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The Trend Towards Global Transparency:

A Challenging New World for the Life Sciences Industry

D. Jeffrey Campbell, Esq.
Brian P. Sharkey, Esq.
Porzio, Bromberg & Newman, P.C.

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PORZIO
BROMBERG&NEWMAN P.C.
ATTORNEYS AT LAW

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Introduction

The quest for transparency in the relationships between life sciences companies and healthcare professionals has become a global movement. Whether it is reporting to the Food and Drug Administration ("FDA") data regarding all prescription drug samples distributed in the United States, submitting to the Estonian State Agency of Medicines a compendium of support awarded to dispensing chemists, pharmacists, and doctors, or disclosing service agreements with Dutch physicians, companies in the life sciences industry are beset by a multitude of obligations designed to make public their interactions with their customers. Effectively managing those obligations while concurrently ensuring compliance with the growing body of international anti-corruption legislation is a significant challenge to the continued growth and success of multi-national life sciences companies.

For a number of years, pharmaceutical companies doing business in the United States have dealt with a host of states that impose limits and reporting obligations on interactions with healthcare professionals.[1] Device companies were brought into the fray more recently when several states expanded the applicability of their laws. The past eighteen months have seen the rise of transparency challenges on several additional fronts.

The first new challenge for life sciences companies is on the federal level in the United States. In its June 28, 2012 opinion, *National Federation of Independent Business, et al. v. Sebelius*, 567 U.S. ___ (2012), the United States Supreme Court upheld the Patient Protection

[1] The following states have marketing disclosure and/or limitation laws: California (CAL. HEALTH & SAFETY CODE § 119402(e)); District of Columbia (D.C. CODE § 48-833.01); Massachusetts (MASS. GEN. LAWS ch. 111N, § 2); Minnesota (MINN. STAT. § 151.47(1)(f)); Vermont (VT. STAT. ANN. tit. 18, §§ 4631a(b)(1), 4632(a)(2), 4632(b)(1)); and West Virginia (W. VA. CODE § 16-29H-8).

and Affordable Care Act ("ACA").[2] While much of the public debate between critics and supporters of ACA focused on the individual insurance mandate, the Supreme Court's ruling has significant consequences for the life sciences industry -- consequences that have been largely ignored by the public. Specifically, one significant consequence of the Court's decision is that the Physician Payment Sunshine Act (section 6002 of ACA) ("US Sunshine Act"), which imposes aggregate spend reporting requirements at the federal level, remains in effect.

Before the Court's decision in *National Federation of Independent Business*, there was uncertainty within the industry, because of the possibility that the Court could find that ACA was unconstitutional and strike it down in its entirety, including the US Sunshine Act. Now that the Court has spoken, however, companies in the life sciences industry know that the US Sunshine Act is here to stay, and, for those who have not started yet, that they must begin preparations to meet reporting obligations. According to recent information from the Centers for Medicare and Medicaid Services ("CMS"), data capture will not begin before January 2013, so the expectation is that the first reporting for section 6002 of ACA will not occur until 2014. However, pursuant to the Prescription Drug Sample Transparency section of ACA (section 6004), manufacturers were responsible for capturing information on samples distributed between January 1, 2011 and December 31, 2011. A samples disclosure report must be submitted by October 1, 2012.[3] Companies are also waiting for the final regulations to be issued by CMS.

The second new challenge is that the trend towards transparency is spreading throughout the world. Two countries, France and Slovakia, have enacted laws that are similar to the US

[2] Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Healthcare and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 109 (2010).

[3] Although section 6004 of ACA indicated that the first samples disclosure report was due on April 1, 2012, the FDA extended the date to October 1, 2012. *See Drugs, Guidance, Compliance and Regulatory Information*, FDA.GOV, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm, (last visited May 21, 2004).

Sunshine Act. In other countries, reform is taking place through industry codes enacted by the relevant industry association. Pharmaceutical industry codes including reporting requirements have been enacted in a number of countries, including, significantly, the Netherlands, the United Kingdom, Japan, and Australia.[4]

It is widely anticipated that numerous countries will join this growing trend. The key question for the life sciences industry is whether reporting requirements will be imposed through governmental action or voluntary industry self-regulation. Although a self-regulatory solution would likely be more consistent and efficient than a plethora of disparate legislative obligations, in either case it is imperative for life sciences companies to monitor which approach is adopted in individual countries and regions.

The third transparency challenge facing the life sciences industry is the burgeoning body of anti-corruption laws. Although these laws are distinct from the reporting requirements previously discussed, in no small part because violations can lead to criminal penalties, anti-corruption laws relate to reporting requirements in two ways: 1) both are aimed at rooting out corruption and reducing the cost of doing business; and 2) the increase in transparency reporting can provide ammunition to prosecutors in seeking indictments.

In the United States, the Department of Justice ("DOJ") and the Securities and Exchange Commission ("SEC") have been aggressively enforcing the Foreign Corrupt Practices Act ("FCPA")[5] against both companies and individuals. Similarly, foreign countries have increased their anti-corruption investigations and prosecutions. Life sciences companies are especially susceptible to this increasingly aggressive posture, because so many of the healthcare professionals with whom they interact are employees of foreign governments. The dangerous

[4] Conversely, medical device industry associations have yet to impose reporting requirements in their codes.
[5] 15 U.S.C. §§ 78dd-1, *et seq*.

combination of intense interaction with public officials and increased government scrutiny and prosecution mandates that life sciences companies have appropriate procedures and policies in place to ensure that they do not violate such laws and subject themselves to criminal liability.

US Sunshine Act

On March 23, 2010, President Obama signed ACA into law. ACA includes the US Sunshine Act, which, among other things, requires certain pharmaceutical, medical device, biological product and medical supply companies to disclose, on an annual basis, gifts and payments provided to covered recipients, as well as covered recipients' ownership and investment interests in the company. On December 19, 2011, CMS of the Department of Health and Human Services published in the Federal Register the long-awaited draft regulations for the US Sunshine Act.[6] Those draft regulations propose various definitions, clarifications and requirements for implementing the US Sunshine Act. In the draft regulations, CMS requested that the public submit comments with respect to the implementation of the US Sunshine Act. The public comment period closed on February 17, 2012. Since that time, CMS has been reviewing the comments,[7] meeting with stakeholders, and revising the regulations.

Although the US Sunshine Act anticipated that companies would begin to capture data on January 1, 2012 for reporting in March 2013, CMS has stated recently that data capture will not begin before January 2013. Thus, initial reports will likely be filed in March 2014.

Although final regulations have not been issued by CMS, it is nonetheless possible to discuss some of the details related to disclosure obligations.

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[6] *See* Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Ownership or Investment Interests, 76 FED. REG. 78741 (proposed December 19, 2011) (to be codified at 42 C.F.R. pts. 402 and 403).

[7] CMS received 325 comments. *CMS-5060-P Comments*, REGULATIONS.GOV, http://www.regulations.gov/#!searchResults;dct=PS;rpp=10;po=0;s=CMS-5060-P, (last visited August 10, 2012).

To be an "applicable manufacturer," an entity must satisfy two elements. There are three ways to satisfy the first element: 1) the entity engages in manufacturing a covered product;[8] 2) the entity is under common ownership[9] with an entity engaged in manufacturing a covered product and provides assistance or support to that entity in its manufacturing, marketing, promotion, sales, or distribution activities for that product; or 3) the entity holds FDA approval, licensure or clearance for a covered product. The second element is that the entity has a covered drug, device, biological, or medical supply that is sold or distributed in the United States.

An "applicable group purchasing organization" ("GPO") is an entity that operates in the United States or one of its territories, possessions or commonwealths and either purchases, arranges for, or negotiates the purchase of a covered drug, device, biological or medical supply. This includes an entity that purchases a covered product for resale or distribution.

Applicable manufacturers must file two different reports: 1) the Payment and Other Transfers of Value Report ("Payment Report"), and 2) the Ownership and Investment Interest Report ("Ownership Report"). Both reports must be submitted electronically as comma-separated value files. The chief executive officer, chief financial officer, or chief compliance officer must certify that the data in the submitted reports is true, accurate and complete. An applicable GPO will only have to submit an Ownership Report. Although there are a number of detailed requirements concerning both the Payment Report and the Ownership Report, this paper will focus on the Payment Report.

In the Payment Report, applicable manufacturers must report payments made to a "covered recipient." Covered recipients are physicians and teaching hospitals. Physicians

[8] A "covered product" is a product for which payment is available for the drug, device, biological, or medical supply under Medicare, Medicaid, or the Children's Health Insurance Program. 76 FED. REG. 78741.
[9] "Common ownership" occurs when the same individual, individuals, entity, or entities, directly or indirectly own any portion of two or more entities. *Id.* at 78743.

include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors. Payments made to physicians who are employees of an applicable manufacturer do not have to be included in the Payment Report. The draft regulations suggest that applicable manufacturers use the National Plan & Provider Enumeration System ("NPPES") to identify physicians, and their National Provider Identifier ("NPI") and business address for reporting. Teaching hospitals are institutions that receive graduate medical education payments; CMS will publish annually on its website a list of qualifying institutions.

