



November 2014

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## *Here We Go Again—The U.S. Government Brings Home Another FCPA Case Against a Life Sciences Company*

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Over the last several years, multinational companies of various sizes and geographical reach in the pharmaceutical, medical device, and biotechnology industries have found themselves in the crosshairs of the U.S. Department of Justice (“DOJ”) and U.S. Securities and Exchange Commission (“SEC”) as both agencies continue their aggressive enforcement of the Foreign Corrupt Practices Act (“FCPA”). Many such life sciences companies have already resolved FCPA matters with the U.S. government, and numerous others have disclosed that they are subject to ongoing investigations.

Last week, the government delivered yet another reminder that this enforcement trend will continue as a California-based, multinational medical diagnostics and life sciences company, Bio-Rad Laboratories (“Bio-Rad”), agreed to pay a total of \$55 million to resolve parallel FCPA investigations by the DOJ and SEC involving payments made to government officials in Russia, Vietnam, and Thailand. Bio-Rad’s settlement with the SEC included \$40.7 million in disgorgement and prejudgment interest, which represents the *tenth largest* disgorgement in any FCPA-related enforcement action brought by the SEC.<sup>1</sup> Bio-Rad also entered into a non-prosecution agreement with the DOJ, pursuant to which it agreed to pay a criminal fine of \$14.35 million and report its compliance efforts to the government for a period of two years.

Further, Bio-Rad is not out of the woods yet, as it finds itself dealing with a familiar headache after the resolution of an FCPA investigation: the potential for follow-on civil litigation. Despite the fact that the FCPA does not provide for a private cause of action, plaintiffs’ firms remain undeterred and continue to push forward with civil lawsuits, usually in the form of shareholder derivative suits or class actions.<sup>2</sup> These actions are typically based on facts similar to those underlying the government cases and, in recent years, have resulted in some significant settlements, which have often included an agreement to institute compliance program enhancements, and almost always required the payment of plaintiff’s attorneys’ fees. As a result, when a company announces an FCPA resolution, it is often followed by more unwanted media coverage regarding follow-on civil litigation. Bio-Rad is no different.

Less than twenty-four hours after the settlements were announced, several plaintiffs’ firms announced investigations to determine whether Bio-Rad’s officers and directors breached their fiduciary duties to shareholders in connection with the compliance breakdowns underlying the government investigations.<sup>3</sup> It remains to be seen whether any derivative suits or other cases will be filed but, in practice, it could be only a matter of time before a complaint hits the docket.

And the fallout does not stop there. The Vietnamese authorities have reportedly launched their own investigation into the misconduct that occurred in Vietnam, namely the payment of \$2.2 million to Vietnamese health officials in exchange for government contracts. With the launch of the investigation in Vietnam, Bio-Rad became the latest victim of so-called “carbon copy” prosecutions, an ever-increasing trend where authorities in multiple jurisdictions will pursue prosecutions arising out of the same facts.<sup>4</sup> As a result, after settling parallel investigations here in the U.S., Bio-Rad now faces the additional costs and potential exposure associated with enduring another investigation in Vietnam.

Given the U.S. government’s continued FCPA enforcement efforts, as well as the ongoing risk of related shareholder litigation and rapidly evolving threat of so-called “carbon copy” foreign prosecutions, it remains imperative that pharmaceutical, medical device, and biotechnology companies be even more proactive in ensuring compliance with the FCPA and other anti-corruption laws.

### **Government Focus on Pharmaceutical, Medical Device And Biotechnology Companies**

In November of 2009, the Head of the Criminal Division of the DOJ announced that the DOJ would be “intensely focused on rooting out foreign bribery in [the pharmaceutical] industry” and forewarned that the DOJ’s “focus and resolve” in this area “will not abate.”<sup>5</sup> Among the reasons cited for this enhanced scrutiny were the unique anti-corruption risks facing the pharmaceutical industry. The DOJ official explained that, because many foreign health care systems are government-operated, companies selling pharmaceuticals overseas will routinely interact with government officials and, in certain circumstances, “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.” As a result, in the government’s view, there is “significant risk” that corrupt payments will infect the process.

