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Critical Legal Issues: WORKING PAPER SERIES

TAKING YOUR MEDICINE:
NAVIGATING INDUSTRY-TARGETED ENFORCEMENT OF THE FOREIGN CORRUPT PRACTICES ACT

By

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INTRODUCTION

The pharmaceutical and medical device industries are well aware of the significant benefits attendant to international business activities. In recent years, these industries have seen an explosion of opportunity in developing markets around the world, where scores of major healthcare companies have become active in establishing research and development facilities, clinical trial programs, and related strategic partnerships. Their efforts are designed to accelerate the development of new drugs, devices, treatments, and techniques, and to open a door to relatively untapped—and potentially lucrative—emerging markets such as India, China, and Brazil. These industries' forward-leaning approach to globalized product and market development has positioned the companies involved for tremendous growth over the next several decades. However, these international activities also involve a variety of significant risks that require careful consideration and close oversight. Over the last year, U.S. and international anti-corruption enforcement efforts that focused specifically

on these industries have become a particularly acute concern.

This WORKING PAPER will discuss those efforts, which have been described as U.S. law enforcement's "FCPA Pharma Initiative," their potential impact on pharmaceutical and medical device companies, and steps those companies can take to minimize and defend against the corruption risks.

I. TAKING AIM

On November 12, 2009, Assistant Attorney General and Department of Justice (DOJ) Criminal Division Chief Lanny A. Breuer took the stage to present the keynote address at the Tenth Annual Pharmaceutical Regulatory and Compliance Congress in Washington, D.C. Breuer's speech represented a shot across the bow of pharmaceutical and medical device companies, in that he described an aggressive Foreign Corrupt Practices Act (FCPA) enforcement agenda focused on those companies in the months and years ahead.

The FCPA is a statute that prohibits corrupt payments by any U.S. person (wherever located) or on behalf of any U.S. person to foreign officials for the purpose of obtaining or keeping any business or business advantage (the anti-bribery provisions). It also carries penalties for any publicly-held company that maintains inaccurate books and records or inadequate internal accounting controls (the accounting and record-keeping or "books-and-records" provisions).[1] Over the last several years, U.S. law enforcement has significantly

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

ramped up FCPA enforcement efforts across all industry sectors, building on expansive interpretations of its jurisdictional reach and theories of liability that remain largely untested in U.S. courts. Recent FCPA settlements with the DOJ and the Securities and Exchange Commission (SEC), which share enforcement authority, have been substantial, regularly reaching into the tens and hundreds of millions of dollars. Breuer's speech was an unusual event; federal law enforcement rarely singles out a specific industry for FCPA scrutiny in a public forum. His remarks indicate that a substantial portion of law enforcement attention and resources are now focused on the pharmaceutical and medical device industries.

At the outset of his remarks, Breuer noted that one third of U.S. pharmaceutical companies' sales, upwards of $100 billion, are generated outside the United States "where health systems are regulated, operated and financed by government entities to a significantly greater degree than in the United States." He explained that in this context the reach of the FCPA is close to its maximum because many healthcare providers in foreign countries could be considered "foreign officials," placing a wide spectrum of day-to-day interactions within that reach. Breuer went so far as to say that "it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA."

From the DOJ's perspective, as outlined in Breuer's remarks, pharmaceutical and medical device companies operating in international markets are very often in an environment where healthcare and government are inextricably intertwined. When combined with what Breuer described as "fierce industry competition," this environment poses a significant risk of corruption. In response, the DOJ has decided to become "intensely focused on rooting out foreign bribery in [the pharmaceutical and medical device] industry." This effort will involve the FBI's dedicated FCPA squad[2] which has been actively investigating the pharmaceutical and medical device industries since at least 2009, in close conjunction with the DOJ's healthcare fraud group.

