BIG PHARMA IN SUB-SAHARAN AFRICA: WATCH YOUR STEP!

A Culturally Competent Guide to FCPA Compliance in Sub-Saharan Africa for Pharmaceutical, Medical Device, and Biotechnology Companies

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Introduction

As a part of our world filled with paradoxes, Sub-Saharan Africa ("SSA") inspires both fear and wonder. On the one hand, it is a mysterious land full of opportunity. At the same time, cultural barriers, unstable politics and a shaky infrastructure cause apprehension.

Pharmaceutical, medical device, and biotechnology companies, commonly grouped together and referred to as the "Life Sciences Industry," have the most to risk or lose if they do not approach their dealings in SSA with special care and caution. In the past, the life sciences industry often focused their clinical trials and business transactions in the U.S., Europe, Latin America and Asia. That is no longer the case as SSA has now fully entered the playing field.

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SSA is one of the only regions in the world where the life sciences industry has not yet fully explored and does not quite understand. Because of the industry's unfamiliarity with SSA and the region's underdeveloped infrastructure as well as its high level of corruption, breaches of ethical standards and prosecution by justice departments around the world are a constant lurking danger. Among the plethora of legal provisions that the industry must comply with in the region, the Foreign Corrupt Practices Act (FCPA) is arguably one of the most important and complex in the context of SSA.

The drugs industry is tightening its code of practice worldwide in attempt to clamp down on corruption and bribery, particularly in emerging markets like Africa. The Geneva-based International Federation of Pharmaceutical Manufacturers and Associations announced recently that it has strengthened its code to ensure "that governments, health-care providers and patients are confident that interactions with our members are conducted to the highest ethical and professional standards is our commitment." Corruption and bribery is rife in many emerging markets that Big Pharma is targeting for growth to offset declining profits in developed markets.[2]

This article will analyze the complex arena of foreign clinical trials and business transactions by the life sciences industry in SSA. In order to fully understand the unique and multifaceted interplay between the life sciences industry and SSA, this article will first provide a general overview of the FCPA and the international business practices of pharmaceutical, medical device, and biotechnology companies. Next, the article will carefully examine the specific FCPA risks the life sciences industry faces in SSA and how to minimize them.

Finally, it is important to emphasize that SSA is considered an emerging market in the pharmaceutical industry. This means that, presently, most clinical trials are still being conducted

[2] *Pharmaceuticals Code Must Be Followed*. The Wall Street Journal. March 1, 2012.

outside of SSA. As this article explains, however, the trend is rapidly changing. At this point, there are few big pharma case studies relating directly to the FCPA and SSA simply because the area is just starting to be explored more seriously by the life sciences industry.[3] For this reason, this article will borrow and utilize some case studies from other parts of the world and apply them to SSA.

I. FCPA Enforcement in the Life Sciences Industry

The FCPA was created by Congress in 1977 after numerous hearings held by the Senate Committee on Banking, Housing, and Urban Affairs revealed that over 400 U.S. companies admitted to questionable or illegal payments to foreign entities and government officials.[4] When the FCPA was first enacted, its sponsors hoped that it would immediately create a more transparent and accountable international business environment. They were wrong. For a long time, the FCPA was an afterthought, not taken seriously by U.S. companies as they increased their global footprints. For a while, these multi-national companies thought that they could do "business as usual," without being bothered by the Department of Justice ("DOJ") and the Securities and Exchange Commission ("SEC").

The time for being complacent is over and it will behoove the industry to take this point to heart. Recently, FCPA enforcement has increased exponentially. To the surprise and discomfort of many, ***FCPA enforcement now trails only terrorism as an enforcement priority***

[3] According to the Office of Chief Counsel for International Commerce, there are currently no cases specifically involving FCPA and the life sciences industry in SSA.

[4] Senate Report, No. 95-114; House Report, No 95-640.

of the DOJ.[5] In the first twenty years of the FCPA's enactment, the government prosecuted only 17 companies and a mere 33 individuals. However, between 1998 and 2008, more than 50 companies were prosecuted and more than 70 individuals were charged with FCPA violations. The large increase in FCPA enforcement has been complemented by unprecedented penalties.[6] In February 2009, *Kellogg Brown & Root*, a former Halliburton subsidiary, paid a fine of $579 million to settle FCPA violations with the SEC and DOJ. Kellogg incurred this fine months after German-based *Siemens AG* paid $800 million in fines to settle FCPA charges.[7] But the overall cost to Siemens at this juncture is estimated at approximately 1.7 billion and rising.[8]

The US Department of Justice is scrutinizing payments by leading pharmaceuticals companies for hospitality, consultants, licensing agreements and charitable donations in markets around the world as part of a wide-ranging corruption probe. Pharma companies had ignored a "systematic risk" inherent in the global drugs business and ignored obligations under local and US anti-bribery law.

There is perhaps no industry that is as vulnerable to violations of US anti-bribery laws as the pharmaceutical industry. In markets round the world the companies deal, sometimes thousands of times in a single day, with doctors, clinicians, hospital operators and regulators who

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[5] As noted by Charles McKenna, Chief, Criminal Division, U.S. Attorney's Office for the District of New Jersey, at a panel in the American Bar Association's Program, "Current Issues in Medical Device and Pharmaceutical Litigation," held at the Schering-Plough Corporation in Kenilworth, New Jersey.

[6] *See* U.S. Department of Justice, Related Enforcement Actions, describing all FCPA prosecution and the respective penalties.

[7] U.S. Department of Justice, Office of Public Affairs, Kellogg Brown & Root LLC Pleads Guilty to Foreign Bribery Charges and Agrees to Pay $402 Million Criminal Fine, February 11, 2009. available at http://www.justice.gov/opa/pr/2009/February/09-crm-112.html.

[8] Eric Lichtblau & Carter Doughtery, Siemens to Pay $1.34 Billion in Fines. New York Times, December 16, 2008.

are considered under US law to be government officials, because they are employed by state-owned facilities.[9]

Multinational pharmaceutical companies operating in countries with state-run medical institutions deal with government officials at every stage of their business: whether it is asking for a go-ahead on a manufacturing site; pursuing drug licenses; conducting clinical trials; importing or exporting drugs; selling and marketing drugs and medical equipment to physicians; or aspiring to place a product on to a hospital's approved list.

One thing that is clear is that the DOJ and the SEC are now placing increased scrutiny on the international business practices of the life sciences industry. The DOJ and SEC have each sent letters to four pharmaceutical giants: AstraZeneca PLC, Baxter International Inc., Eli Lilly & Co., and Bristol-Myers Squibb Co. The letters notified the companies that their international operations are being watched and scrutinized.[10] Additionally, the Fraud Section has begun to utilize several innovative investigative techniques to proactively induce compliance and voluntary disclosures of FCPA violations from the health care industry. As an alternative to using its traditional investigatory and prosecutorial techniques to stamp out international corruption by individuals and corporations on a case-by-case basis, the Fraud Section is testing whether requiring cooperating companies to reveal potentially corrupt industry-specific practices is more efficient to eradicating international bribery schemes.

