ARNOLD & PORTER LLP

ADVISORY

OCTOBER 2009

TRANSPARENCY, DISCLOSURE, AND SUNSHINE: THE GLOBAL PUSH FOR STAKEHOLDER ACCOUNTABILITY

Pharmaceutical and medical device companies are being challenged to explain critical components of their business model: how they relate to their "customers" and other stakeholders, and whether or not those relationships are impacting the clinical integrity or independence of those who help develop, prescribe, or purchase a company's products. Those "customers" or stakeholders include not only physicians and other healthcare professionals who prescribe, install, or recommend products, but also others who impact the entire product lifecycle, including hospitals, government purchasers, healthcare insurers, or managed care organizations, academic medical centers, and researchers who assist in the development of products.

Both the medical device and pharmaceutical industries are under unprecedented scrutiny from regulators and governments worldwide in respect to their relationships with these stakeholders. This scrutiny has, at its origin, a concern that business practices being employed are improperly interfering with the independence of stakeholders as well as creating safety concerns for the end user, the patient. Government and regulator scrutiny is being exhibited in several ways, including an increased number of investigations, both criminal and civil, as well as large fines and monitoring oversight.

The government strategy to address these concerns has found expression in the interplay of two fundamental concepts: (1) increased use of the anti-bribery laws in relation to the interactions between pharmaceutical and medical device companies and their stakeholders worldwide; and (2) a push for disclosure, or transparency, requiring the release of key information about the type and scope of relationships companies have with these stakeholders. The goal of both of these initiatives is to reduce improper influences on stakeholder independence. Transparency helps achieve this goal by encouraging the elimination of questionable practices that now must be disclosed to the public and by incentivizing the restructuring of the relationships that continue because they will now be subject to more direct public scrutiny. It is clear that this two-pronged government oversight will continue and that pharmaceutical and medical device companies must take necessary steps to adjust their business model and compliance controls to reflect this emerging global reality.

As discussed in this advisory, this trend is worldwide and is here to stay, and it extends beyond the now familiar government scrutiny arising from the False

Brussels
+32 (0)2 290 7800

Denver
+1 303.863.1000

London
+44 (0)20 7786 6100

Los Angeles
+1 213.243.4000

New York
+1 212.715.1000

Northern Virginia
+1 703.720.7000

San Francisco
+1 415.356.3000

Washington, DC
+1 202.942.5000

Claims Act and Fraud and Abuse laws used so frequently in the United States. In short, this trend is not just a United States phenomenon, and in fact many of the drivers for transparency are originating in other countries and regions. Accordingly, companies should expect to confront ever more statutory, regulatory, and enforcement initiatives in a number of countries in which they operate.

In addition to increased enforcement under anti-bribery legislation driven by the Organisation for Economic Co-operation and Development, including the US Foreign Corrupt Practices Act, numerous national and international organizations have undertaken initiatives to combat behavior which they characterize as fraudulent or corrupt. Many of these initiatives focus on transparency and bribery. According to the World Bank, corruption is the largest barrier to economic and social development. Transparency International (TI) believes that 10-25% of global spending on public health is lost through corruption. Organizations, such as Medicines Transparency Alliance (MeTA), argue that full disclosure will encourage public scrutiny and lead to more accountability.

The World Health Organization (WHO) began the Good Governance for Medicines (GGM) Program[1] to increase transparency in the pharmaceutical sector using three phases of development. Phase I consists of a national assessment to evaluate a country's current level of transparency and identify areas that are vulnerable to corruption. Specifically, the assessment targets the registration and promotion of medicines, the inspection and licensing of pharmaceutical establishments, the procurement and distribution of medicines, and the control and registration of clinical trials. Phase II focuses on developing a national GGM framework for compliance. In consultation with key stakeholders, each country should adopt a code of ethical conduct, establish regulatory and administrative procedures for evaluating compliance and enforcement, coordinate compliance mechanisms with other anti-corruption initiatives, and establish whistle-blowing mechanisms. During Phase III, each country should ensure that the GGM framework is implemented and sustainable. Governments must facilitate the training of government officials and healthcare professionals so they may provide leadership. Countries should also increase general awareness of transparency initiatives through dissemination of information to promote broad public support.