Since Breuer's November 2009 speech, he and a number of other DOJ and SEC officials have made comments repeating its message. On February 24, 2010, Mark Mendelsohn, then Deputy Chief of the DOJ's Fraud Section within the Criminal Division, addressed the Global Ethics Summit 2010 in New York. Mendelsohn, who at the time was the DOJ's top FCPA enforcement official, described a potential 50 percent increase in the size of his section by 2011 or 2012. At the same time, he stressed that the DOJ expects companies to "adopt stricter standards" with regard to corruption. The following day, Breuer addressed the ABA's 24th Annual National Institute on White Collar Crime in Miami, and described "a new chapter in white collar criminal enforcement"

[2]This group was founded in 2007 within the FBI's Washington, D.C. Field Office, and has grown substantially since then.

that will involve the use of tools "not often seen in white collar cases." This includes wiretaps, undercover agents, and other techniques recently deployed in the Galleon hedge fund insider trading case, and the 22-person "Shot Show" FCPA sting operation that occurred in late January 2010. Citing these and other examples, Breuer said we are entering a new era of "proactive and innovative white collar enforcement."

Also on February 25, 2010, Associate Director Cheryl Scarboro, the recently appointed head of the SEC's new FCPA investigative unit, outlined her plans for the unit during an interview. Scarboro specifically cited the pharmaceutical industry as a current focus area where the SEC expected to begin filing cases in short order. She also noted "many ongoing investigations in which we're working with foreign regulators," and said that this kind of cooperative, cross-border investigation is "something we'd like to do more of."

II. PRESSURE POINTS

A. Individuals Targeted

For industry officials, the most alarming aspect of Breuer's November 2009 speech was his assertion that a significant focus of the enforcement effort would be the investigation and prosecution of senior executives. According to Breuer, "[e]ffective deterrence requires no less . . . . [F]or our enforcement efforts to have real deterrent effect, culpable individuals must be prosecuted and go to jail." In Breuer's February speech in Miami, noted above, he drove

the point home again, warning that "the prospect of significant prison sentences for individuals should make it clear to every corporate executive, every board member, and every sales agent that we will seek to hold you personally accountable for FCPA violations." He described "the aggressive prosecution of individuals" as a cornerstone of the DOJ's "very robust FCPA program," which he held out as a model that "typifies how we are approaching crime in corporate America."

Even before Breuer's comments, officers and directors were already feeling FCPA pressure based on a July 2009 civil settlement between the SEC and Nature's Sunshine Products, Inc. (NSP), its CEO, and its former CFO. In that case, the SEC relied on a "control person" theory to assert FCPA liability against high-level corporate officers for failure to adequately oversee key management personnel charged with making and keeping accurate books and records, and devising and maintaining an adequate system of internal controls.

The charges involved payments made to Brazilian customs officials by a Brazilian subsidiary of NSP, a manufacturer of nutritional and personal care products, to facilitate the import of unregistered products. It also involved falsification of NSP's books and records to conceal the payments. The settlement included a civil penalty of $600,000 against NSP and of $25,000 each against the CEO and former CFO. The complaint alleges that the CEO (who at the time of the payments was COO and a member of the board) and former CFO violated the books and records and internal controls provisions of

the FCPA solely in their capacities as "control persons."

Nowhere does the *Nature's Sunshine* complaint allege that either the CEO or former CFO engaged in any affirmative act related to the improper payments, nor even that they had any awareness of the payments. Rather, it asserts that they were liable because, in their roles as corporate officers, they were charged with supervision of senior management and policies regarding NSP's international operations. This included direct or indirect oversight of key management personnel charged with making and keeping accurate books and records, and devising and maintaining an adequate system of internal controls. By failing to do so, they bore ultimate responsibility for the failures and affirmative misdeeds of personnel below them in the organization.

Nature's Sunshine appears to be the first time that the SEC has charged an individual under the control person provision in Section 20(a) of the Securities Exchange Act of 1934 in the FCPA context. Section 20(a) is commonly used in private securities litigation. However, its use to pursue individuals in *Nature's Sunshine* broke new ground, and substantially raised the stakes for officers and directors who are now faced with the prospect of regulatory and law enforcement scrutiny of their leadership, even in situations where they lack knowledge of or involvement in activities several layers of management below them.

Nature's Sunshine also demonstrates the significant risk of third parties creating liability in the FCPA context. Under the FCPA, companies and individuals can face liability indirectly based on the actions of third parties, even if they did not know or approve of those activities. If, for example, enough unresolved "red flags" surface in the course of dealing with a third party, or there are other reasons for the company to have known that a third party was involved in the provision of improper inducements to foreign officials designed to result in some benefit for the company, the company can be charged with the knowledge of that conduct and be held liable for it. The recent conviction of Frederick Bourke provides an illustrative example.