In the pharmaceutical industry, that example is embodied in the Johnson & Johnson case deferred prosecution agreement (J&J DPA). Announced in April 2011, the three-year DPA and

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[9] Stephanie Kirchgaessner, US probes corruptin in big pharma. Financial Times., August 12, 2010.

[10] Pharma Code Revamp Follows US Industry Sweep, The Wall Street Journal, March 1, 2012. available at http://blogs.wsj.com/corruption-currents/2012/03/01/pharma-code-revamp-follows-us-industry-sweep/

$21.4 million criminal penalty between the DOJ and J&J came out of the company's voluntary self-disclosure and extensive self-investigation of FCPA violations committed by its subsidiaries, employees, and agents.

According to a Financial Times article, as of January 2012, a Pfizer Inc.-DOJ FCPA settlement is close at hand, and probes are ongoing against GlaxoSmithKline, Merck, Baxter, BMS, Eli Lilly, and AstraZeneca. Smith & Nephew, a medical device company mentioned in the same Financial Times article as a DOJ target, entered into a DPA with the DOJ as of February 3, 2012 and will pay a criminal penalty of $16.8 million to the DOJ and $5.4 million in disgorgement of profits to the SEC.[11]

The life sciences industry might be surprised by the DOJ's sudden interest in its practices. However, even a cursory look at the nature of the life sciences industry reveals why it

[11] An example of new style investigative efforts or technique includes the "Shot Show" sting investigation, where federal agents raided a Las Vegas trade show on Jan. 19, 2010, arresting 21 individuals in the military products industry for alleged violations of the FCPA. FBI agents posed as representatives of an African country and allegedly solicited promises of bribes in exchange for government contracts. Press Release, U.S. Dep't of Justice, Twenty-Two Executives and Employees of Military and Law Enforcement Products Companies Charged in Foreign Bribery Scheme, (Jan. 19, 2010), available at: http://www.justice.gov/opa/pr/2010/January/10-crm-048.html. As well all know, prosecutorial effort ultimately failed. *See also* Johnson & Johnson Deferred Prosecution Agreement, (Jan.14, 2011), available at: http://lib.law.virginia.edu/Garrett/prosecution_agreements/pdf/johnson.pdf (last accessed Jan. 25, 2012). Same day, J&J reached a settlement with the SEC agreeing to pay $48.6 million in disgorgement of profits, including prejudgment interest, and DePuy International Limited, a J&J subsidiary, was inflicted with a Civil Recovery Order of £4.826 million, plus prosecution costs, from the U.K. Serious Fraud Office ("SFO"). Press Release, U.S. Securities and Exchange Commission, Litigation Release No. 21922/Accounting and Auditing Enforcement Release No. 3261, (Apr. 8, 2011), available at: http://www.sec.gov/litigation/litreleases/2011/lr21922.htm; Press Release, U.K. Serious Fraud Office, DePuy International Limited ordered to pay 4.829 million pounds in Civil Recovery Order, (Apr. 8, 2011), available at: http://www.sfo.gov.uk/press-room/latestpress-releases/press-releases-2011/depuy-international-limited-ordered-to-pay-4829-million-pounds-in-civil-ecovery-order.aspx. *See also* S&N DPA, supra n. 10; Press Release, U.S. Dep't of Justice, Medical Device Company Smith & Nephew Resolves Foreign Corrupt Practices Act Investigation, (Feb. 6, 2012), available at: http://www.justice.gov/opa/pr/2012/February/12-crm-166.html.

is so susceptible to FCPA enforcement. Specifically, the life sciences industry has become especially vulnerable to FCPA violations due to the increased globalization of the industry. According to the New England Journal of Medicine, "Pharmaceutical and device companies have embraced globalization as a core component of their business models..."[12] Globalization naturally leads to increased contact with foreign governments and officials, and regular exchanges of information between governments multiplies the risk of governmental investigation.

One way in which the life sciences industry has become more globalized is through its massive use of foreign clinical trials. There has been a sudden upsurge in overseas product development and clinical trials with about one third, or approximately $100 billion, of all pharmaceutical transactions taking place in overseas markets. On June 22, 2010, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") published a report revealing that more than 80% of the drugs approved for sale in 2008 involved trials in foreign countries, and 78% of all people who took part in clinical trials were enrolled at foreign sites.[13] The Report also chastised the U.S. Food and Drug Administration's ("FDA") for its inability to properly supervise and inspect foreign clinical trials of drugs.[14]

The Report's conclusions have generated high-level discussion within DOJ about the extent to which payments made by companies and Clinical Research Organizations (CROs) to investigators are being made at fair market value and whether such payments present threat of

[12] Seth Glickman et al., Ethical and Scientific Implications of the Globalization of Clinical Research, 360; 8 New Eng. J. Med. 816, 816 (2009).
[13] Office of Inspector General, Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials (June 2010) *available* at http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf.
[14] *Id*.

corruption with a direct tie to the integrity of data bearing on FDA approval decisions and the safety of U.S. patients.[15]

The risk of FCPA violations is further increased because life sciences companies often perform major clinical trials in developing countries, which often lack and/or do not properly enforce their anti-corruption statutes.[16] As a result, it is easier for U.S. companies within the industry to become involved in questionable business practices and expose themselves to FCPA liability. Of even greater concern to prosecutors in the United States are unusually large payments made to foreign doctors who conduct and/or oversee the growing number of clinical trials that drug and device makers conduct overseas.

Now, prosecutors are focusing on and investigating whether payments made to doctors who conduct these clinical trials or studies overseas are appropriate. If evidence is uncovered that such payments have influenced the results of some clinical trials, SEC/DOJ prosecutors will be inspecting the trials closely. It is well known that at the Justice Department, investigations that involve allegations of patient harm rise straight to the very top of the priority list and will quickly attract the immediate attention of the FBI.

Given the likelihood that foreign clinical trials will garner significantly more government and public attention in the wake of the Report, the FCPA Initiative, and the Trovan litigation, pharmaceutical and medical device companies must reevaluate their approach to conducting foreign clinical trials. To mitigate potential liabilities before the government comes calling, companies should consider a careful assessment and remediation of areas of exposure, with

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[15] The *Foreign Corrupt Practices Act and Clinical Trials: A Trap for the Unwary*. Food and Drug Law Journal; Volume 63, Issue 2. FDLI. 2008, *available at* http://www.arnoldporter.com/public_document.cfm?id=12062&key=17C2.

[16] Seth Glickman et al., Ethical and Scientific Implications of the Globalization of Clinical Research, 360; 8 New Eng. J. Med. 816, 816 (2009).

particular attention to the rigor of monitoring and auditing plans for foreign trials, the risks inherent in engaging third parties such as CROs to undertake such trials, as well as interactions with HCPs who in many countries may be considered government officials under the FCPA.[17]

II. Special Anti-Corruption Considerations Unique to the Life Sciences Industry

Corruption is a complex problem that threatens health care access, equity and outcomes. Increasingly, health sector leaders worldwide are clearly recognizing the serious detrimental effects of corruption, and the need to take action towards its eradication. Striving to identify and understand the root causes, will certainly help with this difficult challenge and quicken the remedial process. Applying theory to carefully studied local realities, we can craft more effective programs to counter corruption.