In addition to this WHO initiative, the World Bank has encouraged efforts to combat corruption and increase transparency in all sectors of society.[2] Politically, governments should document all donations to any party or candidate, disclose conflicts of interest, and register all lobbying activities. Civil society should endeavor to monitor government actions, demand accountability from elected officials, and publicize corruption in the media. In the private sector, companies should disclose financial statements, regularly publish financial audits, and enforce strong ethical standards. Regarding legal systems, countries should have an independent and clean judicial system for enforcement, pass strong anti-corruption laws that address bribery and conflicts of interest, and establish legislative oversight bodies or independent audit organizations to ensure accountability. In the public sector, governments should publish and audit budget expenditures to avoid misappropriation of public funds, standardize tax collection to eliminate unfair treatment, and pay civil servants fairly and based on merit to discourage bribery.

As further evidence of this global trend, the United Nations Global Compact adopted Principle 10 in an effort to fight corruption in the private sector.[3] Principle 10 states: "Businesses should work against corruption in all its forms, including extortion and bribery." Recently, a United Nations Global Compact taskforce issued guidance to businesses on implementing Principle 10.[4] The guidance

1 World Health Org., *Good Governance for Medicines, available at* http://www.who.int/medicines/ggm/en/ (last visited October 7, 2009).

2 The World Bank, *Overview of Anticorruption, available at* http://go.worldbank.org/K6AEEPROC0 (last visited October 7, 2009).

3 United Nations Global Compact, *Overview of the Global Compact: Principle 10, available at* http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/principle10.html (last visited October 7, 2009).

4 United Nations Global Compact, *Working Group on the 10th Principle Against Corruption, Reporting Guidance for the 10th Principle* (2009), *available at* http://www.unglobalcompact.org/docs/issues_doc/Anti-Corruption/REPORTING_GUIDANCE_fieldtest_draft.pdf.

describes a seven-step process for achieving transparency and minimum compliance with Principle 10. First, the company must publicly state that it will not tolerate any corrupt behavior by its employees or business partners. Second, the company must commit to complying with all relevant corruption laws and report the procedures that the company is undertaking to stay compliant. Third, the company must appoint a compliance officer and formulate a program for implementing its anti-corruption procedures. Fourth, the company's leadership must actively support the anti-corruption program through its communications and own actions. Fifth, the company must train all employees regarding the anti-corruption plan and ensure proper enforcement of the rules. Sixth, the company must set up audit plans and checks-and-balances to detect and prevent corruption. Last, the company should establish a monitoring system that provides for internal and external audits and allows for a whistle-blowing hotline.

Also in the global context, the World Trade Organization (WTO) has established the Working Group on Transparency in Government Procurement[5] with the goal of formulating an approach on transparency to which all WTO members could agree. Thus far, the initiative has focused on generally increasing transparency rather than regulating any government's preferences for domestic supplies or suppliers. However, some member countries remain interested in negotiations that would address barriers to fair market access. In evaluating transparency in government procurement, the working group focuses on publication of procurement procedures and records, contract award decisions, anti-bribery and anti-corruption efforts, and providing notice of trade policies and regulations to other countries.

TI encourages companies to implement its Business Principles for Countering Bribery[6] to prevent direct and indirect forms of bribery. Under this program, bribery includes political contributions, charitable sponsorships, gifts, and hospitality. To implement the program, TI requires that officers and board members commit to complying with an anti-bribery policy and that all employees receive training on the program. Furthermore, employees must be free to report violations without fear of retaliation, and businesses should strive for open communication regarding the program. Finally, businesses should keep accurate records and conduct regular audits to monitor the effectiveness of the program.

Regarding transparency in the pharmaceutical industry,[7] TI recommends that companies report all contributions to research organizations and prohibit all gifts to doctors. To limit the influence of pharmaceutical companies on health policy, TI recommends that the pharmaceutical industry only be consulted on scientific matters. In the area of clinical trials, TI suggests starting a database which includes the results of all clinical trials and implementing conflict of interest rules to prevent participation by individuals with an interest in the manufacturer.

