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Update on Regulatory Compliance in the Global Health Care Industry

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A comprehensive understanding of the constantly evolving layers that make up federal anti-corruption statutes, sanctions regulations and export control restrictions is imperative for both the pharmaceutical and health care industries, particularly in light of recent trends in U.S. enforcement actions. One of the most common statutes utilized against these industries is the Foreign Corrupt Practices Act (FCPA), which targets public corruption and fraud in the international marketplace and is enforced by both the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC). The health care industry, including pharmaceutical companies, clinical research organizations and medical device manufacturers, has come under increasing FCPA scrutiny in recent years as anti-bribery enforcement actions have broadened in scope. A more recent health care industry development in the international market concerns an increase in U.S. enforcement actions based on the export of goods to countries subject to sanctions regulations and export-control restrictions.[1] These regulations are enforced by the Treasury Department's Office of Foreign Assets Control (OFAC) and the Department of Commerce's Bureau of Industry and Security (BIS).

This article addresses recent developments in FCPA and OFAC enforcement actions as they pertain to the health care industry. It will first briefly detail the flurry of 2016 FCPA enforcement actions against health care entities, as well as the outlook for enforcement in 2017. It will then explain how the latest updates to U.S. sanctions regulations and export licensing restrictions will affect health care industry entities that seek to export to sanctioned nations such as Cuba, Iran and Sudan. Finally, it will review recent OFAC enforcement actions and recommend stringent compliance policies for companies in the modern health care industry.

FCPA Health Care Industry Trends

Eight substantial FCPA enforcement actions were settled last year against health care related entities, culminating in December 2016 when the SEC and DOJ announced a record-breaking $519 million settlement with the world's largest manufacturer of generic pharmaceutical products, Israeli company Teva Pharmaceutical Industries Ltd.[2] Teva faced parallel civil and criminal charges that it paid bribes to foreign government officials in Russia, Ukraine and Mexico. Its final settlement ultimately constituted the largest ever FCPA resolution involving a health care entity.[3] Similar improper payments to foreign officials in China resulted in multi-million dollar FCPA settlements with UK-based pharmaceutical companies such as GlaxoSmithKline and AstraZeneca PLC, as well as the Swiss-based Novartis LC.[4] While a full report and breakdown of these enforcement actions can be found on the SEC's website, the common thread is that each health care entity conducted business or sales in a foreign market by improperly bribing local officials or government employees.[5] As the globalization of the health care industry amplifies and our international medical markets become further integrated, medical device distributors and pharmaceutical manufacturers must maintain strict compliance programs regarding anti-bribery regulations and must be aware of the broad extra-territorial application of laws such as the FCPA.

Two major FCPA enforcement actions have been taken thus far in 2017 against health care related entities. On January 12, 2017, the Indiana-based medical device manufacturer Zimmer Biomet agreed to pay more than $30 million to resolve its repeat violations of the FCPA.[6] The case arose from Biomet's improper transactions with a prohibited distributor in Brazil, as well as its use of a broker to bribe Mexican customs

officials to illegally import unregistered dental products. On January 18, 2017, the SEC announced that Texas-based medical device company Orthofix International agreed to pay more than $14 million to settle the charges that it made improper payments to doctors at government-owned hospitals in Brazil to increase its sales.[7] These two cases underscore the importance of rigorous FCPA compliance programs for medical device manufacturers engaging with foreign markets.

Sanctions Regulations and Export Licensing Developments

U.S. export control regulations are governed by numerous federal agencies, and enforcement responsibilities are comprehensively divided. OFAC and BIS are particularly relevant to the health care industry. The Treasury Department houses OFAC, which is delegated the authority for the enforcement of U.S. economic and trade sanctions against foreign states, certain organizations and individuals. BIS is an organization within the Department of Commerce and maintains a list of controlled items covered under the Export Administration regulations (EAR). The EAR generally control exports of "dual use" goods, or goods which can be utilized for both commercial and military purposes. Many companies in the health care, biotechnology and pharmaceutical industries often find that their products or technologies are covered under EAR. Both OFAC and BIS can make exceptions and issue licenses for certain medical exports that normally would not be allowed under prevailing sanctions regulations or export control restrictions. It is thus critical for health care industry entities that engage with global markets, particularly those that do so through foreign affiliates or subsidiaries, to be aware of any updates or changes to current sanctions regulations. For example, such companies should be aware of recent changes to the regulations governing sanctions and exports to Cuba, Iran and Sudan, as described below.

