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**HEALTH CARE
COMPLIANCE
ASSOCIATION**

COMPLIANCE TODAY

**Volume Thirteen
Number Twelve
December 2011
Published Monthly**

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The rising tide: Recognizing your criminal prosecution risks abroad

By Winston Y. Chan and Justin S. Liu

Editor's note: Winston Y. Chan is Of Counsel in Gibson, Dunn & Crutcher's San Francisco office. Winston may be contacted by e-mail at wchan@gibsondunn.com.

Justin S. Liu is an Associate in Gibson, Dunn & Crutcher's Los Angeles office. He may be contacted by e-mail at jliu@gibsondunn.com.

In recent years, US law enforcement authorities have demonstrated an increasing willingness to scrutinize the health care industry for criminal conduct. A new academic study,¹ released on August 17, 2011 by Syracuse University, starkly quantifies this trend, finding that health care fraud prosecutions by the Department of Justice (DOJ) during the first eight months of 2011 numbered more than 900 cases, representing a brisk prosecutorial pace that is 85% greater than last year, 157% greater than five years ago, and 115% greater than 10 years ago. Immediately on the heels of the study—as if on dramatic cue—the Department announced on September 7, 2011, that it had

charged 91 health care professionals across eight cities for their alleged participation in schemes that falsely billed more than \$295 million.² Just three weeks later, on September 26, 2011, Assistant Attorney General Lanny A. Breuer announced that “[t]he civil rights, criminal, and civil divisions of the Department of Justice are all working together to fight health care fraud.”³

As part of this escalation in government resources directed against health care fraud, the DOJ has not hesitated to examine the conduct of the health care industry globally, primarily through the lens of the Foreign Corrupt Practices Act (FCPA), which gives prosecutors the ability to focus on wholly foreign conduct in a way that the traditional health care fraud criminal statutes do not. Indeed, in April 2011, Johnson & Johnson paid a \$21.4 million fine in connection with a criminal FCPA settlement with the DOJ, based on acts purportedly occurring inside Greece, Poland, and Romania.⁴

Accordingly, pharmaceutical, biotechnology, and medical device and service companies that do business internationally must be equally vigilant in recognizing and mitigating the compliance risks that they face abroad, as they do within the United States. We set forth some of those primary risks herein: the use of third-party distributors and resellers, health care consultants, and—the newest subject of US law enforcement attention—foreign clinical trials.

FCPA risks in the health care industry

The Johnson & Johnson settlement related to charges that its subsidiaries in Greece, Poland, and Romania bribed publicly-employed health care providers in those nations in order to induce them to use and purchase Johnson & Johnson medical devices and drugs. Similar allegations have abounded. In 2010, Merck revealed that it was subject to an FCPA investigation. In 2009 and 2010, Eli Lilly disclosed that an FCPA probe that began in 2003 with an investigation of its Polish unit, was expanding. Other pharmaceutical companies, including AstraZeneca, Baxter, Bristol-Myers Squibb, GlaxoSmithKline, and Pfizer, reportedly have received letters of inquiry from the DOJ. In 2007 and 2008, six medical device manufacturers (Biomet,

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Medtronic, Smith & Nephew, Stryker, Wright Medical, and Zimmer Holdings) disclosed their own FCPA investigations.

Nor is the DOJ's interest in the health care industry as a target for FCPA investigations likely to wane, particularly because the largest foreign purchasers of pharmaceuticals and medical equipment generally are state-run hospitals and state-affiliated health care providers. Assistant Attorney General Breuer in a November 2009 speech said, "[O]ne area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead... [is] the application of the Foreign Corruption Practices Act to the pharmaceutical industry." He further noted that, in 2009, close to \$100 billion dollars, or one-third of pharmaceutical revenues, stemmed from sales outside of the United States.

Interactions with non-US doctors and hospitals

The DOJ interprets the FCPA to encompass all employees of state-owned enterprises and government agencies, treating them as "government officials" for purposes of the FCPA. This includes staff members and doctors employed by public and quasi-public hospitals and clinics, and so the sales practices of health care companies need to be particularly sensitive

to how gifts, hospitality, and travel expenditures are handled abroad. Rule-of-reason policies on these expenditures, with pre-approval procedures that involve the Compliance or Legal functions, should be put in place; and employees should receive anti-corruption training, including compliance with local law. As the Johnson & Johnson settlement illustrates, health care companies cannot afford to focus only on the risks of violating the traditional health care fraud statutes, which otherwise require a connection to state and federal health care insurance programs.