The law requires that applicable manufacturers report all payments and transfers of value provided to covered recipients. This includes payments or other transfers of value provided indirectly through third parties to covered recipients, so long as the applicable manufacturer is aware of the covered recipients' identities. Some of the information that applicable manufactures must report includes: name of the reporting entity; name of the covered recipient; business address of the covered recipient; specialty (physicians only); NPI number (physicians only); amount of payment; date of payment; form of payment; nature of payment; and name of associated covered drug, device, biological or medical supply. With respect to the "form" of payment, reporting companies must identify whether it was cash/cash equivalent; in-kind items or services; or stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

The "nature" of the payment is important, as it describes the purpose and manner of the payment or transfer or value. The proposed regulations identify the following options for companies to identify the "nature" of the payment: consulting fees; compensation for services other than consulting; honoraria; gift; entertainment; food; travel; education; research; charitable contribution; royalty or license; current or prospective ownership or investment interest; direct

compensation for serving as faculty or as a speaker for a medical education program; grant; or other.

Although reporting requirements are broad, the US Sunshine Act and the draft regulations provide for several key exclusions from reporting, including: payments less than $10 (unless the aggregate amount for the covered recipient exceeds $100 in the calendar year); product samples;[10] educational materials that directly benefit patients or are intended for patient use; in-kind items for the provision of charity care; and payments through a third-party when the manufacturer is unaware of the covered recipient's identity.

One of the key factors that motivated Congress to enact the US Sunshine Act was a desire to expose to the public the interactions between the life sciences industry and healthcare professionals. Therefore, CMS will publish the data reported by applicable manufacturers and GPOs on a publicly available website. According to the draft regulations, data on the website will be searchable, understandable, downloadable and easily aggregated on various levels.

It is significant to note that there are penalties for a failure to comply with the requirements of the US Sunshine Act. There are two classes of penalties: failure to report and knowing failure to report. For the former violation, which involves a mistake or inadvertent violation, a company may be fined between $1,000 and $10,000 for each violation, with a maximum penalty in any one year of $150,000. For a knowing violation or failure to provide complete and accurate information, a company may be fined between $10,000 and $100,000 per violation, with a maximum penalty in one reporting year of $1,000,000.

[10] While samples are excluded from the US Sunshine Act reporting requirements, drug samples must be reported annually pursuant to ACA section 6004, Prescription Drug Sample Transparency.

US State Reporting Requirements

Congress was a relative late-comer to the regulation of interactions between life sciences companies and healthcare professionals. For a number of years, several states imposed expense limitations and reporting requirements. Significantly, the US Sunshine Act does not prohibit states from requiring that manufacturers disclose information not covered by the Act. However, if a state's law requests information that must now be disclosed under the US Sunshine Act, this portion of the state's law is preempted. Conversely, portions of a state's law that are not duplicative of the federal law will stand. Thus, pre-existing state laws remain in effect, and life sciences companies must comply with both the US Sunshine Act and any applicable state reporting requirements that survive preemption.

Although space does not allow a detailed analysis of each state's provisions, the following discussion highlights the more important requirements mandated by the District of Columbia, Massachusetts, Minnesota, Vermont and West Virginia.

In the District of Columbia, pharmaceutical manufacturers and labelers of prescription drugs that employ, direct or utilize marketing representatives in the District must report annually by July 1st "the nature, value, purpose, and recipient" of marketing and advertising expenditures.[11] The following expenses must be disclosed: food, entertainment and gifts valued at more than $25; anything provided to a healthcare professional for less than market value; free or in-kind services; trips and travel; expenses associated with educational or informational programs, materials, seminars; remuneration for promotion or participating in educational or informational sessions (including support for CME programs, charitable grants, and payments for participation in speaker programs or writing articles); and aggregate cost of all employees or

[11] D.C. CODE §§ 48-833.01-.03.

contractors who engage in advertising or promotional activities performed in the District or directed to District residents, including all forms of payment to employees.[12]

Massachusetts requires that pharmaceutical and medical device manufacturers disclose annually by July 1st to its Department of Public Health the value, nature, purpose and recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50, which the company provides, directly or through its agents, to any "covered recipient" in connection with the company's sales and marketing activities.[13] A "covered recipient" is a person or entity authorized to prescribe, dispense or purchase prescription drugs or medical devices in Massachusetts. Pharmaceutical and medical device manufacturers must disclose the following expenditures to covered recipients: food; education or training; grants or educational gifts; charitable donations; compensation for bona fide services; support for CME programs, third-party conferences or meetings; and marketing studies.

In 1993, Minnesota was the first state to adopt requirements that pharmaceutical companies report interactions with healthcare practitioners.[14] Under Minnesota law, wholesale drug distributors[15] must report annually by May 1st payments totaling $100 or more to a healthcare professional for all payments, honoraria, reimbursement or other compensation in the following categories: honoraria and expenses for faculty at educational or professional conferences; and compensation for substantial professional or consulting services in connection

[12] Pursuant to D.C. CODE § 3-1207.41, "[p]harmaceutical representatives must obtain a license from the District of Columbia Board of Pharmacy prior to . . . communicating in person with a licensed healthcare professional . . . for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product."
[13] MASS. GEN. LAWS ch. 111N, § 6.
[14] MINN. STAT. § 151.47(1)(f).
[15] A wholesale drug distributor "means anyone engaged in wholesale drug distribution, but not limited to, manufacturers; repackers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution. A wholesale drug distributor does not include a common carrier or individual hired primarily to transport prescription drugs." Wholesale drug distribution, generally, "means the distribution of prescription drugs to persons other than a consumer or patient[.]" *Id.* at §§ 151.44(a)-(b).

with a genuine research project. Minnesota law also imposes an annual "gift" limitation of $50 per healthcare professional, with "gifts" defined to include meals, real and personal property, promise of future employment, forgiveness of indebtedness and payments for attendance at educational programs and conferences.

The Vermont Prescribed Products Disclosure Law requires pharmaceutical and medical device manufacturers to report to Vermont's Office of the Attorney General annually by April 1st the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the company, directly or indirectly through its marketers.[16] Vermont's law is essentially a gift ban, with certain allowable expenditures and permitted gifts that are subject to disclosure.

In Vermont, pharmaceutical and medical device manufacturers are allowed to make the following expenditures, subject to reporting them: reasonable compensation and reimbursement for expenses related to bona fide clinical trials; honoraria and payment of expenses for faculty at educational and scientific conferences and seminars; payments or reimbursements of reasonable expenses for technical training of individual healthcare professionals related to the use of a medical device; and reasonable fees, payments, subsidies or other economic benefits at fair market value by a manufacturer. Vermont law also permits pharmaceutical and medical device manufacturers to give the following types of gifts, subject to reporting: medical device loans for short-term trial (not to exceed 120 days) for the purpose of evaluation; academic, scientific or clinical articles, or other items that serve a genuine educational function provided to a healthcare professional for the benefit of patients; scholarships or other support for medical students,

[16] VT. STAT. ANN. tit. 18, § 4632(a)(1)(A). Additionally, Vermont requires that manufacturers of prescribed products submit samples disclosure reports, whereby manufacturers disclose the distribution of prescription drug, biological product, or medical device samples, as well as coupons, vouchers and co-pay cards. The samples disclosure reports are due annually on April 1st. *Id.* at § 4632(a)(1)(B).

residents and fellows to attend significant educational, scientific conferences or seminars of professional associations, provided that the association selects the scholarship recipient; and free prescription drugs, devices, biologics, over-the-counter drugs or financial donations to free clinics.

In West Virginia, pharmaceutical manufacturers and labelers of prescription drugs that employ, direct or utilize marketing representatives in West Virginia must file a report with the Governor's Office of Health Enhancement and Lifestyle Planning that includes the following: the total amount spent for direct promotion and advertising to prescribers, consumers, pharmacies and patient support and advocacy groups in West Virginia; the total amount spent on direct-to-consumer advertising directed at consumers in West Virginia and the form of such advertising; and the total number of West Virginia prescribers receiving payments or grants of more than $100.[17] However, companies are not required to report the name of each prescription drug advertised via direct-to-consumer methods or any gift, grant or payment of any kind provided to any pharmacy, disease-specific patient support group or advocacy group. The due date for filing the West Virginia report is April 1st.

In addition to states with payment disclosure and spending limit laws, some jurisdictions, including California, Connecticut, the District of Columbia, Massachusetts and Nevada, have enacted laws setting requirements for compliance codes of conduct that impose additional obligations on life sciences companies.[18]

Despite the passage of the US Sunshine Act, individual states remain free to pass their own reporting requirements and transparency measures. To date, no states have joined those that had laws in place before passage of the US Sunshine Act, but the life sciences industry should

[17] W. VA. CODE § 16-29H-8; W.V. CODE R. §§ 210-1-3.2.a.-.c.

[18] *See* CAL. HEALTH & SAFETY CODE § 119402(a); D.C. MUN. REGS. tit. 17, § 8305; MASS. GEN. LAWS ch. 111N, § 2; NEV. REV. STAT. § 639.570.1(a).

monitor legislative and regulatory activities in all states to determine if additional jurisdictions will impose reporting requirements.