Bourke, co-founder of the high-fashion handbag company Dooney & Bourke, was convicted on July 10, 2009 of violating the FCPA and lying to the FBI, and was subsequently sentenced to over a year in federal prison.[3] The prosecution theory was that Bourke knew or consciously avoided knowing about a scheme in the late 1990's to bribe Azerbaijani government officials to sell off a state-owned oil company. By putting his "head in the sand" regarding a deal that was too good to be true in a country with a reputation for corruption, Bourke found himself in violation of the FCPA under an aggressive prosecution theory. Notably, Bourke was an investor who did not pay any bribes, did not benefit, and actually lost money (along with other investors)

[3]Note that FCPA trials are rare, and of the few that have gone to trial since 1991, none has resulted in acquittal.

because the bribes did not work. This highlights the care that drug and device companies, and their officers and directors, must take in handling key aspects of their non-U.S. activities, including their affiliations with third-party clinical research organizations (CROs), due diligence regarding those and other third party partners and representatives, and relationships with government-affiliated or state-run academic and healthcare facilities.

While FCPA prosecutions of pharmaceutical and medical device executives have yet to occur in the United States,[4] the UK's Serious Fraud Office (SFO) obtained a guilty plea in April 2010 from the former marketing director of an orthopedic device company based on payment of allegedly improper commissions to Greek surgeons within the state-controlled healthcare system in order to induce their purchase of the company's products. The SFO described the official as the first "co-operating defendant" in a major SFO corruption investigation, which it described as ongoing.

B. Greater International Cooperation and Enforcement

The SFO investigation was initiated by a referral from the DOJ in late 2007. This referral is an example of another important enforcement trend: the expanding cooperation between U.S. and non-U.S. law enforcement in the anti-corruption context. In addition to the SFO case noted above, the DOJ has

[4]Both the DOJ and SEC have been focused on FCPA enforcement actions against individuals overall, with a significant recent rise in such cases. Reports indicate that between 2005 and the third quarter of 2010, approximately 104 individuals have faced such enforcement actions. This breaks out by year as follows: 2005 (8 individuals charged), 2006 (9), 2007 (17), 2008 (16), 2009 (42), 2010 (12, as of September 2010).

recently engaged with the SFO and other EU law enforcement agencies on joint investigations such as the January 2010 "Shot Show" sting, which involved the coordinated arrest of 21 individual defendants and execution of parallel search warrants in the UK. These and other examples highlight that cross-border law enforcement cooperation and information sharing is working in anti-corruption cases, placing companies within reach of a wider and wider enforcement net.

For companies with operations in the UK, the risk is growing more acute as they await the April 2011 effective date of the recently-enacted UK Bribery Act 2010. Although similar to the FCPA, the Bribery Act covers a broader range of activities (both governmental and commercial bribery) and has a number of offenses and key provisions that are substantively different than parallel aspects of the FCPA. The Bribery Act has the potential to reach activities occurring outside the UK with very little connection to a company's UK operations.

C. Activities under Scrutiny

The DOJ, along with the SEC, had at least six active FCPA investigations of major medical device companies underway at the time of Breuer's November 2009 speech. This included several companies that settled a kickback case in September 2007 based on activities in the United States similar to those at issue in the SFO prosecution, which led to an ongoing investigation of their overseas activities. Since Breuer's speech, a growing roster of pharmaceutical

and medical device companies both large and small have confirmed that they have received subpoenas and/or letters from the DOJ and SEC putting them on notice that they are under investigation for the development, sale, licensing, and marketing of their products in foreign countries. Reports indicate that activities in several countries in particular are being scrutinized, including Brazil, China, Germany, Greece, Italy, Poland, Russia, and Saudi Arabia.[5] So far, at least five healthcare companies have received such subpoenas or letters, bringing the number of known active FCPA investigations in the pharmaceutical and medical device industries to at least eleven.

Based on what is publicly known about these investigations, several practices appear to be under scrutiny. Some of these practices raise issues when engaged in domestically and have triggered enforcement actions as part of the U.S. government's healthcare fraud crackdown.