The medical device sector, which shares a similar business model, was not to be excluded from the coming events. That same day, the Chief of the Criminal Division for the U.S. Attorney’s Office for the District of New Jersey stated that the FCPA had become the DOJ’s main priority—second only to terrorism—and that medical device companies would also be targeted.<sup>6</sup>

Since these remarks, the DOJ has made good on its promises.

In 2010, the DOJ and SEC embarked on a well-publicized “industry sweep” of the pharmaceutical and medical device industries, and made inquiries to many leading multinational manufacturers in order to determine whether improper payments were made to doctors or other foreign government officials.<sup>7</sup> It didn’t take long for the industry sweep, along with the long line of voluntary disclosures at the government’s doorstep, to make its significant impact.

In the decade that preceded the commencement of the government sweep, a multitude of life sciences companies resolved cases involving kickbacks and other alleged improper payments on the domestic healthcare front, many of which involved settlements for staggering dollar amounts; however, there had been only a corresponding handful of FCPA resolutions in the life sciences sector, and most of them involved relatively low dollars.<sup>8</sup> By the close of 2012, however, approximately 50% of FCPA settlements for the calendar year involved the life sciences sector.<sup>9</sup> It was a virtual onslaught of enforcement, and many prominent companies were netted. And the government’s interest in the sector shows no signs of abating.

As of last year, approximately one out of every four FCPA investigations involved a life sciences company.<sup>10</sup> Last Monday, Bio-Rad became the latest company to make the FCPA headlines.

## The Bio-Rad Investigation

The DOJ and SEC investigations of Bio-Rad primarily focused on the company's sale of clinical diagnostic products, such as HIV kits, in the Russia market, where a substantial portion of Bio-Rad's business consisted of sales to the Russian government. Those sales were made pursuant to government contracts that were awarded to Bio-Rad through a public tender offer process that required approval from various government officials. From approximately 2005 to 2010, a Bio-Rad subsidiary, headquartered in France, made excessive payments to third-party intermediary companies that were retained in order to assist the company in acquiring new business in Russia (e.g., disseminating promotional material and distributing and installing products). These intermediary companies, which were incorporated in the United Kingdom, Belize and Panama, were paid commissions between 15% and 30%, which over the course of nearly five years, amounted to approximately \$4.6 million on \$38.6 million of sales.

However, none of the third-party intermediaries actually provided, or had the capability to provide, the contracted-for services; according to the SEC, the intermediaries had phony addresses, off-shore bank accounts in Lithuania and Latvia, and no employees. The SEC charged that one of the intermediaries "even used a phony office address in Moscow that was actually the office address for a Russian government building." Moreover, each intermediary was created by the same individual, who was known to have important contacts within the Russian government and the ability to influence the tender offer process. Bio-Rad's Russian subsidiary won 100% of its government contracts when utilizing these intermediaries, and then lost its first major Russian government contract after terminating the intermediaries in 2010. The scheme was apparently effective in obtaining and retaining business—while it lasted.

The SEC charged similar wrongdoing in Southeast Asia. In Vietnam, Bio-Rad sales representatives made payments to Vietnamese officials at hospitals and laboratories in exchange for their agreement to purchase Bio-Rad products. The country manager in the Vietnam office recognized the wrongful nature of the conduct, but feared losing 80% of the business without it. In order to "insulate" Bio-Rad from liability, he then channeled \$2.2 million to third-party agents and distributors in the form of "advertising" and "training" fees, which were, in turn, funneled to Vietnamese government officials. In Thailand, Bio-Rad acquired a 49% interest in Diamed Thailand, as part of its acquisition of Diamed AG (Switzerland). There was little due diligence performed in connection with the acquisition and, as it turned out, the Thai affiliate operated a bribery scheme that utilized third-party intermediaries. Specifically, Diamed Thailand paid the intermediary an inflated commission of 13%, the majority of which was provided to Thai government officials in exchange for business contracts.

