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Medical Industries Under the Anticorruption Lens

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The pharmaceutical and medical device industries remain subject to increased anticorruption scrutiny by regulators around the world, largely because of their business models. In the United States, the Department of Justice created a specialized unit to investigate Foreign Corrupt Practices Act violations within these industries, which are heavily regulated, largely serve government health care systems, and rely on extensive third-party manufacturing and distribution networks.

Following a sweep of the medical device industry beginning in 2007, the DOJ turned its focus to pharmaceutical companies in November 2009 by launching its "Pharma Initiative" to investigate potential FCPA violations within the industry. Both sweeps led to several investigations and large settlements. Since 2010, $251.8 million has been paid by pharmaceutical and medical device companies to the Securities and Exchange Commission and DOJ in penalties, disgorgement, and interest.

The stakes are higher than ever. The number of global enforcement actions and the size of fines and monetary settlements have increased exponentially in recent years. Coupled with the increasing potential for simultaneous liability under foreign anticorruption laws, companies are at greater risk for devastating financial and reputational consequences. Pharmaceutical and medical device companies also face denial of market access and regulatory approvals as potential sanctions. Regulators receive information leading to investigations from several sources, including other regulators, cooperating companies, and employees, who are now protected by the Dodd-Frank whistleblower provisions.

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While many have noted the heightened scrutiny the health care industry faces, few have questioned why. Reviewing trends and statements from regulators, there appear to be three driving factors: (1) the pharmaceutical and medical device industries are heavily regulated; (2) many nations have nationalized health care systems; and (3) manufacturers have extensive global sales and distribution networks.

Heavily Regulated Industries

The pharmaceutical and medical device industries are heavily regulated. Prior to marketing or selling drugs and medical devices, a manufacturer must generally satisfy numerous requirements, including obtaining patents, trademarks, licenses, and other regulatory approvals. Research and development and clinical trials are increasingly conducted abroad, creating additional touch points with foreign officials. A 2010 report by the Office of Inspector General of the Department of Health and Human Services estimated that 40 to 65 percent of clinical trials of Food and Drug Administration-regulated products now occur outside of the United States.

Moreover, depending on where the product is manufactured, significant interaction with customs officials may be required. These steps invariably involve substantial interaction with agencies that have significant discretionary power to approve or deny a manufacturer's application to sell or ability to move its product. The risk created by the multiple touch points with foreign officials is exacerbated by the industries' focus on emerging markets where business practices may not yet be fully aligned with applicable anticorruption laws.

Nationalized Health Care Systems

The prevalence of state-run health care systems increases corruption risk for the pharmaceutical and medical device industries, because so many players, including pharmacists and front-line health care providers, can be considered "foreign officials"—the threshold requirement for liability under the FCPA. The statute's definition of "foreign official"

is broad, including "any officer or employee of a foreign government or any department, agency or instrumentality thereof."

The DOJ has specifically warned pharmaceutical and medical device companies that it is "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." Despite calls by many to limit the scope of the definition of "foreign official," the DOJ's and SEC's new joint guidance on the FCPA doubles down on the existing definition by reiterating that the FCPA "broadly" applies to both "low"- and "high"-ranking "employees" of foreign governments. This debate is less relevant today, however, as many foreign anticorruption laws, such as the United Kingdom's recently passed Bribery Act, prohibit all bribery, regardless of whether a "foreign official" is involved.

Given the broad application of anticorruption laws to common business expenses, companies have expended great resources tailoring their gifts, hospitality, travel, and entertainment policies in an attempt to conform to applicable laws, which remain unclear. Recent FCPA guidance states that legitimate business promotion activities and related hospitality do not rise to the level of an FCPA violation. Examples of acceptable conduct include providing business-class airfare on overseas flights as part of a legitimate business trip or taking prospective customers out for reasonably priced drinks. Similarly, the Serious Fraud Office, responsible for enforcing the UK Bribery Act, has taken the position that "sensible and proportionate promotional expenditure[s]" do not violate the Act. While these qualifiers offer some guidance, they do not set a threshold upon which pharmaceutical and medical device companies can rely.

Global Sales and Distribution Networks

Regulators also focus on the pharmaceutical and medical device industries because of the size and complexity of their global distribution networks and heavy reliance on subsidiaries and third parties to sell and distribute products. It has been estimated that more than 90 percent of FCPA cases involve the use of third parties, and in 2011, 100 percent of FCPA enforcement actions implicated a third party.

Despite historical beliefs to the contrary, companies can and are held responsible for the actions of third parties acting on their behalf, including foreign distributors. The "conscious disregard" or "willful blindness" standard of the FCPA requires companies to take affirmative and adequate steps to ensure compliance with applicable laws, including conducting diligence on third parties, entering contracts with adequate representations and warranties, providing training, and monitoring.

More specifically, the new FCPA guidance suggests that companies must understand a third party's business reputation and relationships with foreign officials, assessing the "business rationale for including the third party in the transaction," drafting specific contract terms defining the scope and terms of engagement that are consistent with local and industry standards, and performing ongoing monitoring. The guidance also confirms that "the degree of appropriate due diligence may vary based on industry, country, size, and nature of the transaction, and historical relationship with the third party."

The DOJ and SEC warn that companies must pay attention to red flags and respond appropriately, noting that in many situations, "relying on due diligence questionnaires and anticorruption representations is insufficient." They present a hypothetical situation in which a company agrees to pay its local distributor an additional discount or rebate beyond its standard terms to cover allegedly increased costs, despite the distributor's "vague and inconsistent justifications" and "fail[ure] to provide any supporting analysis" when questioned by a company finance officer. Substantive, thorough investigation is required when assessing third party relationships.

It is not a viable option to accept bribes, and the resulting liability, as merely a cost of doing business. The pharmaceutical and medical device industries remain subject to elevated scrutiny. But as a result many industry players now have in place best-practices anticorruption compliance programs that are tailored to the now well-known and industry-specific risks. There's no time like the present to make sure that your company's compliance programs are among those rising to a higher standard.

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