The most obvious objects of enforcement attention are bribery, kickbacks, or other improper inducements provided in order to drive a company's drug and device sales. According to recent press reports, the DOJ and SEC letters noted above have identified several types of activities under investigation in this area, including bribery to induce drug purchases by doctors employed by the government; commissions passed through sales

[5]Several of these countries rank from moderate to poor on Transparency International's Corruption Perceptions Index (CPI), considered to be the standard benchmark for corruption reputation. *See* www.transparency.org. The CPI ranks countries from best (1) to worst (178) in terms of corruption reputation. The 2010 CPI rankings for the countries noted are: Brazil (69), China (78), Germany (15), Greece (78), Italy (67), Poland (41), Russia (154) and Saudi Arabia (50).

agents to such doctors; payments to hospitals to secure approval for drug purchases; and payments to officials to secure regulatory approvals.[6] While this may appear straightforward, FCPA liability can be triggered by provision of "any thing of value" in exchange for an improper action by the recipient of the benefit. There is no *de minimis* exception, and "any thing of value" is interpreted literally by U.S. law enforcement. This can raise particularly difficult questions with regard to the pharmaceutical and medical device industries, where meals and small gifts have been an integral and accepted part of product marketing and sales. Although those practices have been limited domestically in recent years following scrutiny of issues such as off-label marketing, under the low threshold of the FCPA, seemingly benign day-to-day sales and marketing activities could result in costly law enforcement attention when they occur overseas.[7] Even charitable contributions have resulted in FCPA liability, when the contributions were linked to a foreign official with the ability to influence business opportunities for the donor.

A second avenue of inquiry relates to drug trials occurring in foreign locations. The DOJ is reportedly investigating whether drug companies conducting clinical trials outside the United States may be offering improper

[6]Michael Rothfeld, *Drug Firms Face Bribery Probe*, WALL STREET JOURNAL (October 5, 2010).

[7]One related area that has been a fruitful source of FCPA liability is the provision of travel and entertainment expenses to foreign officials in connection (ostensibly) with facility visits, product demonstrations or other marketing activities. Paying such expenses is not *per se* improper under the FCPA, but the circumstances and arrangements must be carefully analyzed and controlled to ensure they are connected to bona fide marketing and product demonstration activities and stay within reasonable, permissible bounds.

inducements to influence the outcomes of those trials, either directly or through third parties. Companies seeking approval of new drugs are increasingly using data from foreign clinical trials. According to a June 22, 2010 report by the Office of Inspector General of the Department of Health and Human Services, which may have triggered some of the DOJ's investigations,[8] it is "estimated that between 40 percent and 65 percent of clinical trials investigating FDA-regulated products are conducted outside the United States." The report cited a survey that found "the 20 largest United States-based pharmaceutical companies were conducting one-third of their clinical trials exclusively at foreign sites." It further noted that "[e]ighty percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials," with 78 percent of all subjects who participated in clinical trials enrolled at foreign sites and 54 percent of all trial sites located outside the United States, with reliance on such trials likely to grow. The investigation of this issue highlights the critical FCPA risks posed by involvement with third parties in non-U.S. activities.

A third risk area that has been raised by commentators is "medical ghosting." This is the practice of hiring third parties to write articles about a product, which will then be signed by a medical professional acting as its author. The practice is designed to result in publication without the publisher

[8]HHS, Office of Inspector General, *Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials* (June 22, 2010), *at* http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf (last visited Nov. 3, 2010). The report was critical of the FDA's monitoring of foreign clinical trials.

being aware that it was the company, rather than the author, that created the article. Medical ghosting has drawn congressional attention in the United States,[9] which has raised the profile of this practice and caused some to question it on legal and ethical grounds. There is concern that medical ghosting involving a foreign doctor or scientist working in a state-run healthcare system could violate the FCPA because ghosting involves benefits conferred by the company on the "author" (publication credit), in exchange for a benefit to the company (an independent article in a medical journal supporting use of their product).

A fourth risk area is the increasing investment healthcare companies are making in facilities located in regions with poor reputations for corruption. These facilities are designed for product development and to tap other business opportunities in emerging markets. Over the last fifteen years, some of the most respected U.S. hospitals and academic medical centers have opened branches and created partnerships in Europe, Asia, North Africa and the Middle East. The pharmaceutical and medical device industries have not been far behind, and in markets such as Singapore they have been in the vanguard of a boom in globalized biomedical research and product development. After watching Singapore's success over the last several years in developing itself as an international hub of pharmaceutical and medical device research,

