US and International Codes on Pharmaceutical Marketing Practices and Interaction with Healthcare Professionals – A Comparative Analysis and Outlook on Harmonization by FCPA Enforcement

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Introduction
In recent years, there has been an increasing focus on pharmaceutical marketing practices and interactions between pharmaceutical companies and healthcare professionals. Concerns about real and perceived improprieties have led to a progressive general tightening of standards as reflected both in mandatory regulatory requirements and voluntary codes of practice. However, there remains a significant gap between US and international standards as reflected respectively in the voluntary codes of practice issued by the US and international industry associations.

The above described gap has surely not gone unnoticed by the authorities responsible for enforcing the US Foreign Corrupt Practices Act (FCPA), which have recently announced a new focus on the pharmaceutical industry. Remarks by Department of Justice (DOJ) officials in this connection have included reference to sharing expertise between the DOJ Fraud Section’s domestic health care fraud and FCPA teams. To the extent such information sharing results in the attempted harmonization of US and international standards on pharmaceutical marketing practices by FCPA enforcement, this could create significant exposure for multinational pharmaceutical companies.

This exposure is further exacerbated by the pharmaceutical industry’s increasing focus on emerging markets, including increasing emphasis on product diversification toward branded generics as opposed to the traditional reliance on relatively more innovative products with exclusivity based on intellectual property rights. This means that the industry’s business model is shifting both toward geographic markets with higher general compliance risk, and products in more competitive market segments, for which sales are more dependent on brand loyalty as opposed to clear scientific and medical differentiation.

All of the above means that international legal and compliance professionals in multinational pharmaceutical companies will be facing increasing challenges in supporting both ongoing operations and new business initiatives in emerging markets while maintaining compliance programs at an acceptable level of risk.

Overview of Interactions with Healthcare Professionals
Although processes and systems for patient access to medicines are rapidly evolving away from the traditional model of the treating physician as the sole gatekeeper by means of prescribing authority, physicians and other healthcare professionals (HCPs) such as nurses, pharmacists and midwives continue to play a major role in the pharmaceutical market. Their influence is exerted not only through the traditional gatekeeper role of the treating physician, which continues to be important especially in emerging markets outside the US and Europe, but also through positions of authority which HCPs
invariably hold in the various other organizations within the health care delivery system, such as payers (i.e., public reimbursement and private insurance entities) and users (i.e., hospitals and other health care institutions).

It is natural in these circumstances that HCPs have historically been the single most important target of pharmaceutical marketing, and this position is likely to continue for the foreseeable future. Interactions between pharmaceutical companies and HCPs are many and varied. The interactions described below are all legitimate in principle, but as with most business practices, they can be abused. As with other aspects of the pharmaceutical business, interactions with HCPs are highly regulated. The major types of interactions are the following, subject to varying degrees of regulation or restriction in different countries as described in detail in this article:

- **Field promotion**
  - Individual or group meals in connection with product presentations.
  - Socially customary gifts or business courtesies.
  - Product samples for use by patients to start drug therapy immediately at the HCP’s office.
  - Branded product reminders or so called “gimmicks” such as pens, note pads, coffee mugs and the like.
  - Company organized information programs, sometimes with incidental meals.

- **Third party program sponsorship,**
  - Involving sponsoring an HCP’s attendance at a medical education program provided by a third party such as a medical association. The sponsorship would typically cover travel to and from and lodging at the program site, registration fees and meals. The program may be in the HCP’s country, or abroad in the case of major meetings of prominent US and international medical associations which attract worldwide attendance. The program may or may not be accredited for continuing medical education credit for the attending HCP.

- **Service engagements,**
  - Which would involve a service fee and possibly travel, lodging and meal expenses.
  - Engaging an HCP to speak to other HCPs at a company promotional program.
  - Engaging an HCP to train the company’s sales or marketing personnel on medical issues relevant to its product line.
  - Engaging a group of HCPs, typically called an advisory board, to advise the company on current medical practice and trends relevant to its product line.