As a final example of this global trend, MeTA,[8] funded by the United Kingdom and working in partnership with the World Bank and WHO, is seeking to increase transparency in medicines procurement.[9] MeTA believes that increasing transparency regarding the price, quality, availability, and promotion of medicines will foster competition, increase accountability, and improve access to medicines. To increase transparency in pricing, countries need to monitor taxes and tariffs, supplier and retailer charges, and corruption and fraud in the supply chain. Regarding quality, countries should enforce good manufacturing practices and work to eliminate counterfeit medicines. To improve availability, countries must evaluate the cost of medicines and the level of physician knowledge about providing the most appropriate

5 World Trade Org., *Transparency in Government Procurement: Applying a Fundamental WTO Principle on how Governments Buy Goods and Services, available at* http://www.wto.org/english/thewto_e/minist_e/min99_e/english/about_e/17proc_e.htm (last visited October 7, 2009).

6 Transparency Int'l, *Business Principles for Countering Bribery: A Multi-Stakeholder Initiative Led by Transparency International* (2009), *available at* http://www.transparency.org/global_priorities/private_sector/business_principles.

7 Transparency Int'l, *Summary Sheet: Corruption in the Pharmaceutical Sector* (2006), *available at* http://www.transparency.org/content/download/4873/28712/file/gcr2006_pharma.pdf.

8 Meds. Transparency Alliance Homepage, http://www.medicinestransparency.org/ (last visited June 17, 2009).

9 Meds. Transparency Alliance, *Q&A for the Medicines Transparency Alliance Launch May 2008* (2008), *available at* http://www.medicinestransparency.org/fileadmin/uploads/Documents/MeTAQandA.pdf.

medicines. Finally, countries should establish policies on the ethical promotion of medicines that include rules on gifts and bribery, conflicts of interest, and off-label promotion.

Developments in the United States both reinforce this global trend while presenting a unique set of compliance challenges for pharmaceutical and medical device companies. Earlier this year, both Vermont and Massachusetts enacted legislation prohibiting gifts and entertainment for healthcare professionals, and requiring transparency of financial relationships. It can be expected that this trend of state law activity will continue to grow. In addition, the Federal Sunshine Act, if such legislation is enacted, will require sweeping disclosure of financial relationships with healthcare professionals. New federal legislation is likely to increase the complexity, not simplify reporting, when preemption of state law is likely only to be partial.

Developments in the United States on transparency, however, have not been limited to the legislative arena. In recent settlements of investigations of pharmaceutical companies, Corporate Integrity Agreements (CIAs) signed with the Office of the Inspector General of the Department of Health and Human Services (OIG) have mandated disclosure of healthcare professionals (HCP) payments. These agreements with Cephalon, Lilly, and Pfizer require public disclosure of payments in a readily accessible and searchable format and give the OIG discretion to discontinue CIA disclosures in the event that the Federal Sunshine Act becomes law.

Settlements of investigations by states attorneys general have added yet another facet to transparency in the United States. For example, Lilly was required to disclose to each signatory state attorney general any HCP promotional speakers or consultants paid more than US$100. GlaxoSmithKline was required by the New York Attorney General to disclose certain clinical trial results, Pfizer was required by the Oregon Attorney General to disclose relationships in conduct and funding of clinical research and in continuing medical education (CME) sessions, and Merck was required by the Oregon attorney general to disclose relationships in CME. Taken together, these state and federal actions illustrate the multiple and often overlapping requirements various government agencies can and will require of pharmaceutical and medical device companies.

As a result of these requirements, worldwide manufacturers will continue to be challenged to make changes in policies and procedures and training programs to make sure their employees understand these new restrictions. Response times for compliance will be very short to implement the required changes in business process. The trend to transparency will also mean that manufacturers will continue to be challenged to aggregate their data from different functional areas to meet differing reporting and transparency requirements. Technology solutions will need to be found and business process automation will increasingly be utilized. The disclosure of data to the public will bring the next challenge: understanding the implications of the data and responding to third parties who will conduct their own analysis to support their own agendas. Responding to that data analysis may be the most significant challenge yet in this increasingly complex regulatory environment effecting global companies in a global way.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

Marcus A. Asner
+1 212.715.1789
Marcus.Asner@aporter.com

Ian Dodds-Smith
+44 (0)20 7786 6216
Ian.Dodds-Smith@aporter.com

Jeffrey L. Handwerker
+1 202.942.6103
Jeffrey.Handwerker@aporter.com

Daniel A. Kracov
+1 202.942.5120
Daniel.Kracov@aporter.com

Keith M. Korenchuk
+1 202.942.5817
Keith.Korenchuk@aporter.com

Claudius O. Sokenu
+1 212.715.1787
Claudius.Sokenu@aporter.com