[9] *See* Committee on Finance, U.S. Senate, Minority Staff Report, "Ghostwriting in Medical Literature" (June 24, 2010); *see also* Natasha Singer, "Report Urges More Curbs on Medical Ghostwriting," NEW YORK TIMES (June 24, 2010).

development, and manufacture, countries such as China and India are now vying to create another medical research park like Singapore's Biopolis or Tuas Biomedical Park.[10] But unlike Singapore, which is consistently ranked as one of the world's least corrupt countries, China and India have reputations that require a cautious approach to any business or investment opportunity, particularly in the healthcare sector where government involvement and control is extensive.[11]

Any business focusing on or with a physical presence in emerging markets, or actively engaged with third party partners or representatives in those markets, faces a day-to-day battle to address anti-corruption-related risks.[12] But the entanglement of foreign governments in the pharmaceutical and medical device industries, where every representative of a state-owned, state-run or state-affiliated healthcare organization with which a company may be interacting would likely be considered a foreign official, makes the risks an

[10]The Biopolis is a state-of-the-art seven-building biomedical research park in Singapore that opened in September 2003 and has since been populated with a world-renowned collection of scientists and researchers from around the globe. The Tuas Biomedical Park, also located in Singapore, was built for bulk pharmaceutical and medical device manufacturing, and hosts operations for several leading global companies. Between 2000 and 2005, developments such as these attracted at least 25 drug companies to establish operations in Singapore, including many of the most recognizable names in the pharmaceutical and medical device industries.

[11]Singapore has a 2010 CPI ranking of 1, while China's ranking is 78 and India's ranking is 87.

[12]For an entity establishing a facility in an emerging market, everything from construction and operational permits to dealings with tax, labor and other authorities, as well as local, regional and national politicians can pose an FCPA risk. Product development activities raise the additional concern of interactions with authorities overseeing patents, trademarks and other intellectual property.

order of magnitude more significant.[13] Accordingly, activities in these areas must be approached with the expectation that even the slightest appearance of impropriety may draw significant law enforcement scrutiny. This is true not just for pharmaceutical and medical device manufacturers, but also for the academic institutions with which they are frequently involved in drug and device development. Those institutions have their own significant risks to manage based on their increasing global footprint and involvement in foreign clinical trials and other research and development activities outside the United States.

III. ADDRESSING COMPLIANCE

In closing his November 2009 remarks, Breuer counseled potential targets of FCPA scrutiny to ensure they have a "rigorous FCPA compliance policy that is faithfully enforced," to "seriously consider voluntarily disclosing" violations that are discovered, and to quickly remediate the source of any violations. He noted that failure to take these steps can result in substantial negative consequences including significant criminal fines and possible exclusion from Medicare and Medicaid. This is a consistent theme for Breuer, who in his February 2010 speech warned that corporations will face criminal

[13]Those risks extend not just to companies setting up facilities or other operations in country, but also to those entering the market to sell their products, and even to those looking to license new technologies developed in recently established foreign incubators. For example, the Singaporean investment in stem cell technology development is already being monetized into potentially substantial revenue streams from the licensing and sale of technologies developed by government-run or funded institutions. One would expect these other countries to pursue similar opportunities. As with any newly-established market, this will carry the risk of corruption.

charges "when the criminal conduct is egregious, pervasive and systemic, or when the corporation fails to implement compliance reforms, changes to its corporate culture, and undertake other measures designed to prevent a recurrence of the criminal conduct."