- **Scientific and medical collaboration**
  - Engaging an HCP to conduct a clinical study of the company’s product, with the company assuming the responsibility of the sponsor for purposes of Good Clinical Practice requirements. The study may either be pre marketing in order to generate data for the company to submit to regulatory agencies for obtaining marketing approval, or post marketing, either as a condition to the marketing approval or for the purpose of obtaining data for the company’s marketing or other business purposes.
  - Providing a research grant for the HCP to conduct an independent study which the company considers to be relevant or useful to its business or otherwise worthy of support.

- **Others**
  - Medical education scholarships
  - Capital and equipment donations to healthcare institutions
  - Product donations for disaster relief
Overview of Regulatory Structure:

(i) Anti-Kickback Statute and Industry Codes

In the United States, the primary statutory basis for regulation of pharmaceutical marketing practices and interactions with HCPs in terms of financial impropriety (as opposed to the substantive content of promotional communications which is the concern of the Food and Drug Administration) is the federal Anti Kickback Statute, 42 U.S.C. 1320a-7b(b). The purpose of the statute is prevention of fraud, waste and abuse in federally funded healthcare programs. The primary administrative enforcement agency is the Office of Inspector General of the Department of Health and Human Services (OIG), and the DOJ has criminal enforcement responsibility.

The main principle of the Anti Kickback Statute which is relevant for the present purpose is that no payment or value may be provided to an HCP as an inducement or reward for the prescription or purchase of a federally funded medicine, medical device or other healthcare procedure. OIG has issued Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731 (May 5, 2003) (OIG Guidance), which provides general guidance to pharmaceutical companies regarding compliance with the Anti Kickback Statute.

The OIG Guidance refers in turn to the Code on Interactions with Healthcare Professionals issued by the Pharmaceutical Research and Manufacturers of America (PhRMA Code), stating that “Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements”, OIG Guidance, at 68 FR 23737. Thus, while the PhRMA Code is formally a self regulatory code of conduct with no directly binding regulatory effect, it represents the accepted standard of conduct for the industry and also has been given substantial weight through the above quoted reference in the OIG Guidance.

The primary distinguishing factor affecting the regulatory framework for pharmaceutical marketing practices and interactions with HCPs outside the US is the relatively broader and more comprehensive role of government in the healthcare system. This means that HCPs outside the US are more likely to be government employees and that improper interactions with HCPs are therefore subject to legislation regarding bribery.

However, what is similar to the US is that the first practical point of reference for pharmaceutical companies in establishing and evaluating their interactions with HCPs is the applicable industry code of conduct. Atop the hierarchy of codes is the Code of Pharmaceutical Marketing Practices issued by the International Federation of Pharmaceutical Manufacturers’ Associations (IFPMA Code). The IFPMA membership comprises both national industry associations and multinational pharmaceutical companies. The IFPMA Code serves both as a minimum standard for national codes issued by the member national industry associations and a default standard for conduct by the member companies in countries with no national code.

Similar to the IFPMA Code on the European level is the Code on the Promotion of Prescription-Only Medicines to, and Interactions with Healthcare Professionals, issued by the European Federation of Pharmaceutical Industries and Associations (EFPIA Code).

On the national level there are national industry associations which have issued their own codes in all the major developed and emerging markets, including Japan, China, Korea, India, Russia, Brazil and Turkey.
(ii) Unfair Competition Law

Unfair competition law is a related field of legislation which has been actively employed by enforcement authorities in a number of countries with reference to pharmaceutical marketing practices and interactions with HCPs. Particularly prominent in this area have been the State Administration of Industry and Commerce in China in enforcing the PRC Law Against Unfair Competition (which predated the recently enacted and broader Anti-Monopoly Law) and the Korean Fair Trade Commission in enforcing the Korean Fair Trade Law.


In a related development, the Australian industry code issued by the industry association Medicines Australia has been periodically reviewed and approved, with respect to potential competition law issues arising from such concerted action of the industry, by the Australian competition authority, the Australian Competition and Consumer Commission (ACCC). However in 2006 the ACCC’s approval was made subject to certain conditions regarding semi annual public disclosure of third party program sponsorships and company information programs and educational meetings. (ACCC Press release # MR 161/06, July 26, 2006, available at http://www.accc.gov.au/content/index.phtml/itemId/755224/fromItemId/142).