The above conduct resulted in Bio-Rad's agreement to pay \$55 million to settle the SEC's charges, which included violations of the anti-bribery, internal controls, and books and records provisions of the FCPA, as well as the parallel investigation by the DOJ. Interestingly, however, the DOJ was focused not only on Bio-Rad's failure to implement adequate controls, but also on Bio-Rad's lack of "adequate compliance systems." The DOJ's specific mention of Bio-Rad's compliance program—both in the non-prosecution agreement and its accompanying press release—is interesting given that, to date, FCPA liability has not been predicated solely upon a failure to implement a sufficient compliance program.<sup>11</sup> However, it comes on the heels of the recent *Smith & Wesson* settlement, where the SEC's administrative order was similarly focused on compliance program failures, thus raising the question as to whether the government is setting the table to try and impose FCPA liability for the simple failure to implement adequate compliance systems.

## Lessons Learned From Bio-Rad: Managing The Risks

As reflected by the Bio-Rad settlement, life sciences companies remain at risk of enhanced FCPA scrutiny by the U.S. government. For these companies, the best defense will be a good offense in the form of a robust and thoughtful compliance program designed to prevent and detect potential violations of the FCPA and other anti-corruption laws. In that regard, Bio-Rad teaches us important lessons about some essential compliance measures that every company should have in place, including:

1. *Effective Controls And Diligence Around Third-Parties.* Neither the SEC nor DOJ found that Bio-Rad had actual knowledge of bribes paid by intermediaries, yet Bio-Rad still found itself on the hook due to, among other things, its failure to maintain adequate controls with respect to third-parties. To avoid this all-too-common pitfall, it is critical that companies engaging third-parties conduct thorough due diligence, both prior to the engagement and on an on-going basis thereafter. In addition, companies should create standardized third-party agreements and other documentation, which include FCPA compliance certifications. Compliance managers should also implement a system to ensure the existence and retention of documentation supporting third-party payments, as well as the monitoring and auditing of such payments.
2. *Detecting Potential FCPA Violations.* The government found that Bio-Rad's managers ignored "repeated red flags" that permitted the wrongful conduct to continue for nearly five years. Those "red flags" included the use of code words (e.g., "bad debt") to refer to the commissions at issue, as well as facts suggesting that the intermediaries did not have the resources to perform the contracted-for services and the commissions were being paid to foreign bank accounts. In order to avoid perpetuating wrongful conduct, companies must develop a protocol for employees to report potential FCPA violations and adopt a systematic approach for immediately and thoroughly investigating those issues. In addition, companies must not wait for the phone to ring, and should be increasingly proactive with approaches to uncovering latent issues.
3. *Anti-Corruption Policies And Training.* Bio-Rad's failure to provide FCPA training and ensure employees were aware of the company's anti-corruption policies "significantly contributed" to the company's inability to prevent the relevant misconduct. Bio-Rad posted its code of conduct on its company intranet site, but many employees were unaware of its existence, and for those who were aware, it was only posted in English, despite the fact that many employees could not understand the language. Thus, it remains imperative that companies continue to provide appropriate FCPA training to employees and retain records of such training. In addition, anti-corruption policies should be translated and distributed to all employees, who should certify that they have read the policies and understand their compliance obligations.
4. *Acquisition Due Diligence.* Although not the most prominent aspect of this case, it is important to recognize that the improper payment issues out of Thailand were inherited by Bio-Rad when it acquired a substantial interest in Diamed without performing proper due diligence. To avoid "purchasing" costly FCPA problems, companies must conduct thorough due diligence on acquisition targets, which may include, among other efforts: (i) an assessment of compliance policies and procedures; (ii) a review of third-party relationships; (iii) possible forensic testing of historic payments; and (iv) scoping interviews with key senior management in the markets.

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<sup>1</sup> See Richard L. Cassin, *Bio-Rad cracks the disgorgement top ten list*, The FCPA Blog (Nov. 4, 2014), <http://www.fcpablog.com/blog/2014/11/4/bio-rad-cracks-the-disgorgement-top-ten-list.html> (last visited Nov. 11, 2014).