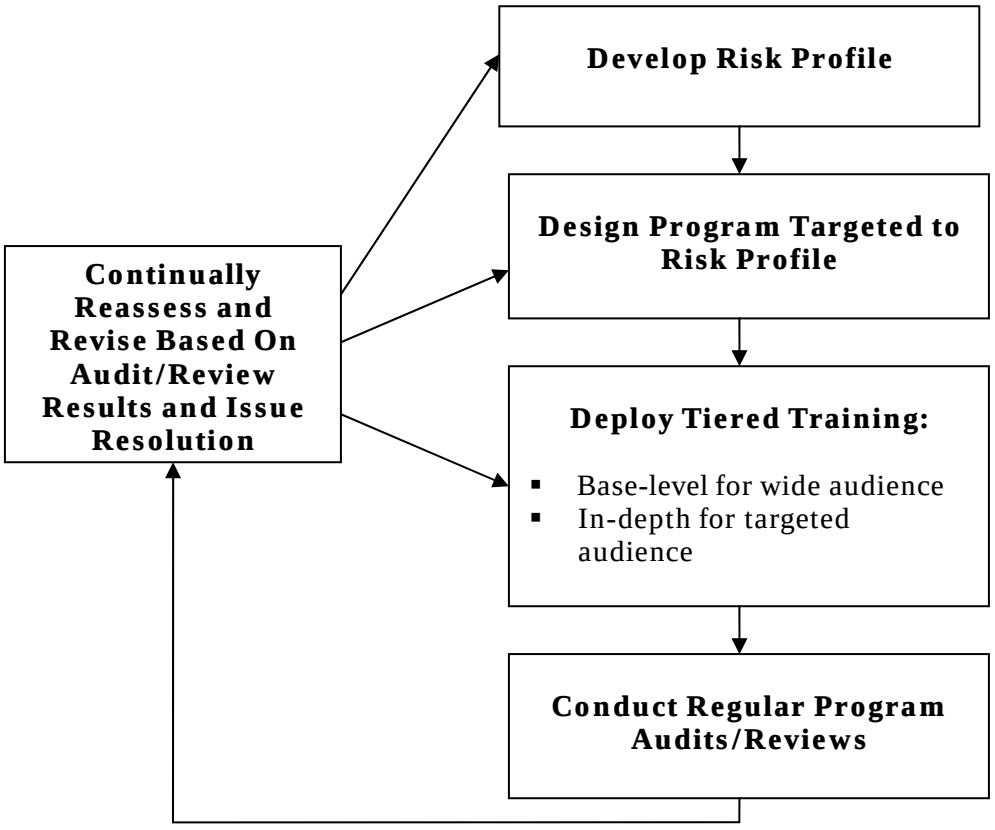
Meeting the DOJ's compliance mandate is neither simple nor inexpensive, but is critical for pharmaceutical and medical device companies hoping to avoid, or at least successfully weather, corruption-related scrutiny from U.S. or non-U.S. law enforcement.[14]

The first step is for the organization to understand its risks by developing a risk profile through detailed analysis of several different types of factors such as generic industry and geography-based risks, business-specific risks, functional risks and third-party risks. Once this profile is in place, it can be used to devise a risk-based approach to developing a robust and effective anti-corruption compliance program. At its core, such a program should include:

- Written policies and procedures that govern the program;
- Internal financial controls designed to prevent and detect improper payments;
- Oversight of the compliance program by responsible personnel with easy access to the most senior management of the company;
- Personnel training; and
- Regular, periodic audits of the program to ensure that it is working.

[14]An effective compliance program has even proved valuable in repelling civil litigation. In January 2010, the Delaware Chancery Court dismissed a shareholder derivative suit against Dow Chemical's current officers and directors based on allegations that Dow officials had bribed Kuwaiti officials in support of a proposed joint venture. The Court based its decision primarily on Dow's deployment of an ethics and compliance program. *See In re the Dow Chemical Co. Derivative Litig.*, Consolidated Civil Action No. 4349-CC (Del. Ch., Jan. 11, 2010).

From there, the key to maintaining the program's effectiveness is to ensure that it is active and sustainable. Company leadership must be engaged in the program, invested in its success, and dedicated to setting the right "tone from the top." Compliance program leadership must ensure that the risk profile is regularly revisited and revised, and that the program's design and execution are as well. The program must evolve and change with the company, with the goal of becoming an integrated part of the corporate DNA. This results in a program life cycle such as the following:



These steps take time, effort, and money, but have been shown to pay dividends. For many in the pharmaceutical and medical device industries, current law enforcement interest in their international activities makes such an investment timely and worthwhile.[15]

[15]Pursuant to the U.S. Sentencing Guidelines and the DOJ's Filip Memo governing charging decisions for corporate defendants, a key consideration regarding whether a company has an effective ethics and compliance program is whether the program was in place before law enforcement scrutiny began. *See* USSG § 8B2.1; USAM, Title 9, Chapter 9-28.000. Recent amendments to the Sentencing Guidelines, effective as of November 1, 2010, include key changes impacting how ethics and compliance programs and the lines of reporting within them should be organized, and providing guidance as to how the compliance program should respond to issues "including assessing the compliance and ethics program and making modifications necessary to ensure that the program is effective."