Increasing Focus on Pharmaceutical Marketing Practices and Industry Response

In recent years, the previously obscure topic of pharmaceutical marketing and in particular pharmaceutical companies’ interaction with HCPs has become the subject of increasing attention both by the public and policy makers. One prominent example was the novel The Constant Gardener by John le Carre, in which the fictional pharmaceutical company KVH’s interaction with HCPs was described:

“Lorbeer claims in his confession that while acting for KVH he obtained the validation of Dypraxa by means of flattery and bribery….In Moscow, a validation by top medical opinion leaders could be bought for twenty-five thousand dollars…. In Germany, influence was more subtle but not very subtle. Lorbeer writes of a famous occasion when he chartered a jumbo jet for KVH and flew eighty eminent German physicians to Thailand for an educational trip….Their education was provided on the journey out, in the form of films and lectures, also Beluga caviar and extremely ancient brandies and whiskies….In Thailand, the physicians were free to do as they wished, but recreation was provided for those who wanted it, also attractive partners. Lorbeer personally organized a helicopter to drop orchids on a certain beach where the physicians and their partners were relaxing. On the flight home, no further education was needed. The physicians were educated out. All they had to remember was how to write their prescriptions and learned articles.” (The Constant Gardener, John le Carre, Scribner paperback edition, 2004, p. 309-310.)
A more moderate but real life example may be seen in a report by the Australian national daily *The Australian* of an event held by Roche Australia hosting more than 200 top cancer specialists to dinner at Guillaume at Bennelong, inside the Sydney Opera House, at a cost of more than A$200 a head, or more than A$65,000 total. As reported, “The restaurant’s ‘degustation menu’ features ‘basil-infused tuna’, sterling caviar, kingfish sashimi and the best of Australian and French wines.” (*The Australian*, “Drug Giant Forks Out $65,000 on Posh Nosh for Doctors”, June 21, 2006). The public reaction to this report was undoubtedly a factor in the ACCC’s decision shortly after, as mentioned above, to require disclosure of various promotional events as a condition to its authorization of the Australian industry code of conduct.

In response to this trend, the industry been adopting increasingly tighter standards in its codes of conduct. The most recent updates of the IFPMA Code and the PhRMA Code included the following notable new restrictive provisions:

**PhRMA Code, 2009**

- No provision of meals to an HCP outside of an HCP’s office or hospital premises by sales representatives or their immediate superiors (Section 2).
- No sponsorship of meals at third party educational events (Section 4).
- No consultants or speaker training meetings at resort locations (Section 6 and Q&A 15).
- Annual cap on speaking fees to individual HCPs (Section 7).
- Gifts must have educational benefit to the HCP or patients (e.g., medical text for the HCP, anatomical model display in the HCP’s office for the benefit of patients). Therefore, the PhRMA Code now prohibits gifts with purely medical practice value such as stethoscopes and blood pressure cuffs, as well as non educational items even with minimal value, such as the branded pens, note pads, coffee mugs, etc. which had been commonly seen in HCPs’ offices (Sections 10 & 11).

**IFPMA Code, 2006**

- Company organized promotional events should be in an appropriate venue, not “renowned or extravagant” Section 7.5).
- No sponsorship of HCP attendance at third party events outside the HCP’s home country unless appropriate andlogistically justified (such as international scientific congresses and symposia with participants from many countries) (Section 7 and Q&A 13).
- No provision of stand alone entertainment, leisure or social activities, as opposed to modest entertainment secondary to a meal (Section 7.5.4).
- No compensation to an HCP for time spent attending a company organized promotional event (Section 7.2).
- New requirements for consulting engagements to avoid token arrangements (written contract, legitimate need for services, no more number of consultants engaged than necessary to perform the service, company maintains record and actually uses the service) (Q&A 6).
- No gifts in cash or other types of gift with purely personal benefit to the HCP (Section 7.6).
Overview of FCPA and its Application to Pharmaceutical Companies’ Interaction with HCPs