International Transparency Laws and Codes

Life sciences companies must consider a variety of sources when preparing for transparency and reporting obligations outside of the United States. For example, companies located in or doing business in Europe must determine whether the European Union ("EU") has transparency and reporting requirements; whether the countries in which they are physically located or doing business have such laws or regulations; whether global industry organizations to which they belong have transparency and reporting requirements contained in industry-adopted codes; whether European industry organizations to which they belong have transparency and reporting requirements in industry-adopted codes; and, finally, whether individual country industry organizations have transparency and reporting requirements in their codes. This is a complicated and time consuming, yet important, undertaking.

Before examining laws and codes, it is important to note that, in the area of interactions with healthcare professionals, the pharmaceutical industry has adopted more self-regulatory measures than has the medical device industry. In that regard, European pharmaceutical industry organizations, both at the European and national level, have tended to impose on their members more reporting and disclosure requirements than have their medical device counterparts. As this paper is not a country-by-country study, but an overview of representative transparency requirements, our focus will be on those industries (i.e., pharmaceutical as opposed to medical device) and those countries, i.e., France, Slovakia, United Kingdom, Netherlands, Japan and

Australia, in which transparency of the relationships between life sciences companies and healthcare professionals is most highly regulated.

European Union

The EU is an economic and political partnership among 27 European countries. Originally created following World War II to spur economic cooperation on the continent, the EU has grown to become an organization that covers all types of policy areas, including health and business, to name just a few.

EU law is comprised of two different categories: "primary" legislation and "secondary" legislation. Primary legislation includes treaties, which form the basis for all EU action. Secondary legislation, which includes regulations and directives, are based on the principles laid out in the treaties. A regulation is a binding legislative act and must be applied in its entirety throughout the EU. In contrast, a directive is a legislative act that outlines a goal all EU countries must satisfy. Unlike with a binding regulation, individual countries may determine how to achieve goals identified in directives.

Relevant to this paper, Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, serves as the foundation for EU members' states laws governing advertising of medicinal products. Medicinal products are defined as: 1) "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;" or 2) "Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical

diagnosis." Under the Directive, "advertising" of medicinal products includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. Despite addressing many aspects of the promotion of medicinal products, the Directive does not include disclosure or reporting requirements or any aggregate spend concepts. Thus, EU member states are not required to include any such obligations in their national laws, though, as discussed *infra*, some European countries have enacted such laws.

France & Slovakia

Motivated by both the US Sunshine Act and specific concerns in their own countries, France and Slovakia have followed the lead of the United States in passing laws that impose reporting requirements on life sciences companies. Understanding the genesis of these laws, passed in 2011, is important, because understanding will provide insight into the potential for future regulation in other countries.

France

In France, the passage of transparency legislation[19] was driven in large part by scandal. For over thirty years, the diabetes drug, Mediator, manufactured by Laboratories Servier, was prescribed to over 5 million French patients. At the urging of Laboratories Servier, the drug was also widely prescribed to stimulate weight loss. In 2009, the French health authorities ordered the removal of the drug from the market because of possible cardiovascular risks.[20] At that time,

[19] LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé" ("French Sunshine Act").
[20] Asher Mullard, *Mediator Scandal Rocks French Medical Community*, THE LANCET, March 12, 2011, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60334-6/fulltext.

there were approximately 300,000 active prescriptions. French health officials estimate that up to 2,000 people have died from taking Mediator and thousands more have been hospitalized as a result of heart valve damage and pulmonary hypertension allegedly caused by the drug.[21]

Since the drug was removed from the market, French authorities have been investigating Laboratories Servier and its active promotion of the drug for weight loss. Criminal and civil charges have been filed against the company and there are several ongoing legal proceedings related to what has been described as the largest health scandal ever in France.

Not only did the scandal result in government investigations and trials, it also led the French government to pass, in December 2011, a major, comprehensive reform of its healthcare system. The French Sunshine Act includes new rules that require disclosure from both pharmaceutical and medical device companies. In addition to the imposition of disclosure requirements, the new law also renamed the government agency responsible for supervision of the health industry and gave it more power to closely monitor pharmaceuticals and medical devices. In addressing the French Senate, Health Minister Xavier Bertrand stated, "We want there to be a 'before' and 'after' as regards Mediator in our country."[22]

The French Sunshine Act sets broad reporting requirements, with details of implementation to be spelled out in a decree. There are two types of transparency rules contained in the French Sunshine Act. The first concerns public declarations of interest that experts must make concerning their relationships with life sciences companies. The second involves disclosure obligations imposed on life sciences companies concerning their interactions with healthcare professionals.

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[21] *Id.*

[22] Scott Sayre, *Scandal Over Mediator, a French Weight-Loss Drug, Prompts Calls for Wide Changes*, N.Y. TIMES, December 11, 2011, http://www.nytimes.com/2011/12/12/health/scandal-widens-over-french-weight-loss-drug-mediator.html?pagewanted=all.

Under the French Sunshine Act, covered companies (including pharmaceutical and medical device companies and others, including, for example, cosmetic manufacturers) must publicly disclose the existence of agreements with:

- Healthcare professionals;
- Associations of healthcare professionals and associations of students for relevant occupations;
- Students for relevant occupations;
- User associations of the health system (public or private);
- Health facilities;
- Foundations, learned societies, and consulting companies or organizations in the health sector;
- Publishing companies: press, radio, television, and on-line media;
- Editors of prescription and dispensing software; and
- Legal entities contributing to the initial training of healthcare professionals.

Agreements that must be disclosed include contracts of any nature, including, for example, research and development contracts, consultancy agreements and invitations to healthcare professionals to attend scientific or medical events. Agreements in effect as of January 1, 2012, or which become effective after that date, must be disclosed.

Not only must the existence of agreements be disclosed, but covered companies must also disclose all benefits in-kind or in cash – above an amount to be set by decree – that they provide, directly or indirectly, to the persons, associations, institutions, foundations, corporations, organizations and bodies mentioned above. This obligation begins with payments made on January 1, 2012 and includes all such payments made thereafter.

The French Sunshine Act includes various criminal sanctions, including monetary fines, for violations. Furthermore, companies may be prohibited from continuing to manufacture products if they violate the law.

As noted, the French Sunshine Act outlines broad requirements and principles. The French Ministry of Health will provide necessary implementing details in a final decree. Although that final decree has not been promulgated, two draft decrees provide some guidance as to what companies may expect from the final decree. The Ministry of Health issued the first draft decree on February 22, 2012.[23] That proposed decree provided that companies would disclose required information on a publicly accessible page of their website, in a form to be developed by the government.

With respect to agreements with healthcare professionals, the draft decree mandated the disclosure of the following information:

- name and other identifying information (i.e., address) of the healthcare professional;
- the date of the contract; and
- the subject or purpose of the contract.

For payments, gifts and other benefits provided directly or indirectly to healthcare professionals, the decree set the reporting threshold at one euro. That is, if a covered company spent one euro or more on a healthcare professional, the covered company would have to disclose the payment. For such payments, the company would have to disclose:

- the name and other identifying information (i.e., address) of the healthcare professional;
- the date on which the payment was made;

[23] Projet Décret n° _ du 22 février 2012.

- the nature and amount of the payment; and
- the grounds for the payment.

As to the timing of disclosures, the first draft decree was draconian, requiring disclosure within 15 days of contract execution or within 15 days of payment.

A second draft decree was issued in April 2012[24] and contained provisions similar to those in the first draft. However, one significant change concerned the threshold for reporting of payments, gifts and other benefits, which was raised to ten euros from the one euro threshold of the first draft decree.

It was widely expected that a final decree would be in effect by August 1, 2012, based on requirements contained in the French Sunshine Act. However, in a July 31, 2012 press release titled, "Transparency in the promotion of health products 'Sunshine Act,'" French Minister of Social Affairs and Health Marisol Touraine advised that that would not happen.[25] Instead, Ms. Touraine stated that the draft decrees, which had been prepared by the previous government,[26] imposed unrealistic and inaccurate disclosure requirements.[27] She further announced that she was creating a working group to revise the draft decree and that the final decree would take effect in October 2012.[28]

Slovakia

Slovakia's adoption of healthcare professional interaction reporting requirements in September 2011 was part of a broad drug policy reform bill that included many provisions and

[24] Projet Décret n° _ du _ avril 2012.
[25] Press Release, Ministry of Social Affairs and Health, Transparency in the promotion of health products "Sunshine Act" (July 31, 2012).
[26] In France's May 2012 presidential elections, incumbent President Nicolas Sarkokzy lost to Francois Hollande. President Hollande was inaugurated on May 15, 2012.
[27] Press Release, Ministry of Social Affairs and Health, Transparency in the promotion of health products "Sunshine Act" (July 31, 2012).
[28] *Id.*

topics beyond transparency and reporting.[29] Slovakia's comprehensive law was reportedly motivated by two concerns: 1) preventing corruption; and 2) cost control. This legislative intent is best evidenced by a press release, "Adoption of the drug policy reform is good news for Slovak patients," issued by the Ministry of Health of the Slovak Republic.[30] That release provided in pertinent part:

> **Health minister Ivan Uhliarik said that the adoption of the drug reform was very good news for all patients, because the medical drugs in Slovakia will be cheaper:** "We have succeeded in setting the medical drug prices to the second lowest level in the European Union. According to the law, the pharmacies will have to share the discounts offered by drug distributors with patients." Additional benefits will include the improved transparency of the categorization, more detailed specification of the conditions for regulatory pricing of drugs, medical devices and dietary foods and consequently the extent of their reimbursement from the public health insurance, increased emphasis on the issues of cost efficiency in association to healthcare reimbursed from public health insurance, implementation of innovative tools in the process of drug categorization, support of cost savings in the area of public health insurance related to introduction of generic products to the market. …
> **These are just some of the benefits of the two laws that in the legislative process resisted the enormous pressure of the pharmaceutical companies and pharmacies who will lose some of their profits. The fact that the new laws came into effect as of December 1, 2011, is a great break-through in the transparency of drug policy in Slovakia. This means that all opinions of the expert authorities on individual drugs will be published to the internet and available for everybody´s review.**
> "We have developed the laws in favor of the patients and the EUR 100 million that will remain in the system will be channeled to the hospitals through insurance companies," emphasized minister Uhliarik.