Many life sciences, biotech, and pharmaceutical companies have characteristics that put them "between a rock and a hard place" with respect to FCPA vulnerability. Although these industries historically have not been subjected to the same degree of enforcement activity as some of the usual suspects, such as defense and energy, these industries are likely to be a source of increased future enforcement activity. The attributes that put them in this predicament include:

- a high degree of regulation, which results in regular interaction with government officials;
- incessant and often huge transactions, making government approvals and purchases extremely valuable;
- constant interactions with state-owned entities, which injects FCPA prohibitions into essentially commercial transactions;
- the global scope of the industry, as well as opportunities in numerous emerging economies rated high in bribery and corruption; and
- the unavoidable use of distributors and agents and decreased control of the hiring firm over third parties.[18]

[17] Heightened Scrutiny of Foreign Clinical Trials. Arnold & Porter LLP. Found at http://www.arnoldporter.com/resources/documents/Advisory-Heightened_Scrutiny_of_Foreign_Clinical_Trials_071210.pdf/

The life sciences and pharmaceutical industries are particularly susceptible to FCPA problems arising through the use of intermediaries. Agents are frequently used in these industries as a means of getting over difficult foreign government procurement hurdles. It is also quite common for U.S. life sciences companies to use local distributors and to establish joint ventures, aimed at risk sharing and to provide foreign companies with sufficient incentive to commit as much energy as possible to increasing sales and getting essential government approvals.

In theory, the use of intermediaries provides some FCPA protections because it has to be established that a payment was made to the third party with the "knowledge" that some of it would be used to bribe a government official. In reality, the additional layer of protection offers little or no advantage whatsoever. Only in the case of formal joint ventures, if there is minority ownership, is it generally possible to provide concrete proof to indicate a true lack of knowledge (i.e., through evidence showing a lack of control).

In what still appears to be the latest major FCPA enforcement action against the medical device industry, on February 6, 2012, Smith & Nephew Inc. (Smith & Nephew) and its British parent company, Smith & Nephew plc (S&N plc) agreed to pay a total of US$22.2 million to settle violations of the Foreign Corrupt Practices Act (FCPA)[18] alleged by the U.S. Department of Justice (DOJ) and Securities and Exchange Commission (SEC). According to the criminal information and deferred prosecution agreement filed in connection with this case, between 1998 to 2008, Smith & Nephew paid up to US$9.4 million in bribes to publicly employed Greek health care providers to encourage the purchase of its products. Smith & Nephew allegedly sold its products to a distributor at full price and then transferred the amount of the distributor

[18] Gregory Husisian, The Foreign Corrupt Practices Act: Risk-Management and Compliance Strategies For Life Sciences and Pharmaceutical Companies, Foley & Lardner, LLP, 2009.

discount to off-shore shell companies controlled by the distributor. The distributor then allegedly paid "cash incentives" to publicly employed health care professionals. The government further alleged that Smith & Nephew then recorded the payments as "marketing services," and that S&N PLC incorporated these records into its books, even though no services were actually or ever performed.

Back in 2010, Cheryl Scarboro, then-Chief of the SEC Enforcement Division's FCPA Unit, warned that the SEC "will continue to focus on industry-wide sweeps, and no industry is immune from investigation."[14] DOJ Assistant Attorney General Lanny A. Breuer explained that a major reason the Justice Department is able to take such an industry-wide approach is because "one way in which corporations obtain credit for their cooperation is by providing [the government] with information about their competitors and their clients.[19]

The enforcement actions against Smith & Nephew and S&N, PLC illustrate the compliance risks for all life sciences and medical device manufacturers that sell their products overseas. In countries with nationalized health care systems, governments run the vast majority of hospitals. This narrow avenue of government procurement presents peculiar risks for life sciences companies and medical device manufacturers who sell their products, either directly or indirectly, to health care providers. When those customers are government officials, simple purchases are considered government procurement decisions that fall well within the ambit of the FCPA. The concerns are characteristically higher in large and growing markets such as SSA.

[19] Assistant Attorney General Lanny A. Breuer Speaks at the 24th National Conference on the Foreign Corrupt Practices Act, National Harbor, Md., Nov. 16, 2010, *available at*: http://www.justice.gov/ criminal/pr/speeches/2010/crm-speech-101116.html.

The S & N case also demonstrates that companies are liable not only for their own direct actions, but also for the actions of their third parties.[20] Because many life sciences and medical device manufacturers sell their products through local distributors who have significant interactions with procurement decision-makers, it is particularly important to maintain appropriate control over distributors and ensure that they comply with all applicable anti-corruption laws, including the FCPA.

III. FCPA and SSA: Why does it Matter?

As discussed earlier, after spending years conducting studies and trials in Europe, the U.S., Asia and Latin America, the life sciences industry is setting its sights on SSA. But why Africa? The answer is that the life sciences industry has finally realized the enormous potential SSA holds. In SSA, the industry has the unprecedented opportunity to make history and change the face of medicine by developing life-saving medications for some of the world's biggest killers, such as the Human Immunodeficiency Virus (HIV), malaria, and tuberculosis (TB), which rage rampant in this part of the world.

SSA is also the least trial-saturated region in the world. According to the World Federation of Science Journalists, Africa is currently the least utilized region for clinical trials.[21] Specifically,

> Until about 1995, clinical trials were mainly conducted in Europe, the U.S. and Japan. Experts estimate more than 100,000 trials are

[20] Keith M. Korenchuk, Samuel M. Witten, and Dawn Y. Yamane Hewett, Anti-Corruption Compliance: Avoiding Liability for the Actions of Third Parties, Financial Fraud Law Report, July/August 2011, *available at*: http://www.arnoldporter.com/resources/documents/Arnold&PorterLLP_FinancialFraudLawReport_July- August2011.pdf.

[21] Ntaryike Divine Jr, *Africa Blamed for Tolerating Unethical Clinical Trials*, World Federation of Science Journalists, July 12, 2011.

> now underway worldwide yearly, with 10 percent of them in the developing world and ***one percent in Africa***.[22] (emphasis added).

The patients involved in such trials in SSA, however, are often misinformed of the reasons they are entering clinical trials. At the World Conference of Science Journalists in Doha, Qatar, Sonia Shah, author of the book *Body Hunters*, made the following sobering point:

> Informed consent [in developing countries] is not being done well and sometimes patients enrolled in clinical trials in developing countries are misinformed to think they are actually getting therapy.[23]

A lack of informed consent easily produces clinical trials, which are vulnerable to FCPA prosecution because of their questionable ethical standards. Thus, even though the life sciences industry is eager to explore SSA's emerging pharmaceuticals market, they must understand that with such new opportunities come difficult and sometimes unexpected challenges. In 2004, the Journal of American Medicine published a study, examining clinical trials in SSA.[24] The study found that:

> **rates of adherence to established clinical guidelines of care** in randomized clinical trial of HIV treatment, tuberculosis treatments, and malaria prophylaxis **varied considerably between disease categories**. (emphasis added).[25]

The study is one indicator out of many that the life sciences industry must work hard on complying with acceptable ethical business standards, which includes FCPA compliance, when conducting clinical trials in SSA. Otherwise, the industry will miss the opportunity to develop

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[22] *Id*.
[23] *Id*.
[24] David M. Kent at al., Clinical Trials in Sub-Saharan Africa and Established Standards of Care: A Systematic Review of HIV, Tuberculosis, and Malaria Trials, 292 JAMA 237, 239 (2004).
[25] *Id*.

and invest in an emerging market, which has the potential to change the face of modern medicine. Moreover, good Corporate Social Responsibility practices are both fundamental and crucial for companies looking to build their market share in SSA.