The FCPA (codified at 15 U.S.C. §§ 78m(b)(2), 78m(b)(3), 78dd-1, 78dd-2, 78dd-3, and 78ff) has two major elements: 1) anti-bribery and 2) accounting (often referred to as “books and records”) and related internal control requirements. The books and records requirement is often the practical basis for enforcement due to its relatively wider jurisdictional scope (unlike the anti-bribery requirement, the books and records requirement applies directly to transactions conducted entirely outside the US by majority owned foreign subsidiaries of US entities) and less burdensome evidentiary requirements for the government to establish a violation (it is in the nature of improper or questionable transactions that they are usually not recorded accurately, and there is no de minimus or materiality requirement for a books and records violation). However, although the government may choose to proceed solely on the basis of a books and records violation for these tactical reasons, the fact pattern of FCPA enforcement actions and reported investigations almost always involves an alleged underlying bribery issue. Accordingly, this article will focus on the anti-bribery provisions of the FCPA, in which there are five elements:

- A “covered” person or entity
- Must offer or give something of “value”
- To a “foreign official”
- To “obtain or retain business”
- With “corrupt intent”

Without going into a detailed analysis of all five elements, which is beyond the present scope, we may briefly note that 1) any entity which is incorporated in the US or listed on a US securities exchange is covered by the first element, and 2) the fourth and fifth elements (like most of the statute) are widely interpreted to include any attempt to obtain a business advantage by improperly influencing a foreign governmental official.

This leaves us to focus on the second and third elements which are most relevant to pharmaceutical marketing practices. The definition of the second element referring to something of value is very broad and goes far beyond the stereotypical cash envelope, including free products from a pharmaceutical company, other tangible goods, entertainment, travel, meals, training or education, and employment, consulting or other business opportunities. This element may also be satisfied if value is provided to a family member or other recipient related to or designated by the government official whereby the government official can be deemed to derive benefit, e.g., a favored charity.

The interpretation of the third element referring to foreign officials in the context of HCPs requires a case by case factual analysis of the organization and financing of the healthcare system in the country in question and the role and source of compensation of the individual HCP within that structure. Although the factual situations vary widely from country to country, the most common situations, which cover a large proportion of HCPs in many countries, involve 1) HCPs employed either full or part time by government owned or controlled hospitals or other healthcare institutions, 2) HCPs performing a government function with or without pay, such as advising regarding marketing or reimbursement or formulary approval for drugs and 3) employees at any level in government agencies such as Ministries of Health, public reimbursement agencies or pharmaceutical regulatory agencies.
FCPA Enforcement Against the Pharmaceutical Industry

The historical pattern of FCPA enforcement against the pharmaceutical and medical device industries is similar to that of the statute generally, i.e., a long initial period of relative inactivity after the statute's initial enactment in 1977, followed by a steep rising curve of increasing activity in recent years. The following are the major reported enforcement actions.

- The first reported enforcement case in the pharmaceutical industry was a settled proceeding in 2002 against a California based radiopharmaceutical company Syncor and its Taiwan subsidiary, involving alleged payments to government employed doctors in several countries. (*SEC v. Syncor International Corporation*, No. 1:02-cv-2421 (D.D.C. 2002)).

- A settled proceeding against a multinational pharmaceutical company Schering-Plough Corporation, alleging violation of the books and records provisions of the FCPA in the recording of payments to a Polish charitable foundation headed by an individual who was also Director of a provincial health fund, allegedly to induce the purchase of Schering-Plough’s products by the fund. (*SEC v. Schering-Plough Corporation*, No. 1:04-cv-00945 (D.D.C. 2004)).

- A settled proceeding against a privately held medical device company Micrus involving alleged payments to government employed doctors in several countries. (Department of Justice press release, March 2, 2005, available at http://www.usdoj.gov/opa/pr/2005/March/05_crm_090.htm).