Foreign distributors and resellers

Health care companies should be particularly careful when relying on third-party distributors and resellers, which can be necessary in regions where the pharmaceutical, biotechnology, medical device, or medical service company may not have a sufficient indigenous sales capability—particularly in vast geographic markets, such as China and Russia. These third parties pose compliance risks, because of pass-through liability under the FCPA coupled with their often opaque business practices. When utilized, third-party distributors and resellers should not be injected into transactions without a clear and legitimate business purpose, and localized due diligence on these business partners should be conducted

to ensure that they are reputable and they abide by anti-corruption laws. This due diligence should occur prior to any partnership, and should be actively supplemented on a recurring basis. Anti-corruption provisions should be included in contracts and agreements with distributors and resellers, and the health care company should seek to make clear to its sales channel partners its commitment to anti-corruption compliance, including by sharing best practices and training.

Foreign health care consultants

Another risk area is the use of consulting arrangements with prominent foreign doctors or health experts to promote the health care company's products or services. Often these "key opinion leaders" will be employed by or affiliated with a government agency or state-owned enterprise. These individuals can be legitimately contracted to research, review, and promote health care products and services, of course, but particular care should be exercised to ensure that the consultant has not been implicated in corruption in the past and is being reasonably compensated relative to a bone-fide and value-adding service, such as conducting an independent medical study or providing necessary education in relation to the company's health care product or service. Pre-approval by the Compliance or

Legal function of any consulting arrangement abroad may be desirable, as would be a requirement that no consultant be retained while the company or its affiliates has business pending before any entity related to the consultant.

Foreign clinical trials

Outside of the international sales and marketing context, a novel area of concern to US officials is the growing reliance on non-US clinical trials when seeking approval of new drugs and medical devices. A 2010 report by the Office of the Inspector General of the Department of Health and Human Services, entitled “Challenges to FDA’s Ability to Monitor and Inspect Foreign Clinical Trials,” found that 80% of drugs approved by the Food and Drug Administration (FDA) relied on non-US clinical trials and that 78% of all subjects who participated in clinical trials did so outside of the United States.⁵ The report also noted the lower rate at which the FDA audited foreign clinical trial sites. Congress has also recognized these concerns. US Representative Rosa DeLauro said the report “highlights a very frightening and appalling situation” because of “clinical trials in foreign countries with lower standards and where FDA lacks oversight.”

Government scrutiny has expanded to law enforcement, who reportedly are reviewing

foreign clinical trials for potential FCPA violations. Because such trials generally would be conducted by doctors at state-run or state-affiliated hospitals or academic institutions, payments by pharmaceutical, biotechnology, or medical device companies could be viewed as potential conduits for bribes. A health care company that seeks to utilize foreign clinical trials should conduct the same level of localized due diligence and active monitoring of its clinical trial partners abroad, just as the company would do with respect to an international third-party business partner. Significantly, a company should be especially mindful when the proposed clinical trial operator is a current or potential customer of the company’s products—a likely scenario if the trial operator is a state-affiliated health care provider.

Conclusion

Health care companies now face the highest levels of DOJ criminal enforcement scrutiny that they ever have, not just for domestic behavior in violation of traditional health care fraud statutes, but also for international conduct in violation of the FCPA. Such companies should implement robust global compliance policies and procedures, and tailor them to the special risks of doing business in foreign countries where, in the health care context, the line between public and private can be

especially blurred. For pharmaceutical, biotechnology, and medical device and services companies, three of the primary international corruption risks arise through their use of third-party distributors and resellers, consultants, and foreign clinical trials. ■

- 1 Syracuse University Transactional Records Access Clearinghouse: Health Care Fraud Prosecutions for 2011. August 17, 2011. Available at <http://trac.syr.edu/tracreports/crim/258/>
- 2 Dept of Justice press release: Medicare Fraud Strike Force Charges 91 Individuals for Approximately \$295 Million in False Billing. September 7, 2011. Available at <http://www.justice.gov/opa/pr/2011/September/11-ag-1148.html>
- 3 Dept of Justice press release: Assistant Attorney General Lanny A. Breuer Speaks at the American Health Lawyers Association and Health Care Compliance Association’s 2011 Fraud and Compliance Forum. September 26, 2011. Available at <http://www.justice.gov/criminal/pr/speeches/2011/crm-speech-110926.html>
- 4 Dept of Justice press release: Johnson & Johnson Agrees to Pay \$21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations. April 8, 2011. Available at <http://www.justice.gov/opa/pr/2011/April/11-crm-446.html>
- 5 Available at <http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf>



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