As one of the few remaining emerging markets for clinical trials, SSA presents a unique business profile because of its cost-effective drug sites and a constant stream of dedicated patients to participate in the trials. Furthermore, Public International Organizations, such as the African Development Bank, African Development Fund, International Monetary Fund, United Nations, World Health Organization and more specifically, the Global Fund to Fight AIDS, Tuberculosis and Malaria provide an enormous amount of funding to the developing nations of SSA for health related projects.

Over the past decade, The Global Fund to Fight Aids, Tuberculosis, and Malaria allocated billions of dollars in grant funding to various related healthcare projects in SSA. For South Africa alone, over US$3.7B in grant funding was awarded and over US$2.2B in funding was disbursed. West and Central African nations received similar awards of over US$3.5B and disbursements exceeding US$2.3B. The Fund currently has reserves of over US$23.7B in approved funding, making it by far the largest funder of programs related to the elimination of AIDS, Tuberculosis, and Malaria in the world. About 40% of allocated funds are being used to purchase drugs produced and patented by big pharma.[26]

The AIDS pandemic, and the accompanying influx of funding to expand access to treatment in low-income countries, has heightened concern about corruption in drug supply systems. The President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund for

[26] A detailed summary of the Global Fund's grant portfolio is provided at its website: http://portfolio.theglobalfund.org/en/Home/Index

AIDS, TB and Malaria, and other development partners are contributing hundreds of millions of dollars per year, and generating pressure to rapidly utilize the available funds, which increases the risk of corruption by requiring quick decisions with limited data. Country-level procurement infrastructure is often weak, lacking clear policies, documentation and other management tools to control corruption and assure accountability.[27]

IV. The Life Sciences Industry in Sub-Saharan Africa: A Cautionary Tale

Numerous examples exist of multinational pharmaceuticals trying to penetrate and integrate their work in SSA, but not all of these examples are hopeful. Below is a sampling of some optimistic developments, but also some cautionary tales.

GlaxoSmithKline Biologicals, headquartered in the United Kingdom and with a major U.S. research center, launched one of the largest malaria vaccine trials in SSA, which are now in their final stage in seven SSA countries. Approximately 15,000 newborns and infants are being inoculated across the region, which includes Malawi. In Malawi, 5.5 million cases of malaria were reported in 2010, which amounts to about one third of the country's population. [28]

Additionally, Anacor Pharmaceuticals, based out of Palo Alto, California, has developed a promising experimental drug designed to combat African sleeping sickness. The oral drug

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[27] Taryn Vian. *Review of corruption in the health sector: theory, methods and interventions a*t 90. University School of Publich Health. 2008.

[28] *A First-Ever Malaria Vaccine, Time Magazine Specials*, December 7, 2011. available at http://www.time.com/time/specials/packages/article/0,28804,2101344_2100769_2100762,00.html; Malaria Vaccine in Final Stage, VoxAfrica, June 22, 2011. available at http://www.voxafrica.co.uk/news/health/2011/06/22/malaria-vaccine-in-final-stage-malawian-trial-site-states/?PHPSESSID=44515f139e189746fc10a0ede79471b9

SCYX-7158 has shown promise in treating the parasite responsible for the disease, which is transmitted to humans via the tsetse fly.[29]

Other examples of drug companies' public-private relationships that is helping improve healthcare in SSA is AstraZeneca's partnership with the African Medical and Research Foundation (AMREF).[30] Since establishing a partnership in 2004, AstraZeneca, an international biopharmaceutical company, and AMREF have been working to develop new treatments for malaria, HIV/AIDS, and tuberculosis, with a special focus on South Africa and Uganda. The partnership has significantly improved and streamlined the treatment of the diseases.[31]

Unfortunately, these hopeful stories are overshadowed by the negative press coming out of SSA. This must be rectified because the life sciences industry has much to gain from doing good in this part of the world. In order to achieve its lofty goal of ending some of the world's deadliest diseases, it must steer clear of unethical behavior, which appears rampant at this point.

For example, in the 2008 7th World Conference of Science Journalists in Qatar, speakers focused on SSA regions, such as South Africa, where mostly the vulnerable and illiterate poor are recruited for drug trials and ethical misconduct is rampant. Perhaps the most notorious example of this unfortunate trend is Pfizer's fiasco in Nigeria's northern Kano District in 1996.

In 1996, Kano was hit with the worst ever African cerebrospinal meningitis (CSM) epidemic. Physicians caught up in the midst of the epidemic reported more than 109,000 cases of

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[29] *Anacor Pharmaceutical announces commencement of Phase I Clinical Trials of Boron-Based Compound for Sleeping Sickness*, The New York Times, March 12, 2012. available at http://markets.on.nytimes.com/research/stocks/news/press_release.asp?docTag=201203121600BIZWIRE_USPRX____BW6525&feedID=600&press_symbol=27486326

[30] *See,* AMREF and AstraZeneca: Working towards better treatment of Africa's 'killer diseases.' available at http://uk.amref.org/our-partners/corporate-partners/astrazeneca/

[31] *Id.*

meningitis and 11,717 deaths. The infected were treated in crowded conditions in Kano's infectious diseases hospital. Even after Doctors Without Borders flew into the region, the epidemic still could not be contained.[32]

CSM epidemics are rare in the U.S. and in Europe. Thus, the Nigerian epidemic presented a rare opportunity for a trial, which Pfizer undertook. Doctors from Pfizer flew into Kano with the experimental oral antibiotic drug, trovafloxacin ("Trovan"). The doctors' goal was to test Trovan against the drug typically used to treat CSM in the western world, ceftriaxone.

Pfizer claimed that it gained permission to enter Kano after an "independent review" and "approval by a Kano hospital ethics committee."[33] But the legal action initiated by the Nigerian Attorney General, as confirmed by a Washington Post article, contradicts Pfizer's claims:

> Pfizer did not seek Nigerian government permission to import or administer Trovan and knew the drug would not cure meningitis, the charges say. Seven of the federal charges refer to an approval letter that Pfizer says was issued by a Nigerian ethics committee but that was "forged and backdated," the federal charges state. Pfizer paid a Nigerian physician $20,000 to produce the letter, according to the charges. [34]

At the time of Pfizer's drug trials, the corrupt payment was not discovered and Pfizer's doctors took over part of Kano's hospital and administered a clinical trial, in which 200 children participated. Half of the children took Trovan, and the other half were given a lower dose of ceftriaxone, which was the established and trusted medication used to treat CSM. Of those given Trovan, it is believed that between five and eleven children died and numerous were left with disabilities. Six of the children given ceftriaxone died. When Pfizer's trial ended, it was initially

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[32] Barnaby Phillips, Nigeria's Drug Trial Fears, BBC News, Mar. 14, 2001, http://news.bbc.co.uk/2/hi/africa/1220032.stm

[33] Joe Stephens, Where Profits and Lives Hang in Balance, Wash. Post, Dec. 17, 2000 at A1.