- The multinational pharmaceutical companies Bristol-Myers Squibb, AstraZeneca and Johnson & Johnson all reported being the subject of pending FCPA investigations in their annual 10K filings for fiscal year 2007.

- In late 2007, the SEC and DOJ opened informal inquiries of several medical device producers for alleged payments to government employed HCPs in various countries. The inquiries were reported by Biomet, Stryker, Zimmer, Smith & Nephew and Medtronic in their annual 10K filings.


- A settled proceeding against AGA, a Minnesota based medical device company, involving alleged payments to Chinese government employed HCPs and officials of the State Intellectual Property Office, *U.S. v. AGA Medical Corporation*, No. 0:08-cr-00172-1 (D. Minn. 2008)

The most significant recent event relating to FCPA enforcement against the pharmaceutical industry was a speech given on November 12, 2009 by Lanny A. Breuer, Assistant Attorney General of the Criminal Division of DOJ, before an industry conference (Lanny A. Breuer, Assistant Attorney General, Criminal Division, Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance
In the speech, Mr. Breuer confirmed the developing trend by specifically announcing that the application of the FCPA to the pharmaceutical industry would be a focus area for the DOJ in the coming months and years, noting the following key points:

- **High international profile of the industry** - "According to PhRMA's 2009 membership survey, close to $100 billion dollars, or roughly one-third of total sales for PhRMA members were generated outside of the United States, where health systems are regulated, operated and financed by government entities to a significantly greater degree than in the United States."

- **Broad involvement of non US governments in healthcare and interpretation of "foreign official"** - "Indeed, it is entirely possible...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."

- **Analogy between the FCPA and the US Anti-Kickback Statute** – Mr. Breuer stated: "...the types of corrupt payments that violate the FCPA because they are given to obtain or retain business in other countries are not any different than the items of value that would violate the Anti-Kickback Statute if given within the United States – cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements, to name a few." In addition, Mr. Breuer noted that the DOJ's FCPA unit and its domestic health care fraud unit had already begun to work together to apply the industry knowledge and expertise of the domestic health care fraud unit to FCPA enforcement.

Finally, just in case the warning of his speech was not sufficiently clear, Mr. Breuer went on to make the point that the DOJ's efforts "...will mean investigation and, if warranted, prosecution of corporations to be sure, but also investigation and prosecution of senior executives. Effective deterrence requires no less."

Since the Breuer speech, the enforcement authorities have followed up promptly, according to published reports and securities filings by the concerned companies. As recently reported in The New York Times, "At least a dozen major drug and device makers are under investigation by federal prosecutors and securities regulators in a broadening bribery inquiry into whether the companies made illegal payments to doctors and health officials in foreign countries." (The New York Times, "U.S. Inquiry of Drug Makers is Widened", August 13, 2010).

**Comparison of US and International Codes of Conduct**

Although both the US and international industry codes of conduct on pharmaceutical marketing practices have become increasingly restrictive as outlined above, there remain major discrepancies between the two standards, which could potentially create significant exposure for multinational companies if the US standards were strictly applied to their international operations as suggested by the Breuer speech. The major areas of discrepancy are outlined below.

- **Third party program sponsorship** – Under section 4 of the PhRMA Code, companies may not provide financial or material support for attendance at third party organized events directly to an HCP, but must provide such support to the program organizer, who can use such funds in order to reduce registration fees for all attendees.
Under section 7.2 of the IFPMA Code, such sponsorships are permitted subject to various restrictions, most notably that no such sponsorship may be conditional on an obligation to prescribe, recommend or promote a pharmaceutical product. The national codes outside the US generally follow the IFPMA Code on this point, with the major exception being Korea, where sponsorships 1) must be provided through a publicly recognized academic society or research institution rather than directly to an HCP (although the support can be designated for the support of a particular sponsoree HCP); 2) can only be provided for a speaker, presenter, moderator or panelist (i.e., not for a passive attendee at the event); and 3) must be reported with relevant details to the industry association. (KRPIA Code, Article 8). Also, as previously discussed, a more detailed and publicly transparent reporting requirement for all company organized events as well as sponsorship of third party events applies in Australia.

