of conferences addressing doing business in Brazil, especially geared to pharmaceutical compliance, is remarkable.

It is early for suggestions for modification of the Clean Companies Act, yet it is important to begin the discussion. To wait eleven years, as was the case in modifying the FCPA, would be too long in this internet-connected global world of the twenty-first century.

The first obvious priority necessary to improve the new anti-corruption law in Brazil would be to empower a central enforcement agency comparable to the Department of Justice or the Serious Fraud Office with both authority and necessary funding. There can be no serious enforcement otherwise. It goes without saying that to have a “strict liability” statute with no central enforcement makes little

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152 See supra, notes 63–65 and accompanying text.
154 See supra, note 94 and accompanying text.
155 The FCPA was enacted in 1977 and substantially amended in 1988. If the Clean Companies Law were to follow a similar timeline, revisions would not occur until 2024. For a discussion on how globalization and the advent of the “network society” in the modern era drive social change at an accelerated pace, see Brian M. Stewart, Chronolauy: A Study of Law and Temporal Perception, 67 U. MIAMI L. REV. 303, 309–15 (2012).
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sense.\textsuperscript{156} Just as the ramped up enforcement in the United States has put the FCPA in a new light, so would a robust focus by enforcement authorities in Brazil accomplish much in a short time.

Second, Brazil must build upon the self-regulatory standards of the IFPMA, Interfarma, and Abimed and enhance the regulatory framework of ANVISA with respect to the embedded culture of establishing business relationships through meals and hospitality, travel, and promotional gifts. Although the multinationals subject to the FCPA and UKBA regulatory requirements have embraced the best practices outlined above, it is most doubtful that international businesses not so constrained have paid much attention to them. Needless to say, the same is likely true of local companies. Accordingly, the Clean Companies Act must more clearly define the proper amount and type of meals, hospitality, travel, and gifts. The pharmaceutical industry is mindful of the power of such incentives to affect business decision-making, and amplification of the proper limits would go a long way to establishing a strong foundation for acceptance of the new Act in the country. Obvious examples to consider in offering guidance include: What kind of meals may be offered for physicians? May there be entertainment? How far may physicians, who are often state employees, travel for such education? Is a trip to Buenos Aires appropriate? Miami? California?

Third, focusing on the pharmaceutical industry but keeping in mind that it serves as a template for other government purchasing arrangements, Brazil’s decentralized approach to the tender system is problematic.\textsuperscript{157} Although this may reflect deeply ingrained local sentiments—and, as outsiders, our recommendations will no doubt be discounted—this presents serious opportunities for graft. Economies of scale will never occur without a more comprehensive analysis and overhaul of the bidding process in the medical and pharmaceutical sectors as a precursor to truly imposing a Clean Companies presence in Brazil.

Finally, modifying the “strict liability” approach to enforcement by adopting a measure similar to the UKBA’s “adequate procedures” approach, *de facto* mirrored in enforcement of the FCPA, seems to reduce the invitation to “cooperate” with Brazilian authorities in an improper way. Although such cooperation, together with having “effective internal compliance procedures” and being willing to self-disclose, is recognized as a possible way to mitigate the large fines,\textsuperscript{158} one


\textsuperscript{157} See supra, note 101 and accompanying text.

must be wary of any invitation to cooperate with authorities in Brazil. A more flexible hand is likely to wield a less open invitation to find unauthorized ways to cooperate.

VI. CONCLUSION

Change is possible. One need only examine the startling figures of the enforcement of the FCPA in the last ten years to see the extraordinary growth in the fines and punishment of corporations and individuals. While it may seem that the enforcement structure in Brazil will never change, we have seen that it too is possible. The pharmaceutical industry’s voluntary efforts will never be effective, however, unless there is the accompanying pressure of serious enforcement with respect to all who do business in Brazil. The U.K. and the United States’ enforcement of their respective national laws will never rein in the behavior of Russian, Chinese, or other nations’ firms if they do not face legal accountability in their home nation. Having said that, the fact remains that Brazil’s action in 2014—with its showcase of the upcoming World Cup and Olympics—will help move the anti-bribery agenda forward in a global context.