[34] Joe Stephens, Pfizer Faces New Charges Over Nigerian Drug Test, Wash. Post, June 2, 2007 at D1.

considered a success; it had about a 10.7% death rate, as reported by some sources, which was much better than the 20% death rate in other regions where CSM epidemics occurred.[35]

Thus, initially, Pfizer did not believe it had anything to worry about. However, that changed in 2000 when the *Washington Post* published a story about Pfizer's trial in Nigeria.[36] The article and subsequent investigations revealed that Pfizer's presence in Kano may have breached the ethical standards for clinical trials. The ensuing scandal confirmed that, due to the nature of the epidemic and the Kano hospital's crowded conditions, the trial was set up phenomenally quickly. Further, parents came forward revealing that they did not know that Trovan was an experimental drug and that it had never been tested on children.

On August 29, 2001, 30 plaintiffs filed an 83-page complaint alleging, among other things, that Pfizer failed to advise them of the risks associated with taking Trovan and a lower dose of the established medication ceftriaxone and thereby failed to seek informed consent for the trial.[37] Jurisdiction in U.S. Courts was provided by the Alien Tort Claims Act. In December 2010, after years of discovery, motions, and appeals, Pfizer announced that it had reached a $75 million settlement with the Kano state government.[38]

Despite the settlement in the Kano case, Pfizer's seemingly poor handling of this matter should serve as an example of what not to do if a similar situation arises in the future. In an effort to mitigate its damages during the civil trial in this case, Pfizer is said to have employed the

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[35] Pfizer Statement of Defense, Trovan, Kano State Civil Case, July 2007. available at http://www.pfizer.com/files/news/trovan_statement_defense_summary.pdf

[36] *Compensation Paid to Victims of Nigerian Drug Trial*, Corporate Social Responsibility @ Suite 101, January 19, 2012. available at http://rupert-taylor.suite101.com/compensation-paid-to-victims-of-nigerian-drug-trial-a401446

[37] Compl. ¶¶ 135-40.

[38] *Compensation Paid to Victims of Nigerian Drug Trial*, Corporate Social Responsibility @ Suite 101, January 19, 2012. available at http://rupert-taylor.suite101.com/compensation-paid-to-victims-of-nigerian-drug-trial-a401446

misguided tactics of seeking to damage the reputation of the Nigerian Attorney General pursuing the case. Pfizer's actions were later published by the Guardian on December 9, 2010 after WikiLeaks released a diplomatic cable showing that the company hired investigators to find evidence of corruption on Nigeria's Attorney General, Michael Aondoakaa, to expose him and put pressure on him to drop the civil suit. The cable, classified confidential by Counselor Robert Tansay further showed that "A series of damaging articles detailing Aondoakaa's 'alleged' corruption ties were published in February and March. Liggeri (Pfizer's Nigerian country manager) contended that Pfizer had much more damaging information on Aondoakaa and that Aondoakaa's cronies were pressuring him to drop the suit for fear of further negative articles."[39]

Pfizer's clinical trials in 1996, and subsequent actions supposedly designed to cover-up wrong doings and mitigate their related damages, should serve as a morality tale for the life sciences industry. The Pfizer scandal could have been prevented if the company had dealt with the right folks in Kano's medical circles and observed the highest ethical standards in conducting the clinical drug trials. If the litigation against Pfizer was initiated in today's enforcement environment, it may well have led to Pfizer being charged with FCPA violations, as its conduct appears to have involved the bribery of foreign officials. The lack of an FCPA charge may have been largely due to the fact that, at the time the litigation was initiated, the DOJ and the SEC were not focused on prosecuting pharmaceutical companies. That is no longer the case, as Deputy Attorney General Gary Grindler stated at the National Institute of Health Care Fraud in Miami on May 14, 2010:

[39] WikiLeaks Cables: Pfizer 'used dirty tricks to avoid clinical trial payout,' The Guardian, December 9, 2010. available at http://www.guardian.co.uk/business/2010/dec/09/wikileaks-cables-pfizer-nigeria

> …in the months ahead, ***you can expect to see the department increasingly using the Foreign Corrupt Practices Act to prosecute kickbacks and bribes paid to foreign government officials by pharmaceutical companies.*** As the drug companies do more and more of their business overseas where so much of the health care business is government run, we unfortunately see the opportunities for FCPA violations proliferating. In some foreign countries, nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product may involve a "foreign official" within the meaning of the FCPA. ***The department will not hesitate to charge pharmaceutical companies*** and their senior executives under the FCPA if warranted to root out foreign bribery in the industry.[40]

The Pfizer case informs that the life sciences industry in SSA must realize that it has much to lose from skirting its ethical duties, especially in the present era of intense FCPA enforcement. There was a time when SSA was deemed a backward region, where companies could escape the watchful eye of the DOJ and SEC. The time for being complacent is over. A new era is beginning in which pharmaceuticals are eager to develop and explore SSA but the DOJ and SEC will be following them closely behind and paying attention.[41]

V. Peculiar FCPA Compliance Issues & Challenges in SSA for the Life Sciences Industry

The remainder of this article will focus on specific pitfalls that the life sciences industry may face in SSA with respect to FCPA compliance. Pharma's unique structure and operations also present unique FCPA compliance obstacles. For one thing, the FCPA's definition of "foreign official" is expansive, and the prohibition against bribing foreign officials extends well beyond government ministers and other obvious political administrators. Another challenge stems from the Pharma model of engaging subsidiaries, agents, consultants and distributors, many of whom either qualify as foreign officials or may have connections to foreign officials.

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[40] Deputy Attorney General Gary Grindler, National Institute of Health Care Fraud in Miami, May 14, 2010.

[41] *See* The Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq.

In the Pharma context, where many companies are multinational in scope, an increase in anticorruption enforcement globally means that all corporate activity is being carefully monitored and even rumored infractions will draw immediate attention from aggressive regulators in multiple jurisdictions.

Pharmaceutical companies typically conduct a wide range of activities overseas, from the earliest stages of pre-clinical tests and product design to post-production marketing and sales. These processes are often undertaken in a decentralized fashion, involving any combination of subsidiaries, third-party contractors, distributors, and contract sales forces. This structure – whereby managers may operate separately and autonomously without close supervision from a "central command" – usually presents a massive monitoring and compliance nightmare. Even the best-intentioned company may find itself afflicted with an FCPA investigation stemming from the actions of any of the numerous parties involved in the chain of operations. Under the "knowing" standard, corporate officials can be held culpable if they fail to take action when reasonable signs of an FCPA violation exist. The standard covers actions that federal courts have previously described as "conscious disregard" and "willful blindness."