- **Meals** – As previously noted, PhRMA Code section 2 prohibits companies from providing meals to HCPs outside of an HCP’s office or hospital premises by sales representatives or their immediate superiors, although it does permit modest and occasional meals in an appropriate venue for informational communication by non sales personnel such a senior business executives. (PhRMA Code, Q&A 12).

  The IFPMA Code and other national codes contain no such restriction on 1:1 or small group meals, although they contain other limitations in connection with meals at larger events, stating that they should be moderate and reasonable, incidental to the main purpose of the event and provided only to participants in the event and not their guests. (IFPMA Code, section 7.5.2).

- **Entertainment and Recreation** – The PhRMA Code in section 3 completely prohibits entertainment and recreation for HCPs, as does the EFPIA Code in section 9.07. The IFPMA and many non European national codes take a more liberal approach by permitting modest entertainment or recreation secondary to a group event or meal, while prohibiting stand alone entertainment. (IFPMA Code, section 7.5.4). Thus, the focus is on the proportion of the entertainment in relation to the substantive part of the program. Some national codes go into more detail on this point; for example the Chinese code provides that no more than 30% of the total program time should be spent on hospitality activities (Code of Practice on the Promotion of Pharmaceutical Products, R&D-Based Pharmaceutical Association under the China Association of Enterprises with Foreign Investment, 2006 Revision, attachment 1, section 3); while the Korean Code states more broadly that "An academic conference must be focused on medical topics, and the proportion of non-academic activities, such as leisure activities, should not exceed the portion of medical activities" (KRPIA Code, Working Guideline, Article 5(1)).

- **Gifts** – As previously noted, the PhRMA Code in sections 10 and 11 provides that gifts must have educational benefit to the HCP or patients, thus prohibiting gifts with purely medical practice or office operational value, as well as non educational items even with minimal value, and of course items with purely personal value for the HCP. The IFPMA Code provides that cash or cash equivalent gifts (section 7.6.1) and purely personal gifts (section 7.6.2) may not be provided to HCPs, but makes an exception in section 7.6.5 for infrequent and inexpensive "cultural courtesy gifts" in accordance with social custom, local law and practice, in acknowledgement of
"significant national, cultural or religious holidays". The national codes in a number of countries such as China, Korea, Turkey, Russia and Japan provide more detailed guidance on the subject of "cultural courtesy gifts" by specifying the relevant customary social occasions and nature and value of permitted gifts. For example, the Korean Code specifies 1) a flower or fruit basket with value up to 100,000 Korean Won as an expression of congratulations on the wedding of an HCP or his/her child, or condolence at the funeral of an HCP or his/her spouse or parents and 2) food, beverages or flowers with value up to 50,000 Korean Won for Lunar New Year or Chuseok (mid autumn festival). (KRPIA Code, Article 9(3).

The IFPMA Code also continues to follow the prior position of the PhRMA Code prior to the 2009 revision of the latter, in permitting branded reminders of minimal value (section 7.6.3) and items of medical utility "provided that such items are of modest value and are beneficial to the provision of medical services and for patient care." (section 7.6.4).

- **Institutional Grants and Donations** – Although the PhRMA Code is silent on this topic, the Anti-Kickback Statute and OIG Guidance directly apply to benefits provided to healthcare institutions as well as to individual HCPs, unlike the FCPA which requires an implication of benefit to the HCP in order to find an anti-bribery violation, and/or an inaccurate record for a books and records violation. Therefore, the industry practice in the US in this area again is relatively restrictive as compared to that in many other countries. Outside the US, while the IFPMA is also silent on this topic, the EFPIA and many national Codes such as those in Korea, India, Turkey and Brazil expressly permit institutional grants and donations subject to requirements that there be proper documentation, no quid pro quo for product purchases, and with statements generally encouraging transparency. (EFPIA Code, Article 11).