Cuba

OFAC and BIS announced in October 2016 updated amendments to U.S. sanctions regulations and export control restrictions applicable to Cuba that could potentially have major effects on health care industry entities.[8] OFAC authorized the importation of Cuban-origin pharmaceuticals that have been approved by the U.S. Food and Drug Administration; as well as their marketing, sale and distribution in the U.S. Additionally, it authorized U.S. citizens to engage in joint medical research projects, whether for commercial or non-commercial purposes, with Cuban nationals.[9] While President Trump has indicated a desire to roll back portions of Obama-era Cuba policies, it is unclear if these particular amendments will be subject to those changes.[10] Regardless, the amendments were designed to stimulate valuable commercial activity in the health care industry, and companies in the field should always be aware of circumstances in which OFAC and BIS ease sanctions or export restrictions for a particular region.

Iran

On December 23, 2016, and again on February 2, 2017, OFAC updated, expanded, and clarified the scope of licenses for medical devices authorized for export to Iran.[11] The update eased the existing licensing restrictions in several ways. Previously, only specific items on a "whitelist" issued by OFAC were eligible for a General License. The amendments inverted this regulation, and now medical devices are presumed to be within the scope of a General License unless included on a "blacklist" of items that require a specific authorized license. The expanded General License list allows greater flexibility for medical device training and maintenance, including exports of the required associated software. The February 2 update finalized the List of Medical Devices Requiring Specific Authorization.[12] While these changes allow companies to obtain a General License in a more efficient manner for devices that previously required specific authorization, numerous severe restrictions are still in place regarding Iranian exports, and it is vital to maintain compliance procedures and to conduct proper due diligence when determining the appropriate license for an Iranian transaction.

Sudan

On January 17, 2017, OFAC amended the Sudanese Sanctions Regulations and BIS amended the EAR to ease licensing restrictions for exports to Sudan.[13] OFAC no longer requires specific licenses to export medicines or medical devices to Sudan, instead utilizing a 12-month time restriction for such General License exports to be completed.

The recent trends discussed above show a general easing of restrictions for medical device and pharmaceutical licenses in sanctioned nations, which is a positive development for the health care industry. However, it does not relieve companies of the responsibility to maintain robust compliance programs to insulate themselves from potential liability in their actions abroad. Two recent cases provide valuable lessons for health care entities seeking to enhance and improve their regulatory compliance policies.

Recent Enforcement Actions by OFAC

Since 2003, 12 OFAC enforcement actions have been levied against medical device or pharmaceutical companies, all of which involved sanctions regimes in either Cuba, Iran or Sudan.[14] Recently, OFAC has shown aggressive interest in medical device companies.

For example, in 2016 the international eye-care company Alcon was charged with 513 violations involving Alcon's engagement, over a three-year period, in the unlicensed sale and exportation of surgical and pharmaceutical products to distributors in Iran and Sudan.[15] OFAC's enforcement action against Alcon helped shape the future analysis for health care industry companies, as it articulated numerous mitigating and aggravating factors. Aggravating factors for Alcon's case were that: (1) Alcon did not voluntarily self-disclose its violations; (2) senior management knew or should have known about the violations (giving rise to willfulness); and (3) Alcon's compliance program was virtually non-existent despite the company's experience in international trade.[16] However, mitigating factors for Alcon's case were that: (1) Alcon was a first-time offender; (2) the violations were not egregious; (3) the violations did not harm U.S. sanctions programs; and (4) Alcon implemented a compliance program in response to the investigation.[17] Alcon's agreement to toll the statute of limitations during the investigation was also a key mitigating element. The company ultimately settled with OFAC for more than $7.6 million.[18]

The most recent OFAC enforcement action against a medical device company involved the California-based ultrasound supplier United Medical Instruments, Inc. (UMI).[19] The company knowingly exported its equipment to Iranian buyers through a company in the UAE on 56 different occasions. OFAC noted that the aggravating factors included that: (1) UMI knowingly exported goods to Iran; (2) UMI had knowledge it required a license to export these goods, as demonstrated by a prior 2003 license application; and (3) UMI failed to manage an effective compliance program. However, OFAC considered other mitigating factors, including that: (1) the violations were due to the actions of a single UMI employee; (2) UMI took remedial action and voluntarily ceased transactions involving Iran; and (3) UMI is a "small business" with significant financial difficulties. Once again, OFAC provided a roadmap for future companies in the industry by articulating the aggravating and mitigating factors utilized in its investigation.