Compliance Issue One: The FCPA's Broad Definition of "Foreign Official"

FCPA compliance is often complicated because of its many seemingly benign provisions that have hidden pitfalls. A perfect example of this fact is the definition of a "foreign official," which states the following:

> any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department,

> agency, or instrumentality, or for or on behalf of any such public international organization.[42]

Many companies have made the mistake of glancing at this definition and concluding that it is clear and straightforward. It is anything but that. The only clarity the FCPA statute provides is that a "foreign official" includes persons holding official titles, such as President, Prime Minister, Oil Minister, Secretary of Health and Human Services, and Customs Service Agent.

Problems arise when companies fail to realize the fact that the definition of "foreign official" also includes a much larger and less obvious range of individuals. With respect to the life sciences industry, in many countries doctors and hospital administrators are actually "foreign officials" because medical facilities are often owned and run by the state. Whether they realize it or not, when U.S. companies communicate with any individuals involved in hospital operations, irrespective of their rank or position, they are actually communicating with "foreign officials" and must comply with the FCPA.

Life sciences companies operating in the SSA region must fully appreciate the broad definition of "foreign official". Thus far, it appears that some companies have woefully failed to do so in other regions, as evidenced by the DOJ's and the SEC's prosecution of numerous companies and executives. Even though the following cases did not arise in SSA, they still serve as cautionary tales that could easily be repeated in SSA, if the life sciences industry is not adequately diligent.

On December 10, 2002, *Syncor Taiwan, Inc.*, a subsidiary of the California-based radiopharmaceutical *Syncor International Corporation*, pled guilty to one count of violating the

[42] 15 U.S.C. §§ 78dd-1(f)(1)(A); 78dd-2(h)(2)(A); 78dd-3(f)(2)(A).

FCPA, for which it paid $2 million in penalties.[43] *Syncor* made payments to physicians, employed by Taiwan's state hospitals, in exchange for their referrals of patients and for the purpose of retaining and obtaining business from those hospitals.[44] Also, on June 3, 2008, medical device manufacturer *AGA Medical Corporation* agreed to pay a $2 million penalty in violation of the FCPA.[45] Between 1997 and 2005, a high ranking *AGA* officer and other *AGA* employees agreed to make corrupt payments to Chinese physicians in state-owned hospitals.[46] The purpose of the payments was to encourage the state-owned hospitals to purchase *AGA* products over those of its competitors.[47]

Syncor and *AGA* are just two cautionary tales out of many, which signify that the FCPA's classification of "foreign officials" does not only include the obvious individuals holding official titles, but that it also incorporates less obvious "suspects", such as physicians and hospital administrators.

Accordingly, it is of utmost importance that pharmaceutical companies monitor the actions of every subsidiary, agent, consultant and employee of its company in order to avoid potential liability. This can be no small feat, but extensive due diligence in the contracting process, insistence on familiarity and compliance with the FCPA's requirements, and ongoing certification and disclosure requirements are critical steps.

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[43] Press Release, U.S. Department of Justice, Syncor Taiwan, Inc. Pleads Guilty to Violating the Foreign Corrupt Practices Act (Dec. 10, 2002), http://www.justice.gov/opa/pr/2002/December/02_crm_707.htm.
[44] *Id*.
[45] Press Release, U.S. Department of Justice, AGA Medical Corporation Agrees to Pay $2 Million Penalty and Enter Deferred Prosecution Agreement for FCPA Violations (June 3, 2008), http://www.justice.gov/opa/pr/2008/June/08-crm-491.html.
[46] *Id*.
[47] *Id*.

Compliance Issue Two: Payments Made In The "Normal Course of Business" May Violate the FCPA

As part of the accepted course of business globally, pharmaceutical, medical device, and biotechnology companies in SSA regularly employ marketing strategies necessary to attract new clients and build relationships, such as provisions of gifts, travel, and entertainment. Marketing programs have always been used regularly and rigorously by the life sciences industry. In fact, an effective marketing program is often especially thought of as the cornerstone of a successful business strategy in this industry. Problems, however, arise when U.S. companies fail to consider that marketing in the normal course of business can actually lead to FCPA liability. As previously discussed, the DOJ and the SEC have recently started scrutinizing the marketing strategies of the life sciences industry by penning letters to major pharmaceutical giants to notify them that there are vulnerabilities in their business practices and that their actions are being carefully monitored and scrutinized.[48]

The FCPA statute defines bribery to include acts "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 giving ***of anything of value***..."(emphasis added).[49] The key phrase in this language is "anything of value," and it is another reason why the life sciences industry has been inundated with DOJ investigations. Gifts, entertainment, travel, and lodging that are provided to physicians and hospital administrators can be deemed to be of "value" and may trigger an investigation by the DOJ and the SEC. Specifically, FCPA liability can be triggered when everyday marketing provisions are received by "foreign officials" and the gifts or payments are

[48] Pharma Code Revamp Follows US Industry Sweep, The Wall Street Journal, March 1, 2012. available at http://blogs.wsj.com/corruption-currents/2012/03/01/pharma-code-revamp-follows-us-industry-sweep/

[49] 15 U.S.C. §§ 78dd-2(a) (domestic concerns); §§ 78dd-1(a) (issuers).

either deemed unreasonable under the circumstances or are not directly related to business with the "foreign officials."[50]

In the June 2004 enforcement action against the pharmaceutical company, *Schering-Plough Corporation*, the SEC asserted that a donation to a charity, which did not provide a tangible monetary benefit to a foreign official, still conferred something of value to that official because the official knowingly received and welcomed the donation.[51] Additionally, in December 2007, *Lucent Technologies Inc.*, a manufacturer of broadband networking and information science technologies, agreed to pay a $2.5 million penalty to settle allegations that it violated the FCPA when it provided travel and other provisions of value to Chinese government officials.[52]

In the Pfizer scenario, the $20,000 said to have been paid to the Nigerian doctor to write a letter saying the Trovan trials were approved by the Kano hospital could certainly be considered something of value. As such, Pfizer is fortunate that, at the time of the litigation, the DOJ and the SEC were not particularly focused on FCPA prosecutions with respect to big pharmaceuticals.

"Anything of value" is also a broad FCPA provision that deserves a lot of attention given that it may trigger liability for everyday marketing programs, which are in the normal course of business within the life sciences industry. Therefore, life sciences executives need to be extra careful with the products and services they use to try to attract new business. If they are not, they will inevitably join the long list of pharmaceutical, medical device, and biotechnology companies

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[50] FCPA Op. Proc. Rel. No. 07-01 (July 24, 2007), http://www.justice.gov/criminal/fraud/fcpa/opinion/2007/0701.pdf.
[51] *In re Schering-Plough Corp.*, Exchange Act Releases No. 49, 838 (June 9, 2004), 2004 SEC LEXIS 1185.
[52] Press Release, U.S. Department of Justice, Lucent Technologies Inc. Agrees to Pay $1 Million Fine to Resolve FCPA Allegations (Dec. 21, 2007), http://www.justice.gov/opa/pr/2007/December/07_crm_1028.html.

who have incurred astronomical fines and costly investigations from their failure to narrowly conform their marketing strategies to be compliant with the FCPA.