(emphasis added)

Under Slovakia's Sunshine Act, companies must annually submit, no later than January 31, a report to the Ministry of Health providing the value of advertising and marketing expenses and non-monetary benefits provided directly or indirectly to healthcare professionals. The

[29] Act no. 362/2011, *available at* http://jaspi.justice.gov.sk/jaspiw1/jaspiw_mini_fr0.htm.
[30] Press Release, Ministry of Health of the Slovak Republic, Adoption of the Drug Policy Reform is Good News for Slovak Patients (September 13, 2011).

Ministry must then publish a report of that information on its website. In addition, the new law prohibits companies from directly or indirectly financing, sponsoring or otherwise supporting healthcare professionals to attend events, including conferences and seminars, unless the purpose of the events is expert, scientific or educational. Companies that provide support pursuant to that exception must provide to the National Centre for Healthcare Information a list of the healthcare professionals it supports, which is then published online.

Although France, Slovakia and the United States have taken the most comprehensive approach to sunshine laws, it is worth noting that other countries have discrete healthcare practitioner interaction reporting requirements. For example, pursuant to Estonia's Medicinal Products Act,[31] companies must submit, by February 1 of each year, to the State Agency of Medicines a report concerning support awarded to dispensing chemists, pharmacists, doctors and their associations for participation in medical or pharmaceutical events or for the organization of such events. Thus, life sciences companies must closely scrutinize laws and regulations in all countries in which they do business to ensure compliance with the growing body of legislative transparency requirements.

Codes of International Industry Associations

International Federation of Pharmaceutical Manufacturers & Associations

As noted above, life sciences companies must not only be concerned with EU directives and national laws and regulations, but they must also adhere to codes promulgated by industry groups to which they belong. One such organization is the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"). Founded in 1968, IFPMA is a global, non-profit, non-governmental organization that represents the research-based

[31] Medicinal Products Act, RT[2] I, 2001, 2, 4, *available at* http://www.sam.ee/en/medicinal-products-act.

pharmaceutical industry, including the biological and vaccine sectors. Members of IFPMA include not only companies, but also national and regional pharmaceutical industry associations.

Because of its commitment to high ethical standards, IFPMA adopted a code in 1981 to outline principles to govern its members.[32] That code has been updated numerous times since then, most recently in March 2012. The IFPMA Code governs the promotion of pharmaceutical products to healthcare professionals and applies to all pharmaceutical products, including prescription, generic and over-the-counter medicines promoted to healthcare professionals by member companies worldwide. Significantly, the IFPMA Code does not include disclosure or reporting requirements. Although national codes promulgated by national organizations that are members of IFPMA must be consistent with the IFPMA Code, national organizations are allowed to impose more stringent requirements.

European Federation of Pharmaceutical Industries and Associations

The European Federation of Pharmaceutical Industries and Associations ("EFPIA") is the representative body of the pharmaceutical industry in Europe. Its members include over thirty-five pharmaceutical companies and the national industry associations of the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Russia, Poland, Portugal, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Romania, Turkey and the United Kingdom.

[32] *IFPMA Code of Practice 2012 (EN)*, IFPMA.ORG, http://www.ifpma.org/ethics/ifpma-code-of-practice/ifpma-code-of-practice.htm, (last visited August 10, 2012).

EFPIA has adopted two relevant codes: 1) EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions With, Healthcare Professionals;[33] and 2) EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organizations (together, the "Codes").[34] The Codes apply to EFPIA member companies, their subsidiaries and any companies affiliated with EFPIA member companies or their subsidiaries, if such affiliated companies have agreed to be bound by the Codes. The Codes contain minimum standards that all national industry associations must have in their own national codes. Like the IFPMA Code, the Codes permit national organizations to impose stricter obligations or requirements upon member companies.

The EFPIA Code on Interactions With Healthcare Professionals, most recently amended in June 2011, does not contain actual reporting or disclosure requirements. However, it encourages companies to make publicly available information about donations, grants or benefits in-kind made to institutions, organizations or associations comprised of healthcare professionals or that provide healthcare or conduct research.

In contrast, the EFPIA Code on Relationships with Patient Organizations, also most recently amended in June 2011, contains reporting requirements. The requirements apply to activities commenced as of or ongoing on January 1, 2012, with the first reports to be made public by the end of the first quarter of 2013.

Pursuant to the EFPIA Code on Relationships with Patient Organizations, companies must make publicly available a list of patient organizations to which they provide financial

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[33] *EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with Healthcare Professionals*, EFPIA.EU, http://www.efpia.eu/articles/e4ethics, (last visited August 10, 2012) ("Code on Interactions with Healthcare Professionals").

[34] *EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations* [sic] , EFPIA.EU, http://www.efpia.eu/articles/e4ethics, (last visited August 10, 2012) ("Code on Interactions with Patient Organizations").

support or significant indirect or non-financial support. The information may be provided on a national or European level and should be updated at least once a year. The reporting of this information must include a description of the nature of the support in a manner that is sufficient for the reader to understand the support's significance. The description must include the monetary value of financial support and invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the description must describe clearly the non-monetary benefit the patient organization receives.

In addition, each company must make publicly available a list of patient organizations it has engaged to provide significant contracted services. The disclosure must include a description of the nature of the services that allows the reader to understand the nature of the arrangement, and the total amount paid to each patient organization over the reporting period.

The EFPIA Codes set minimum standards that national industry associations must implement in their own codes. Each national industry group that belongs to EFPIA[35] has adopted its own codes to apply to its members. Although these codes are largely similar, they contain some differences, as national groups have chosen to deviate from the EFPIA Codes in various ways. For example, national industry associations have diverse requirements concerning the dates by which disclosure must be made and the type of information to be disclosed. Instead of addressing the national industry association codes that are largely similar, we will focus below on the codes in the United Kingdom and the Netherlands, which have taken a more aggressive approach to reporting and created additional disclosure obligations for their members.

[35] *See infra.*

Eucomed

Eucomed represents the medical technology industry in Europe. Eucomed members include both national and pan-European trade and product associations, in addition to medical technology manufacturers. Eucomed represents approximately 22,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.[36]

Like IFPMA and EFPIA, Eucomed is committed to high ethical standards for its members. In that regard, Eucomed works to ensure that its members adhere to the highest ethical and professional standards when they collaborate with healthcare professionals. Eucomed has published a Code of Ethical Business Practices, which, among other things, includes Guidelines on Interactions with Healthcare Professionals.[37] While the Code and Guidelines embrace the concept of transparency in a general sense,[38] neither mandates reporting of interactions with healthcare professionals.

Codes of National Industry Associations

As noted above, the pharmaceutical industry associations in the United Kingdom and the Netherlands have taken an active role in amending their codes of practice to include reporting requirements that supplement those contained in EFPIA Codes. Those actions can be at least

[36] *About Us*, EUCOMED.ORG, http://www.eucomed.org/about-us, (last visited August 10, 2012).
[37] *Code of Ethical Business Practice, Eucomed Guidelines on Interactions with Healthcare Professionals*, EUCOMED.ORG, http://www.eucomed.org/key-themes/ethics, (last visited August 10, 2012).
[38] *Id.* For example, the Preamble to the Code discusses "The Principle of Transparency," and states:

> Interaction between industry and Healthcare Professionals must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.

partially explained by a desire on the part of industry to avoid the imposition of legislative requirements such as those enacted in France and Slovakia.

United Kingdom

In the United Kingdom, the promotion of medicines and interactions with healthcare professionals are subject to two complementary systems of control: 1) self-regulation by the pharmaceutical industry, via the Association of the British Pharmaceutical Industry ("ABPI") Code of Practice for the Pharmaceutical Industry ("ABPI Code"),[39] administered by the Prescription Medicines Code of Practice Authority ("PMCPA"); and 2) UK law,[40] administered by the Medicines and Healthcare products Regulatory Agency ("MHRA"). PMCPA, ABPI, and MHRA entered into a Memorandum of Understanding[41] that established arrangements for the regulation of promotion of medicines and the industry's leading role in policing itself.