Preparing to Respond to an Investigation: A Reality of the International Health Care Marketplace

Even for companies that have a robust compliance program, the reality of doing business in the heavily regulated health care industry and the closely scrutinized international marketplace is that companies can expect to be subject to administrative or DOJ investigations from time to time, even if they have not engaged in misconduct. The growth of whistleblower claims, coupled with the government's own independent investigations, makes interaction and responding to one of these types of investigations all but inevitable. As part of a compliance initiative, companies should, through their in-house or outside counsel, address and train key leaders and staff for common situations including: (1) how to respond if served with a subpoena; (2) the appropriate actions, notifications and responses to agents executing a search warrant; (3) how to effectively preserve electronic and other information during litigation or an investigation; (4) how to efficiently organize

data to ensure responding to subpoenas and investigations can be cost effective; (5) how to properly protect whistleblowers from retaliation and to encourage and reward an atmosphere of internal reporting and voluntary disclosure; and (6) how to respond if approached by an investigator while outside of the workplace. Including topics like these as part of training and planning not only will help ensure an atmosphere of compliance, but will enable a company to respond to an investigation in the most efficient and cost effective manner possible.

Rigorous Compliance Programs: A Modern Necessity

As government scrutiny of the health care industry's international trade practices expands, so too must the compliance regimes of its numerous participants. Whether enforcing anti-bribery legislation, sanctions regulations or export restrictions, government regulators have the authority and jurisdiction to prosecute actions for wrongdoings across the globe. However, each enforcement body has laid out careful roadmaps in its regulations and investigatory proceedings to help ensure that companies in the industry have all the tools they need for efficacious compliance. In regards to the recent trends in OFAC enforcement actions, it is essential to keep in mind the aggravating and mitigating factors that can help or hinder a potential investigation, articulated in proceedings such as those against Alcon and UMI. The most significant lesson to take away is the importance of compliance programs that incorporate stringent training of employees, robust oversight of international transactions and a mechanism for addressing violations when they do arise. These programs can save companies in the health care industry from potentially ruinous actions resulting in large scale civil settlements.

[1] *See Managing Sanctions and Export Control Risks in the Health Care Industry*, Ropes Gray (May 15, 2017).

[2] *See Teva Pharmaceutical Industries Ltd. Agrees to Pay More Than $283 Million to Resolve Foreign Corrupt Practices Act Charges*, Dep't of Justice Press Release (Dec. 22, 2016).

[3] *See* Melissa Jampol and Elena Quattrone, *A Record FCPA Year for Pharma*, Law 360 (Jan. 12, 2017).

[4] *See SEC Enforcement Actions: FCPA Cases*, Securities and Exchange Commission (Feb. 9, 2017).

[5] *Id.*

[6] *See Biomet Charged With Repeating FCPA Violations*, Securities and Exchange Commission Press Release (Jan. 12, 2017).

[7] *See Medical Device Company Charged With Accounting Failures and FCPA Violations*, Securities and Exchange Commission Press Release (Jan. 18, 2017).

[8] *See Treasury and Commerce Announce Further Amendments to Cuba Sanctions Regulations,* Department of Treasury Press Release (October 14, 2016).

[9] *Id.*

[10] *See* Niv Ellis, *Report: Trump to reverse Obama's Cuba policy*, The Hill (May 29, 2017).

[11] *See Publication of Updated Iranian Transactions and Sanctions Regulations,* Dep't of the Treasury (Dec. 22, 2016; *see also Update to the Iranian Transactions and Sanctions Regulations, List of Medical Devises Requiring Specific Authorization*, Dep't of the Treasury (Feb. 2, 2017).

[12] *Id.*

[13] *See Sudan and Darfur Sanctions*, Dep't of Treasury (Jan. 17, 2017).

[14] LI-COR, Inc. (2008); Confi-Dental Products, Co (2008); Iridex Corporation (2008); Zimmer Dental, Inc. (2008); Philips Electronic of North America Corporation (2009); Robbins Instruments, Inc. (2011); Sandhill Scientific, Inc. (2012); Ellman International, Inc. (2013); American Optisurgical, Inc. (2013); Hyperbranch Medical Technology, Inc. (2016); Alcon Laboratories, Inc. (2016); United Medical Instruments, Inc. (2017). *See* Dan Calloway, *Alcon to pay $7.6M fine as OFAC takes a harder line against medical tech companies with faulty sanctions compliance programs,* Sanctions Alert (Oct. 15, 2016).

[15] *Id.*

[16] *Id.*

[17] *See* Enforcement Information for July 5, 2016, Dep't of Treasury (July 5, 2016).

[18] *Id.*

[19] *See* Enforcement Information for February 28, 2017, Dep't of Treasury (Feb. 28, 2017).