<sup>2</sup> See Amy Deen Westbrook, *Double Trouble: Collateral Shareholder Litigation Following Foreign Corrupt Practices Act Investigations*, 73 Ohio St. L.J. 1217, 1224–26 (2012).

<sup>3</sup> See, e.g., *U.S. Securities and Exchange Commission Charges Bio-Rad with Violating the Foreign Corrupt Practices Act*, Robbins Arroyo LLP, <http://www.robbinsarroyo.com/shareholders-rights-blog/bio-rad-laboratories-inc/> (last visited Nov. 11, 2014).

<sup>4</sup> See Andrew S. Boutros & T. Markus Funk, *“Carbon Copy” Prosecutions: A Growing Anticorruption Phenomenon in a Shrinking World*, 2012 U. CHI. LEGAL F. 259, 269 (2012).

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- <sup>5</sup> Lanny A. Breuer, Assistant Attorney General, Criminal Division, Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009), *available at* <http://www.justice.gov/criminal/pr/speeches-testimony/documents/11-12-09breuer-pharmaspeech.pdf>.
- <sup>6</sup> See David W. Simon et al., *No Doctoring the Books*, Medical Device and Diagnostic Industry (May 1, 2010), *available at* <http://www.mddionline.com/article/no-doctoring-books> (citing Charles McKenna, Chief, Criminal Division, U.S. Attorney's Office for the District of New Jersey, Panelist, "Criminal Issues in Medical Device and Pharmaceutical Litigation" (Nov. 12, 2009)).
- <sup>7</sup> See, e.g., Gardiner Harris and Natasha Singer, *U.S. Inquiry of Drug Makers is Widened*, New York Times (Aug. 13, 2010), *available at* [http://www.nytimes.com/2010/08/14/health/policy/14drug.html?\\_r=0](http://www.nytimes.com/2010/08/14/health/policy/14drug.html?_r=0).
- <sup>8</sup> See Sammy Amashat and Sidney Wolfe, *Pharmaceutical Industry Criminal and Civil Penalties: An Update*, at 18, n. 41 (Sept. 27, 2012), *available at* <http://www.citizen.org/documents/2073.pdf> (noting "only three settlements, for a combined \$79 million, were reached between pharmaceutical manufacturers and the federal government to resolve allegations of FCPA violations from 1991 through July 18, 2012").
- <sup>9</sup> See Jennifer Saperstein, *Managing Your FCPA Risk: Lessons for the Device Industry from 2012 Enforcement Actions*, Inside Medical Devices (Jan. 10, 2013), <http://www.insidemedicaldevices.com/2013/01/10/managing-your-fcpa-risk-lessons-for-the-device-industry-from-2012-enforcement-actions-2/> (last visited Nov. 11, 2014).
- <sup>10</sup> See Saul B. Helman, *Increased Corruption Exposure for Healthcare Institutions, Manufacturers and Providers—Tips on Mitigating This Risk*, Navigant, Evolving Healthcare Regulations (Jan. 1, 2013), [http://www.navigant.com/insights/library/disputes\\_and\\_investigations/2013/evolving-healthcare-regulations/](http://www.navigant.com/insights/library/disputes_and_investigations/2013/evolving-healthcare-regulations/) (last visited Nov. 11, 2014).
- <sup>11</sup> See Press Release, U.S. Dep't of Justice, *Bio-Rad Laboratories Resolves Foreign Corrupt Practices Act Investigation and Agrees to Pay \$14.35 Million Penalty* (Nov. 3, 2014), <http://www.justice.gov/opa/pr/bio-rad-laboratories-resolves-foreign-corrupt-practices-act-investigation-and-agrees-pay-1435>; see also Bio-Rad Non-Prosecution Letter Agreement, dated Nov. 3, 2014, at A-7, ¶ 24-25 (Nov. 3, 2014), *available at* <http://www.corporatecrimereporter.com/wp-content/uploads/2014/11/Bio-Rad-NPA.pdf>.