ABPI is the trade association that represents prescription medicine companies involved in research, development and manufacture of branded and generic products in the UK. The ABPI Code establishes requirements governing promotion of medicines to, and interactions with, UK "health professionals"[42] and administrative staff. The goal of the ABPI Code is to ensure that medicines are promoted to health professionals in an appropriate, ethical manner.

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[39] *Code of Practice for the Pharmaceutical Industry 2012*, ABPI.ORG.UK, www.pmcpa.org.uk/files/sitecontent/ABPI_Code_2012.pdf, (last visited August 10, 2012) ("ABPI Code").

[40] *MHRA Overview of Medicines legislation and Guidance*, MHRA.GOV.UK, http://www.mhra.http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/Glossaryoflegislation/index.htm, (last visited August 10, 2012).

[41] Memorandum of Understanding Between the ABPI, the PMCPA, and the MHRA (November 3, 2005), *available at* www.mhra.gov.uk/home/groups/pl-a/documents/.../con2022582.pdf.

[42] In the rest of this paper, we refer to healthcare professionals; however, because "health professionals" are specifically defined in the ABPI Code, we will refer to "health professionals" in discussing that code. Clause 1.4 of the ABPI Code states: "The term 'health professional' includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may prescribe, supply or administer a medicine."

The ABPI Code was created in 1958 and goes beyond the government's statutory requirements. It was promulgated in consultation with MHRA, the British Medical Association, The Royal Pharmaceutical Society and the Royal College of Nursing. Compliance with the ABPI Code is a condition of membership in ABPI. Companies found to have breached the ABPI Code may be subject to penalties, including monetary charges. The ABPI Code covers all matters relating to the promotion of prescription medicines to UK health professionals and administrative staff. It also addresses some areas that are non-promotional. It does not apply to the promotion of over-the-counter medicines to the general public or to health professionals when the object is to encourage purchase by the general public.

The ABPI Code includes disclosure requirements in the following areas: 1) provision of medical goods and services in the form of donations, grants and benefits in-kind to certain institutions, organizations or associations; 2) meetings, hospitality and sponsorship; 3) the use of consultants; and 4) relationships with patient organizations.

1. Items for Patients, Promotional Aids, the Provision of Medical and Educational Goods and Services, Agreements to Benefit Patients such as Joint Working, Outcome Agreements and Patient Access Schemes

The ABPI Code permits pharmaceutical companies to provide medical and educational goods and services in the form of donations, grants and benefits in-kind to institutions, organizations or associations comprised of health professionals or that provide healthcare or conduct research if certain conditions are met, including that companies "make publicly available details of donations and grants provided[.]"[43] The information required to be made publicly available concerns donations and grants made in 2012 and in each calendar year thereafter. Public disclosure must be in the calendar year following that in which donations and

[43] *ABPI Code*, *supra* note 39, at Clause 18.6.

grants were provided, and information must be made public within three calendar months of the end of the company's financial year.

Details of grants or donations must be disclosed, giving, in each case, the financial amount or value and the name of the recipient institution, organization or association. Companies are also encouraged to request that recipients of grants or donations make such funding public. Further, "[a]ll reasonable steps should be taken by the local operating company to similarly disclose donations and grants provided by overseas affiliates, head offices in the UK or overseas and UK based European offices."[44] Lastly, companies "are encouraged to make publicly available the information about benefits in kind provided by them which are covered by Clause 18.6."[45]

2. Meetings, Hospitality, and Sponsorship

The ABPI Code requires pharmaceutical companies to "make publicly available financial details of sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings organised by third parties. Sponsorship in this context includes registration fees, costs of accommodation (both in and outside the UK) and travel outside the UK."[46] The information required to be made publicly available concerns attendance at meetings held in 2012 and each year thereafter. Disclosure must take place in the calendar year following that in which the payments were made, and information must be made public within three calendar months of the end of the company's financial year.

[44] *ABPI Code*, *supra* note 39, at Clause 18.6 Supplementary Information.
[45] *Id.*
[46] *Id.* at Clause 19.4.

The information to be disclosed "is the total amount paid in a calendar year in respect of all recipients and the total number of recipients. The total number of attendances at meetings sponsored in the year must also be given. The names of the recipients need not be disclosed."[47]

Additionally, meeting registration fees for UK health professionals and appropriate administrative staff must be included when they are paid by overseas affiliates, head offices in the UK, and UK-based European offices. Lastly, companies must take "[a]ll reasonable steps" to disclose their best estimates of the amounts for accommodation costs (both in and outside the UK) and travel outside the UK for UK health professionals and appropriate administrative staff that is paid by overseas affiliates, head offices in the UK, or overseas and UK-based European offices.

3. The Use of Consultants

The ABPI Code outlines the requirements that companies must satisfy in order to utilize health professionals and administrative staff as consultants and advisors. In that regard, the Code requires pharmaceutical companies to

> make publicly available details of the fees paid to consultants in the UK, or to their employers on their behalf, for certain services rendered by them such as chairing and speaking at meetings, assistance with training and participation in advisory boards, etc. It does not include payments to consultants in relation to research and development work, including the conduct of clinical trials. Nor does it include payment of UK travel costs or the cost of subsistence in relation to fees for services which are dealt with [elsewhere in the Code].[48]

Other ABPI Code provisions require companies to "make publicly available details of payments made to consultants in relation to market research (unless the company concerned is not aware of the identities of those participating in the market research) and payments in respect of accommodation (both in and outside the UK) and travel outside the UK in relation to fees for

[47] *Id.* at Clause 19.4 Supplementary Information.
[48] *Id.* at Clause 20.2.

services as defined in [the Code]." This requirement only relates to "market research using consultants whose identity is known to the pharmaceutical company." When disclosure is required, consultant names do not need to be disclosed. This reporting requirement applies to payments to consultants in 2013 and thereafter.

Apart from market research consultant payments referenced in the preceding paragraph, the information required to be made publicly available concerns payments made to UK consultants in 2012 and each calendar year thereafter. The disclosure must occur in the calendar year following that in which payments were made, and information must be made public within three months of the end of the company's financial year. The following information must be provided: 1) the total amount paid in a calendar year to all consultants who provided services; and 2) the total number of consultants. Consultant names do not need to be disclosed. However, companies are allowed to provide greater detail than that which is required; for example, they can provide separate figures for different categories of services or provide details of maximum and minimum payments.

Local operating companies must take "[a]ll reasonable steps to disclose their best estimates of fees paid to UK consultants by overseas affiliates, head offices in the UK or overseas and UK-based European offices."[49]

4. Relationships with Patient Organizations

Lastly, the ABPI Code outlines circumstances under which pharmaceutical companies may have relationships with and interact with patient organizations. Each company must "make publicly available, at a national or European level, a list of patient organizations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader

[49] *Id.* at Clause 20.2 Supplementary Information.

to form an understanding of the significant of the support."[50] The list of supported organizations must be updated at least once a year.

The published information must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organization receives. A list of patient organizations that includes the monetary value of support, regardless of its level, must be made publicly available by the end of the first quarter of 2013 and cover activities commenced on or after January 1, 2012.

Until that information is made publicly available in 2013, the following requirements apply: each company must make publicly available, at a national or European level, a list of patient organizations to which it provides financial support or significant indirect or non-financial support, which must include short descriptions of the nature of support. The list of organizations provided with support must be updated at least once a year. The published information must include the monetary value of financial support or significant indirect or non-financial support provided to a patient organization with a value to the organization of £250 per project or more (excluding VAT). The requirement to include the monetary value of support given to patient organizations applies to activities commenced on or after May 1, 2011, or ongoing on that date. An indication of the patient organization's total income and the company's support as a percentage of the patient organization's total income may be given, but neither is obligatory.

The ABPI Code also outlines how a company may enter into a contract with a patient organization for the organization to provide services, and the requirements for such relationships. Each company must make publicly available, at a national or European level, a list of patient

[50] *ABPI Code*, *supra* note 39, at Clause 23.7.

organizations it has engaged to provide significant contracted services. The list must include a description of the nature of services rendered that is sufficiently complete to enable the average reader to form an understanding of the arrangement without the necessity to divulge confidential information. Companies must also make publicly available the total amount paid each patient organization over the reporting period. The list of organizations must be updated at least once a year. This list must be published for the first time at end of first quarter 2013, covering activities begun in 2012 or ongoing as of January 1, 2012.

Netherlands

As in the United Kingdom, the pharmaceutical industry association in the Netherlands has taken an active role in self-regulating disclosure and transparency. In 2009, the Dutch Minister of Health requested that the industry develop a mechanism to disclose financial relationships between industry members and Dutch healthcare professionals. This request was seemingly motivated not only by the US Sunshine Act but also by public and political attention in the Netherlands that had focused on the relationship between industry and healthcare professionals.[51]

As a result of the request, the pharmaceutical industry worked with healthcare professionals in a cooperative manner to develop self-regulation that addressed the issues and concerns of all stakeholders, ultimately developing a code that includes disclosure requirements for pharmaceutical companies. Under the Dutch code,[52] companies must disclose two different

[51] Matthijis M. Van Blokland, LLM, General Counsel, Prosensa; General Counsel and Senior Policy Advisor Legal Affairs, Association Innovative Medicines, Nefarma; Board Member, Stichting CGRz, Amsterdam, The Netherlands, Presentation at the Sixth International Pharmaceutical Compliance Congress in Budapest, Hungary: Transparency Declaration of Payments (May 15, 2012).