**Industry Push to Emerging Markets**

To further increase the pharmaceutical industry's FCPA risk profile, it has been responding to the increasingly unfavorable business environment in the developed markets of the US, Europe and Japan, which are more and more characterized by slower growing economies and increasingly restrictive regulatory and reimbursement environments for marketing approval and reimbursement of new products, by aggressively pushing into emerging markets such as China, India, Russia, Turkey, Brazil and South Africa with branded off patent or generic products. The strategy is to take a premium position in relation to unbranded or "no name generics" based on the multinational company's reputation for reliable quality, but a discount in relation to the original branded product when under patent protection. Over the last several years, virtually all of the major multinational pharmaceutical companies, including GlaxoSmithKline, Pfizer, Sanofi-Aventis, Abbott, Merck, Astra-Zeneca and Novartis, have made acquisitions, joint ventures or other forms of alliances with local companies either present in the target emerging markets and/or in a position to produce for export to those markets. (The New York Times, "Drug Firms Apply Brand to Generics", February 16, 2010). With this trend, the industry's business model is shifting both toward geographic markets with higher general compliance risk, and products in more competitive market segments, for which sales are more dependent on brand loyalty as opposed to clear scientific and medical differentiation.
Analysis and Conclusion

Based on all the developments reviewed above, it would appear that the multinational pharmaceutical industry is now entering a "perfect storm" of FCPA enforcement. However, although the situation will certainly be challenging, there is also reason to believe that the risks can still be managed through tried and true risk based compliance programs. This was one of the messages of the Breuer speech: "So what can you do to protect your clients? First and foremost, every company should have a rigorous FCPA compliance program that is faithfully enforced."

The risks and potential solutions may be illustrated by further analyzing the practice of third party program sponsorships. This is certainly a high risk area due to the potential high value of frequent international program sponsorships for HCPs and the clear discrepancy between industry practice in the US and that in other countries.

The essence of the issue is that third party program sponsorships involve both a personal benefit to the HCP (i.e., travel, meals and lodging, sometimes in desirable overseas destinations) and a legitimate educational benefit by facilitating the HCP obtaining information relevant to his or her medical practice as well as the sponsoring company's products. This dual nature of third party program sponsorships points toward the compliance solution, which is put in place policies and procedures to minimize the element of personal benefit and maximize the educational element.

The starting point for limiting the element of personal benefit in connection with third party program sponsorships is implementation of the relevant IFPMA Code requirements which were introduced in the 2006 revision, as outlined previously. Placing appropriate limits on the frequency and value of sponsorships for individual HCPs is another obvious step. Companies can also introduce controls in their internal processes by requiring internal approval for such sponsorships outside of the sales and marketing function and based on a justification other than potentially increasing sales. An additional step which would clearly decrease risk, although often more difficult to implement in practice, is to either notify third party program sponsorships to, or obtain approval of them from, a superior of the HCP or other independent administrative authority in the HCP's institution.

The KRPVer Code prohibition on sponsorship of passive attendees (as opposed to speakers, presenters, moderators or panelists) is a practice which has a dual benefit of risk reduction by both limiting the number of sponsorships and requiring that those which are granted have an additional educational benefit. A less restrictive variation is to require a sponsored attendee who does not actively participate at the event to commit to presenting the meeting results or highlights to an appropriate audience in his or her home medical community.

If third party program sponsorships are granted in accordance with a compliance program including policies and procedures such as those described above, together with the other recommended elements of a effective corporate compliance program in accordance with the United States Sentencing Guidelines (United States Sentencing Commission, Guidelines Manual, §3E1.1 (Nov. 2009) (effective communication of the compliance policy, management accountability, effective training, monitoring and enforcement, ombudsman or concern-line for employees to report concerns, and discipline and remediation), and provided that the related transactions were accurately recorded, it would be difficult to find the necessary elements for either an anti-bribery or a books and records violation under the FCPA.
A similar analysis to develop appropriate safeguards for FCPA compliance can be performed for the other activities and practices described above where there are discrepancies between US and international standards. Therefore, in the opinion of the author, although the non US marketing practices of multinational pharmaceutical companies are likely to continue to become more conservative and restrictive under the pressure of the present FCPA enforcement campaign, complete harmonization of the US and international standards is unlikely in the foreseeable future.

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