Life sciences companies should also examine their Public-Private partnerships with Public International Organizations (PIO). Although these groups are often viewed as semi-autonomous funding sources for research and development around the world, these sources of funding are not immune from FCPA regulations and prosecution. The value of these partnerships should not be underestimated either, given the vast amount of capital available for projects around the world. As with the case of The Global Fund to fight AIDS, Tuberculosis and Malaria, more than US$6B have already been awarded to SSA countries over the past decade with 40% of said funds being used to purchase drugs from pharmaceutical companies. This fund also has current reserves exceeding US$23B for future projects.

The FCPA's anti-bribery provisions make it illegal to bribe foreign officials for the purpose of obtaining or retaining business and/or to secure any improper advantage. As referenced above, the FCPA prohibits payments, offers or gifts of money or anything of value, with corrupt intent, to "foreign officials". As previously discussed, a foreign official means any officer or employee of a foreign government or any department, agency, or instrumentality thereof (including a government-owned or government controlled state enterprise) or of a Public International Officer, …."[53]

A January 23, 2011 Associated Press article regarding corruption and The Global Fund highlighted the level of corruption that is possible in this arena. The Huffington Post also commented on this issue reporting that:

[53] See Lay Person's Guide to the FCPA, U.S. Department of Justice. available at http://www.justice.gov/criminal/fraud/fcpa/docs/lay-persons-guide.pdf

> the fund's newly reinforced inspector general's office, which uncovered the corruption, can't give an overall accounting because it has examined only a tiny fraction of the $10 billion that the fund has spent since its creation in 2002. But the levels of corruption in the grants they have audited so far are astonishing. A full 67 percent of money spent on an anti-AIDS program in Mauritania was misspent, the investigators told the fund's board of directors. So did 36 percent of the money spent on a program in Mali to fight tuberculosis and malaria, and 30 percent of grants to Djibouti. In Zambia, where $3.5 million in spending was undocumented and one accountant pilfered $104,130, the fund decided the nation's health ministry simply couldn't manage the grants and put the United Nations in charge of them. The fund is trying to recover $7 million in "unsupported and ineligible costs" from the ministry.[54]

Despite these setbacks, managers of the Global Fund continue to see SSA as a worthy partner in this noble heath care fight and continue to fund projects in SSA through various Health Ministries and governmental agencies. A fine example of such funding initiatives and the Fund's trust in their SSA partners was recently displayed when the Fund awarded US$30,210,266 directly to the Ministry of Health of Liberia and its recipient Minister Dr. Walter T. Gwenigale for FY 2011-2013.[55] Companies will indeed be disadvantaged if they ignore growth possibilities in SSA life science industries, through the use of Public-Private partnerships with PIO. Despite the great growth potential, cautionary, and ethical execution will almost always rule the day.

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[54] Fraud Plagues Celebrity-Backed Global Fund, The Huffington Post, January 23, 2011. available at http://www.huffingtonpost.com/2011/01/23/global-health-fund-fraud_n_812801.html

[55]The Global Fund Program Grant Agreement For Single Stream of Funding, The Republic of Liberia. available at http://www.google.com.pr/url?sa=t&rct=j&q=liberia%20global%20fund%20gwenigale%20million%202012&source=web&cd=4&sqi=2&ved=0CGkQFjAD&url=http%3A%2F%2Fwww.theglobalfund.org%2FgrantDocuments%2FLBR-M-MOH_GA_0_en%2F&ei=496qT-vtPImE8ASAwL3GAw&usg=AFQjCNGoS0p5HqXn9hXMlGagm89hSLxZSw&cad=rja

Compliance Issue Three: Clinical Trials and Selection of Third Party Agents in SSA

While companies can generally identify red flags when they are dealing directly with the foreign government, the risk of FCPA violations grows markedly when a third-party agent is brought into the mix or equation. Often, the use of an agent increases FCPA concerns because a company has less ability to oversee and to direct a third party's actions, and yet the company retains the ultimate responsibility for the agent's actions.

Traditionally, FCPA compliance efforts have focused on sales and marketing agents or distributors. These folks are hired largely because of their familiarity with the industry and/or good understanding of the country, and the company seeking to engage in business is usually left in a position of reliance upon the representations of the agent. Some countries require having local agents under the "local content" principle as a condition of doing business within its boundaries. Where the company has a reasonable understanding that there is a high probability that an agent may have offered payment to a foreign government, the company may be held liable for an FCPA violation, as the government will likely impute knowledge of the improper payment or offer of a payment.

Other types of third-party agents can also present severe vulnerabilities. In particular, third-party individuals or entities involved in conducting clinical trials may present FCPA concerns similar to those encountered by the more traditional sales and marketing paradigm. There are three common ways for a company to transfer many of its responsibilities for conducting or otherwise complying with the FDA's regulatory requirements for reviewing a clinical study under third parties.

First, pharmaceuticals may choose to manage clinical trials through the use of CRO. Under FDA regulations, the sponsor of a study is allowed to transfer many of its responsibilities

for a study to a CRO.[56] The sponsor is still required to continue monitoring the investigators to ensure compliance with established protocols and correct any errors that may arise during the study.[57] Second, a company may contract with clinical investigators who are responsible for the actual conduct of the study. The FDA regulations require that a PI be identified as the lead clinical investigator, and the regulations permit sub-investigators to work for PIs.[58] Third, an entity may rely on an IRB, a committee designated by an institution, such as a university medical center, a CRO, or a hospital to review clinical research. Under FDA's regulations, among the many requirements, the IRB "must continue to monitor the research as it progresses."[59]

Companies may seek out CROs, PIs, or IRBs in other countries. In many foreign nations these clinicians and laboratory workers may, in fact, be employees of the foreign government, and, therefore, "foreign officials" for purposes of the FCPA.[60]

There are other arrangements within the pharmaceutical arena where scrutiny for FCPA concerns is critical, and a third-party relationship may be implicated. For example, discounting arrangements are not uncommon in the industry, but a company cannot merely rely on this common practice without vetting the arrangement. Rather, due diligence requires that the company ensure that foreign officials were not paid or given anything of value to induce the price reductions during the negotiations, especially if a third party agent were employed for the negotiations.

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[56] 21 C.F.R. § 312.52 (2002).
[57] *See* "Drugs and the Pharmaceutical Sciences"*,* Vol. 144, *Clinical Research Requirements for New Drug Applications*, by Gary Yingling & Ann Begley at 355.
[58] *See* 28 C.F.R. § 80.
[59] 21 C.F.R. § 56; *See also A Practical Guide to Food and Drug Law and Regulation* 2d Ed., Chapter 5, at 93.
[60] *See, e.g.,* SEC v. Diagnostic Products Corporation, SEC Admin. Proc. Rel. No. 34-51724 (May 20, 2005); SEC v. Syncor International Corporation, SEC Lit. Rel. No. 17887 (Dec. 10, 2002) (finding that doctors and laboratory workers were foreign officials).