[52] *See* Foundation for the Code for Pharmaceutical Advertising (CGR), Code of Conduct Disclosure (effective January 1, 2012).

types of financial relationships with healthcare professionals: 1) service agreements; and 2) sponsorship agreements of meetings between a company and associations of professionals/institutions that directly or indirectly improve healthcare to patients or promote medical science. There are five types of service agreements: 1) consulting; 2) advisory; 3) speaker; 4) non-speaker research; and 5) other.

The substance of the mandated disclosure depends upon the nature of the agreement, service or sponsorship. For a service agreement, the company must provide the personal information of the healthcare professional, including name; specialization; work address; amount paid to the professional; and name, business address and/or registration number of the association or institution that employs the healthcare professional. For sponsorship agreements, the company must disclose the name, business addresses and registration number of the recipient group, along with the amount paid to the group during the calendar year.

Not all financial relationships between companies and Dutch healthcare professionals must be disclosed. Rather, the Dutch Code sets the threshold amount at 500 euro per calendar year. That is, if the total amount of the financial relationship between a company and a professional, association or institution is greater than 500 euro per calendar year, it must be disclosed. If the financial relationship is less than 500 euro per calendar year, the relationship does not have to be disclosed.

With respect to the manner of disclosure, companies must upload relevant data to a central registry, the details of which must still be promulgated. The Foundation for the Code for Pharmaceutical Advertising will establish the registry in collaboration with the Ministry of Health, Welfare and Sport; the Royal Dutch Medical Association; the Association for Innovative Medicines in the Netherlands; and the Association for the Generic Drugs Industry in the

Netherlands.[53] The registry, which will be managed by an independent foundation, is expected to be operational by October 2012.[54] Ultimately, the public will have access to the transparency registry via the Internet.[55]

These transparency rules became effective on January 1, 2012, with the first disclosure scheduled to take place in 2013.

Ex-European Transparency Obligations

Transparency requirements promulgated by industry associations are not limited to those in Europe; the march toward disclosure is spreading throughout the world. Although the trend has not yet taken hold in Latin or South America, industry experts believe that such reporting requirements will soon arrive in the Middle East and Africa.[56] In that regard, there is the Middle East and Africa Code of Promotional Practices, with guiding principles that pharmaceutical companies have developed and enforced in order to self-regulate marketing and promotional practices in that region. Although there are no reporting or disclosure requirements in this Code, it provides guidance on topics like promotion, events and hospitality, grants and donations and samples distribution, to name just a few. The Code was created in 2005 and was most recently amended in 2010.

The shift toward transparency in the region is also evidenced by other recent events. For example, the Saudi Food and Drug Authority recently issued a new Saudi Code of Pharmaceutical Practice in the Kingdom of Saudi Arabia.[57] Further, in Tunisia, a new

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[53] *Transparency Register*¸ CGR.NL, www.cgr.nl/getattachment/...3.../NIEUWSBRIEF-3-ENG-2012.pdf.aspx (last visited August 10, 2012).
[54] *Id.*
[55] *Id.*
[56] Joe Henien, President & CEO NewBridge Pharmaceuticals, Presentation at the Sixth International Pharmaceutical Compliance Congress in Budapest, Hungary: MEA Annual Compliance Update (May 14, 2012).
[57] *Id.*

association representing the innovative sciences sector held a launch meeting in March 2012, which included the signing of a new code of promotional practices. Although full-blown disclosure requirements have not arrived yet in the Middle East and Africa, those involved in the industry in that region expect such changes in the not-too-distant future.[58]

Japan

In contrast to these developing regions of the world, sunshine provisions are already in place in both Japan and Australia. In Japan, disclosure requirements have been implemented by the Japan Pharmaceutical Manufacturers Association ("JPMA") via the "JPMA Guidelines on Transparency on Corporate Activities with Medical Institutions and Healthcare Professionals" ("JPMA Guidelines"), issued in March 2011. JPMA is a voluntary association comprised of approximately 70 research-oriented pharmaceutical companies; it is affiliated with both EFPIA and PhRMA.[59] The objective of the JPMA Guidelines and its transparency provisions was to give the public a better understanding of the ways in which pharmaceutical companies contribute to the development of life sciences and conduct their businesses with high ethical standards.[60]

Under the JPMA Guidelines, members must do two things. First, they must establish a transparency policy to govern activities in accordance with the Guidelines. Second, they must publicly disclose payments to medical institutions and healthcare professionals by uploading data on their websites. Payments made in fiscal year 2012 are to be disclosed in fiscal year 2013. There are five categories of payments that must be disclosed: 1) research and development-related costs; 2) grants/donations; 3) honoraria (speaking, writing and consulting); 4) information

[58] *Id.*
[59] The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a trade group representing the pharmaceutical research and biopharmaceutical companies in the United States.
[60] Press Release, EFPIA, About Enactment of JPMA Guideline (March 2, 2011), (*available at* http://efpia.jp/English/download-e.html).

exchange costs (i.e., speaker programs); and 5) meals and hospitalities provided to healthcare professionals.

The JPMA Guidelines require that companies obtain the consent of healthcare professionals in order to disclose the aforementioned information. If, however, healthcare professionals refuse to provide consent, companies must stop working with them. At present, the Guidelines do not provide for any penalties for violations.

Australia

In Australia, the pharmaceutical industry is represented by Medicines Australia, which, among other things, promulgates and implements the Medicines Australia Code of Conduct ("Australia Code"). Established in 1960, the Australia Code sets the standard for ethical marketing and promotion of prescription pharmaceutical product in the country. In doing so, the Australia Code complements the legislative requirements of the Therapeutic Good Regulations[61] and the Therapeutic Good Act.[62] The Australia Code has been updated since its creation in 1960, and is currently in its 16th Edition as of January 1, 2010. In addition to the Australia Code, Medicines Australia also makes available interpretive guidance to ensure that companies understand and comply with the various provisions of the Code, including those involving disclosure. Compliance is important not only as a goal unto itself, but also because violation of the Australia Code can lead to penalties like corrective action and monetary fines.[63]

Under the Medicines Australia Code of Conduct,

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[61] *Therapeutic Goods Amendment Regulations*, 2011, *available at* http://www.comlaw.gov.au/Details/F2011L00434.
[62] *Therapeutic Goods Act, 1989*, available at http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/.
[63] *Medicines Australia Code of Conduct ed. 16*, 2010, *at §§* 24.1-.3, MEDICINESAUSTRALIA.COM, medicinesaustralia.com.au/files/2010/09/Code-of-Conduct-Edition-161.pdf (last visited August 10, 2012).

> each company must make publicly available on its website, a list of Health Consumer Organisations to which it provides financial support and/or significant direct/indirect non-financial support. The list must include a brief description of the nature of the support. The list of organisations being given support must be updated on an annual basis. Companies that do not have Australian websites must make this information available on request.[64]

In addition, companies are permitted to sponsor individual patients or health consumer organizations' representatives to attend third-party scientific and medical conferences so long as the companies satisfy various criteria. Moreover, each company must provide a report to Medicines Australia with respect to all educational meetings and symposia held or sponsored by the company. Companies must complete specific forms and tables provided by Medicines Australia. For each event, the company must provide a description of the function, including duration of educational content; venue; professional status of attendees; hospitality provided (food, drinks, travel entertainment); number of attendees, and total cost.

Anti-Corruption Laws and Treaties

Anti-corruption laws, though not geared exclusively to the life sciences industry, are also relevant to the worldwide trend demanding more transparency in the relationships between life sciences companies and healthcare professionals. In recent years, governments throughout the world have increasingly focused on enacting and enforcing anti-corruption laws. One of the underlying premises for this trend is to improve transparency in governmental procurement processes and, in doing so, preserve governmental monies and resources. As governments become more aggressive in investigating and prosecuting violations of anti-corruption laws, companies must ensure that their employees and agents are familiar and compliant with all relevant laws. This is a particular concern for life sciences companies, because, in many

[64] *Id. at* 13.4.

countries, most healthcare professionals are government employees. Thus, nearly every interaction with healthcare professionals may potentially expose a company to criminal and civil liability under applicable anti-corruption laws.

Anti-Corruption Efforts of International Organizations

A number of international organizations strive to prevent corruption. For example, the United Nations and Council of Europe have adopted various measures to reduce corruption, including adopting model codes to govern the conduct of public officials.[65]

Likewise, the Organization for Economic Co-operation and Development ("OECD") has been a leader in combating corruption on a global basis. In 1999, the OECD's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions was adopted. In a message accompanying the OECD Working Group on Bribery's 2011 Annual Report, Angel Gurria, the Secretary-General of the OECD, explained that the

> Convention is one of the world's most powerful tools to promote more transparent international business practices. It sets the highest and toughest standards for fighting bribery in business. Bribing public officials in international business transactions is a crime that distorts markets, undermines good governance and, at the end of the day, hurts the world's most vulnerable. Proper implementation and active enforcement of the Convention can help countries save billions of dollars **and improve public services by increasing competition and transparency in their procurement systems**.[66]

(emphasis added)

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[65] *Anti-Corruption*, UN.ORG, http://www.unglobalcompact.org/Issues/transparency_anticorruption/, (last visited August 10, 2012); *Council of Europe anti-corruption body calls on states to increase transparency of political funding*, COE.INT, http://www.coe.int/t/dghl/monitoring/greco/news/news(20120509)actrep2011_EN.asp, (last visited August 10, 2012).

[66] *OECD Working Group on Bribery*, *Annual Report 2011*, OECD.ORG, http://www.oecd.org/daf/briberyininternationalbusiness/anti-briberyconvention/oecdworkinggrouponbribery-annualreport.htm, (last visited August 10, 2012) ("OECD Report").

The Convention requires all Convention members to make foreign bribery of public officials a criminal offense and obligates them to investigate and, where appropriate, prosecute those who offer, promise or give bribes to foreign public officials.

According to the aforementioned 2011 Annual Report, since the Convention took effect in 1999, 298 companies and individuals have faced criminal sanctions for bribery of public officials in international business transactions and 66 individuals have gone to jail. Further, at the time of the report, there were approximately 300 ongoing investigations. The 39 members of the Convention are: Argentina; Australia; Austria; Belgium; Brazil; Bulgaria; Canada; Chile; Czech Republic; Denmark; Estonia; Finland; France; Germany; Greece; Hungary; Iceland; Ireland; Israel; Italy; Japan; Luxembourg; Mexico; Netherlands; New Zealand; Norway; Poland; Portugal; Russia; Slovakia; Slovenia; South Africa; South Korea; Spain; Sweden; Switzerland; Turkey; United Kingdom and United States. Each country has anti-bribery laws and legislation in effect. Although it is beyond the scope of this paper to examine the laws of each of those countries, we will discuss the anti-bribery laws in the United States and United Kingdom, and highlight several important global trends.

United States

The United States' anti-corruption law, the FCPA,[67] pre-dates the OECD's Convention. Broadly stated, the FCPA prohibits U.S. companies from making payments to foreign officials for the purpose of getting or keeping business. The FCPA was enacted in the wake of SEC investigations in the 1970s that led to over 400 U.S. companies admitting to making questionable or illegal payments of over $300 million to foreign governmental officials. Congress passed, and President Carter signed, the FCPA to stop American companies from bribing foreign officials for

[67] 15 U.S.C. §§ 78dd-1, *et seq*.

business opportunities and to restore public confidence in the American business system. The passage of the FCPA was a watershed event, because prior to that time no government had made it illegal to bribe officials of a foreign country. In fact, bribing foreign officials was, in some senses, an accepted cost of business.

For a violation of the FCPA to occur, five elements must be satisfied.[68]

1) Who is covered: The FCPA may apply to any individual, firm, officer, director, employee or agent of a firm, and any stockholder acting on the firm's behalf. Individuals and firms can also violate the FCPA if they order, authorize or assist someone else to violate the Act's anti-bribery provisions or if they conspire to violate the provisions. The FCPA applies not only to U.S. companies (i.e., every business entity organized under U.S. law or with its primary place of business in the U.S.), but also to many foreign companies. In that regard, a foreign company or person is subject to the FCPA if it causes – either directly or through an agent – an act in furtherance of a corrupt payment to take place within the territory of the U.S. Moreover, U.S. parent companies may be liable for acts of foreign subsidiaries if they authorized, directed or controlled the activity in question.

2) Corrupt Intent: The individual or firm making or authorizing the payment must have a corrupt intent, and the payment must be intended to cause the recipient to misuse his or her official position in order to steer business wrongfully to the payor. More specifically, the FCPA bars any corrupt payment intended to influence an act or decision of a foreign official, to induce the official to do or fail to do something in violation of his or her duty, to obtain an improper advantage, or to induce a foreign official to improperly influence or affect any act or decision. The FCPA does not require that the corrupt purpose "succeed." That is, the mere offer or

[68] 15 U.S.C. §§ 78dd-1 to -3.

promise of a corrupt payment may be a violation, even if the offeror does not obtain the sought-after business.

3) Payment: The FCPA bans paying, offering or promising to pay (or authorizing such payment or offer) money or anything else of value.

4) Recipient: The FCPA's scope extends to corrupt payments to a foreign official, a foreign political party or party official, or any candidate for foreign public office. "Foreign officials" include any officer or employee of a foreign government, public international organization or any department or agency thereof, or any person acting in an official capacity.

5) Business Purpose Test: The FCPA bars payments made to assist the payor in obtaining or retaining business or directing such business to itself. The Department of Justice broadly interprets "obtaining or retaining" business; in fact, the business to be obtained or retained does not have to actually be with a foreign government or foreign government instrumentality. Indeed, "obtained or retained" business may come from a private foreign entity, so long as it was the result of improper intervention by a bribed foreign public official.

The FCPA includes an exception to the anti-bribery provision for "facilitating payments" for "routine governmental action."[69] The Act lists the following examples that would not constitute a violation of its anti-corruption provisions: obtaining permits, licenses or other official documents; processing governmental papers such as visas or work orders; providing police protection, mail pick-up and delivery; providing phone service, power and water supply; loading and unloading cargo; protecting perishable products; and scheduling inspections associated with contract performance or transit of goods across country.[70] "Routine

[69] 15 U.S.C. § 78dd-1(b), 15 U.S.C. § 78dd-2(b), 15 U.S.C. § 78dd-3(b).
[70] 15 U.S.C. § 78dd-1(f)(3)(A), 15 U.S.C. § 78dd-2(h)(4)(A).

governmental action" does not include a decision by a foreign official to award new business or to continue doing business with a particular company.

The FCPA permits a number of affirmative defenses. For instance, a person charged with violation of the FCPA may argue that the disputed payment was lawful pursuant to the written laws of the foreign country, or that money was expended as part of demonstrating a product or performing a contractual obligation.[71] Because these are affirmative defenses, the prosecution does not have the burden of proving that the payment did not satisfy those descriptions; rather, the burden is on the defendant to prove that those requirements are satisfied.

Violations of the FCPA may lead to significant criminal and civil penalties.[72] The following criminal penalties may be imposed:

- Corporations and other business entities may be subject to fines up to $2,000,000;
- Officers, directors, stockholders, employees and agents may be fined up to $100,000 (cannot be paid by employer) and face imprisonment for up to five years; and
- Under the Alternative Fines Act,[73] the above fines may be significantly higher, as the actual fine may be as much as twice the benefit the defendant sought to obtain in making the violative payment.

Civil penalties may also be severe, including the following:

- The SEC or Attorney General may bring a civil action with a fine of up to $10,000 against the firm and any officer, director, employee or agent of the firm who violates the FCPA.

[71] 15 U.S.C. § 78dd-1(c)(1), 15 U.S.C. § 78dd-2(c)(1), 15 U.S.C. § 78dd-3(c)(1), 15 U.S.C. § 78dd-1(c)(2), 15 U.S.C. § 78dd-2(c)(2), 15 U.S.C. § 78dd-3(c)(2).
[72] 15 U.S.C. §§ 78dd-2(g)(1), 78dd-3(e)(1), 78ff(c)(1), 78ff(c)(2), 78dd-2(g)(2), 78dd-3(e)(2), 78dd-2(d).
[73] 18 U.S.C. § 3571.

- In a SEC enforcement action, the court may impose an additional fine that does not exceed the greater of: 1) the gross amount of monetary gain to the defendant as a result of the corrupt payment, or 2) a specific dollar limitation. The limitation is based on the egregiousness of the violation and ranges from $5,000 to $500,000.
- The SEC or Attorney General may also bring a civil action to enjoin any act or practice of a company if it appears the company or an officer, director, employee or agent is in violation of the FCPA.

In addition to those penalties, a person or company in violation of the FCPA may be barred from doing business with the federal government.

United Kingdom

In the United Kingdom, the Bribery Act of 2010 ("Bribery Act"),[74] which went into effect on July 1, 2011, imposes criminal liability for various bribery offenses. Three significant and unique features of the Bribery Act are: 1) it applies to all bribery, whether in the public or private sector; 2) it applies to both the giving and receiving of bribes; and 3) it creates a new corporate offense if a corporation fails to prevent bribery. Additionally, there is no express exception for facilitation payments as there is under the FCPA.

The Serious Fraud Office ("SFO") is the lead governmental agency responsible for enforcing the Bribery Act. The PMCPA, ABPI, and SFO have entered into a Memorandum of Understanding[75] concerning the interaction between the ABPI Code and the Bribery Act and

[74] *Bribery Act 2010*, LEGISLATION.GOV.UK, http://www.legislation.gov.uk/ukpga/2010/23/contents (last visited August 10, 2012).
[75] Memorandum of Understanding Between the ABPI, the PMCPA, and the SFO, (April 1, 2011), *available at* www.pmcpa.org.uk/.../Memorandum%20of%20Understanding%20between%20the%20ABPI.

how the organizations will address potential overlap between the industry's self-regulation and SFO's enforcement of the new criminal law.