Therefore, companies must be aware that the arrangements most common in the pharmaceutical industry may be subject to FCPA problems. In many instances, a company's failure to properly investigate or monitor the various arrangements setup by its third-party agents may result in inadvertent FCPA violations, the consequences of which could be quite harmful both professionally and financially, to both the company and the third party agents.

Simply stated, the pharmaceutical and life sciences industry is highly regulated, and the intersection of the FCPA and other FDA regulations that govern clinical trial conduct may pose serious danger for companies operating/conducting trials outside the United States.

VI. Tips to Reduce Risks and Exposure Under the FCPA in SSA for the Life Sciences Industry

The life sciences industry in SSA faces unique challenges that can lead to FCPA violations. This article will now provide a general overview of the main ways in which the industry can manage risks with cultural fluency and avoid FCPA liability.

Even a company with the most robust compliance program and the best of intentions and efforts may still fail to prevent a foreign bribe. Having a demonstrably effective compliance program will weigh heavily in that company's favor in the event of an investigation. With rising government scrutiny on an industry fraught with FCPA risk, big Pharma must be on high alert and proactive in seeking its compliance with the FCPA. It is also essential for these companies to take proactive measures to ensure that they do not acquire liability for the past sins of a target company, as well as invite or incur securities law violations in their further operations.

A necessary feature of an effective FCPA compliance program in SSA involves meaningful due diligence and oversight of third party representatives and business partners acting on the company's behalf. FCPA compliance programs must also include, for example, internal finance controls and protocols designed or reasonably calculated to detect and prevent

corruption, and reward the deserving for ethical behavior. Additionally, every life sciences company should adhere to the following policies:

1. Have in place detailed uniform guidelines specifying the company's business ethics standards and obligations under the FCPA, and establish a clear protocol on what persons should do if they suspect an FCPA violation has occurred.
2. Translate company ethical guidelines, code of conduct, etc. into the languages of each country where the company operates, and ensure that the translations are distributed to officers, employees, consultants, and agents.
3. Distribute guidelines and policies and post them on the corporate website and public visible meeting places in local languages.
4. Provide interactive Internet-based educational programs and training to overseas employees, consultants, agents, and distributors in their native languages, and require ongoing attendance and certification. Also, strive to provide in-person training by company lawyers or ethics official where feasible.
5. Create a confidential compliance hotline, website, or other mechanism for individuals to report violations. Act upon credible allegations in a timely manner and enforce appropriate disciplinary action for all violators to ensure that policies are implemented consistently.
6. Provide standardized documentation and contractual terms for foreign agents and third party representatives, including clear and concise language that third-party contractors agree to comply with FCPA obligations.
7. Maintain sound accounting and monitoring practices locally and internationally.
8. Conduct risk assessments according to the reality of corruption and nature of interactions with foreign government officials in countries where the company is doing business.
9. Conduct inspections of any foreign agents, distributors, or consultants, including in-person interviews by in-house compliance lawyers as well as extensive background checks. Include audits of expenditures made by agents and consultants, frequently in high-risk countries. Prohibit compensation systems for agents and consultants that create incentives to engage in corrupt payments to foreign officials.
10. Implement best practice due diligence procedures or protocols for the engagement of third parties.
11. Require prior written authorization by a specific compliance officer for any payment, or anything that could be deemed as a payment, to a foreign official in order to assess a bona fide business opportunity and accurately document it in the company's records.
12. Implement any additional compliance measures deemed necessary in light of the internal risk assessment discussed above.

With respect to hiring and managing third party agents or distributors, no agent or distributor should be paid until there is a written agreement in place that includes appropriate FCPA provisions. You want the agent or distributor to acknowledge the requirements of the FCPA, to agree to be bound by them, and to agree to substantial penalties or punishment if a violation occurs. The following are types of provisions for the U.S. firm to consider in intermediary contracts and interactions:

1. The intermediary is not an employer, officer, or representative of the foreign government, nor a candidate for office. The intermediary should also certify that it will not run for government office without first notifying the U.S. firm and allowing it to take appropriate remedial measures.
2. The intermediary is very aware of the requirements of the FCPA and agrees not to indulge in any action that would cause your firm to violate the FCPA. The clause should explicitly state that the intermediary agrees not to bribe foreign officials.
3. The U.S. company will be excused from performance or payment if it has any reason to believe that there is any violation of either the U.S. or the foreign company's antibribery laws.
4. The intermediary will not assign its rights or duties under the agreement to another party under any circumstances without prior written consent of the U.S. corporation.
5. The intermediary will keep accurate books that show the expenses, the person to whom any payment was made, and a detailed and accurate description of the services, with the company having the right to audit the intermediary's books.
6. The intermediary is an independent contractor with no nexus to commit violations of the FCPA.
7. The intermediary agrees to allow the issuer's accounting firm to review the intermediary's books on request.
8. The intermediary will conduct all purchases pursuant to an itemized list of expenses. All reimbursements will occur pursuant to a documented check or wire transfer, never in cash.
9. The intermediary will notify the U.S. firm if there are any relevant changes in facts, such as a member of the firm becoming a government official.
10. The intermediary agrees that certain expenses, including gifts to any government official exceeding $100, or expenses over a certain amount, shall

be paid by the intermediary only after it gets approval in writing from the U.S. corporation.

In addition, the best procedure is for agents and distributors to provide annual certifications that they are aware of the requirements of the FCPA, have not made any improper payments, and will not do so in the future. Annual certifications have the advantage of providing a regular mechanism to capture new hires and also provide ongoing protections should the agent stray and make a payment in violation of the FCPA.[61]

Use of the DOJ FCPA Opinion Procedure

The DOJ's Opinion Procedure allows for hospitals, pharmaceuticals, and medical device and biotechnology companies to determine whether any of their business practices could be considered illegal under the FCPA.[62] Specifically, the procedure can be used to establish whether a certain individual qualifies as a "foreign official" and whether a particular marketing activity would trigger FCPA liability. The DOJ's Fraud Section is required to respond to such inquiries within 30 days of receiving all of the information necessary to issue an informed opinion.[63] Utilization of this avenue or process is consistent with the universal adage that "an ounce of prevention is better than a pound of cure."

[61] Hussian, *supra* note 19, at 44-45.
[62] 15 U.S.C. §§ 78dd-1(e), -2(f).
[63] *Id*.

Conclusion

Should the life sciences industry fear SSA or jump at the chance to develop this exciting emerging market? In the end, apprehension is actually an illusion if the industry takes the simple steps outlined in this article and becomes more conscious of the ethical and legal rules that govern business operations, as well as the humane dimension. Sub-Saharan Africa is truly the last great frontier for the pharmaceutical industry. Life sciences companies can either step up and ethically develop it and change the lives of millions of people while enjoying decent profits, or they can choose to continue in the old, discredited and outdated direction. The choice is theirs.