In the Memorandum of Understanding, SFO recognized that implementation of the Bribery Act may overlap with the Code. Further, although recognizing that self-regulation by industry is valuable, SFO nonetheless stressed that it will take a "vigorous approach" to companies that act in a corrupt manner and gain an unfair competitive advantage, and that it retained discretion to select cases to pursue.[76] To achieve balance, the Memorandum of Understanding outlined "SFO's approach" to subjects covered by the ABPI Code in the following way:

- Companies need to have in place robustly defined and implemented anti-bribery procedures with clear ownership from the top of the organisation;
- The SFO and others agree that sensible proportionate promotional expenditure is entirely legitimate and not outlawed by the Bribery Act 2010;
- The SFO will not routinely intervene in matters covered by the Code but reserves the right to take action if the issue is deemed serious enough to merit SFO investigation. It will submit complaints to the PMCPA when appropriate;
- The SFO will not seek to prosecute unless it considers this is in the public interest and in reaching such a decision the SFO will take into account relevant action taken by the PMCPA and the MHRA;
- The SFO is aware of the requirements of other industry codes including the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Pharmaceutical Marketing Practices.[77]

The Bribery Act has four bribery offenses: 1) offering, promising or giving a bribe; 2) requesting, agreeing to receive or accepting a bribe; 3) bribery of a foreign public official; and 4) failing to prevent bribery on behalf of a commercial organization. Those offenses will not be scrutinized in great detail, but it is important to emphasize that the first offense applies to both

[76] *Id.*
[77] *Id.*

the public and private sectors. A person may be guilty of this offense for offering a bribe to a private individual, as the offense is not limited to public officials.

With respect to bribery of a foreign public official, such a violation occurs when a person or firm offers, promises or gives a financial or other advantage to a foreign public official with the intent to influence that official's performance of his or her official duties. Further, the person making the offer or promise or giving the advantage must also intend to obtain or retain business or an advantage in business. An offense is not committed, however, if the foreign official is permitted or required by governing local law to be influenced by the offered advantage.

Perhaps most significant to life sciences companies is the offense applicable to commercial organizations for failing to prevent bribery. Under the Bribery Act, a commercial organization will be liable if an individual associated with the organization bribes another person with the intent to obtain or retain business or advantage in business for the commercial organization. Organizations subject to this offense include those incorporated or formed in the United Kingdom, as well as those that carry on a business or part of a business in the United Kingdom, regardless of where they were formed. Pursuant to this violation, an "associated person" is an individual who performs services for or on behalf of the organization, and may be a natural person or corporate entity.

Although broadly defining the offense, the Bribery Act nonetheless affords companies a full defense if they are able to demonstrate that, despite the particular case of bribery at issue, they had adequate procedures in place to prevent "associated persons" from committing bribery.

The United Kingdom's Ministry of Justice has developed six principles that companies should reference in formulating anti-bribery procedures.[78]

[78] *Bribery Act 2010 Guidance*, March 2011, JUSTICE.GOV.UK, http://www.justice.gov.uk/legislation/bribery, (last visited August 10, 2012).

1) Proportionate Procedures: a company's anti-bribery procedures should be proportionate to the bribery risks it faces and the nature, scale and complexity of its commercial activities. Procedures must also be clear, practical, accessible and effectively implemented and enforced.

2) Top-Level Commitment: a company's top-level management must be committed to stopping bribery by associated persons and must foster an organizational culture in which bribery is unacceptable.

3) Risk Assessment: a company must assess the nature and extent of its exposure to potential bribery risks, and perform and document such assessments periodically.

4) Due Diligence: a company must apply due diligence procedures with respect to individuals who perform services on its behalf.

5) Communication (including training): a company must try to ensure that its anti-bribery policies are understood throughout the company using internal and external communications, including training.

6) Monitoring and Review: a company must monitor and review procedures designed to prevent bribery and make improvements as necessary.

The United Kingdom's Bribery Act raises two potentially disconcerting questions for the life sciences industry. First, will more governments follow the United Kingdom's lead and broaden anti-corruption laws to apply to the private sector? Second, will more countries establish corporate "failure to prevent bribery offenses?" These new concerns only add to existing challenges posed to life sciences companies by anti-corruption laws.

As noted above, investigations into and prosecutions of anti-corruption violations have significantly increased in recent years.[79] That trend is readily evident in the U.S., with the DOJ and the SEC investigating and prosecuting numerous companies and individuals, including those in the life sciences sector. A recent example of such activity, which included the use of a deferred prosecution agreement, is the settlement of an alleged FCPA violation by Pfizer Inc.

On August 7, 2012, the SEC charged Pfizer with violating the FCPA, alleging its subsidiaries had bribed doctors and other healthcare professionals employed by foreign governments in Bulgaria, China, Croatia, the Czech Republic, Italy, Kazakhstan, Russia and Serbia to obtain business.[80] Separately, the SEC charged a Pfizer subsidiary, Wyeth LLC, with FCPA violations. Pfizer and Wyeth agreed to pay more than $45 million to settle those charges. In a related matter that same day, the DOJ announced that Pfizer H.C.P. Corporation, an indirect wholly owned subsidiary of Pfizer Inc., had agreed to pay $15 million in penalties to resolve a FCPA investigation the DOJ was pursuing relating to improper payments allegedly made to healthcare professionals in Bulgaria, Croatia, Kazahkstan and Russia.[81] As part of the resolution, Pfizer H.C.P. Corporation and the DOJ entered into a deferred prosecution agreement.

Prosecutions are also on the rise in other large countries. The OECD reports that Germany has taken a "leadership position" in investigating and prosecuting foreign bribery cases. Germany lags only the U.S. in the number of foreign bribery cases tried.[82] Russia has

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[79] *OECD Report*, *supra* note 66, at 6-18.

[80] Press Release, U.S. Securities and Exchange Commission, SEC Charges Pfizer with FCPA Violations, (August 7, 2012).

[81] Press Release, Department Of Justice, Pfizer H.C.P. Corp. Agrees to Pay $15 Million Penalty to Resolve Foreign Bribery Investigation, (August 7, 2012).

[82] T. Markus Funk and Jess A. Dance, *Germany's Increasingly Robust Anticorruption Efforts*, AMERICAN BAR ASSOCIATION (August 10, 2012, 5:12 PM), http://www.americanbar.org/publications/litigation_journal/2011_12/spring/global_litigator_potential_collateral_estoppel_effect.html.

also increased its efforts to stamp out corruption. The Criminal Code of the Russian Federation of 1996,[83] as amended, includes many criminal offenses for bribery in both the public and private sectors (the Code does not criminalize corruption by legal entities, only individuals). In 2011, Russia increased criminal fines for bribery and violations of its Code of Administrative Offenses.[84] Moreover, within the last eighteen months, Russia has enacted legislation to regulate interactions between healthcare professionals and life sciences companies[85] (though it has no reporting or disclosure requirements, as do France and Slovakia), and joined the OECD's Convention.[86]

These developments pose significant concerns for all businesses, but especially for the life sciences industry. The fact that, in many countries, most healthcare professionals are government employees and therefore "foreign officials" creates unique risks. The trend towards transparency in relationships between companies and healthcare professionals heightens the risk that disclosed data will trigger an anti-corruption investigation or prosecution.

Conclusion

The global march toward transparency is irreversible, both generally, with respect to passage and enforcement of anti-corruption laws, and specifically, in the relationships of life sciences companies and healthcare professionals. The key question for the life sciences industry is whether or not it can perform a meaningful role in the development of pragmatic, advantageous regulation.

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[83] Criminal Code of Russian Federation, 64-FZ (adopted on June 13, 1996), *available at* http://www.russian-criminal-code.com/.

[84] *OECD Report*, *supra* note 66, at 24-5.

[85] *Id.*

[86] Other countries are also increasing their anti-corruption efforts. For example, in 2011 the Czech Republic passed a law that imposes corporate liability for foreign bribery. *OECD Report*, *supra* note 66, at 21; *see generally id.* at 25-49.

The life sciences industry has significant incentive to construct meaningful self-regulation. Industry promulgated codes could obviate the need for draconian and expensive governmentally enacted "sunshine" legislation. If transparency regulation is left to government, it is likely that new laws will be at least as strict as the laws of the United States, France and Slovakia. These laws have effectively set a minimum standard for other countries, as no nation wants to be perceived as soft on industry. Moreover, a plethora of dissimilar national transparency laws will create a byzantine labyrinth of requirements for globally operating entities. Thus, industry must proactively tout the benefits of meaningful self-regulation:

- potential for uniformity across borders;
- efficient development and revision of regulations;
- effective achievement of buy-in from all stakeholders; and
- sparing public funds otherwise required to monitor and enforce compliance with onerous obligations.

Although government interest in further regulating the relationships between life sciences companies and healthcare professionals will not be easily diverted, due to perceived expense reductions or the political pressure created by scandal, meaningful trans-national industry self-regulation is the most promising avenue for achieving a marketplace that balances the interests of patients, healthcare providers, industry and the general public.