Do Start Believin':
The Life Sciences Industry's Journey to Global Transparency

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August 2014

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Introduction

Over the past several years, we have monitored, analyzed, presented on, and written about a major challenge facing the life sciences industry: the ever-expanding movement toward greater transparency with respect to financial interactions between industry and healthcare professionals ("HCPs") and other actors in the healthcare field. Specifically, life sciences companies have been forced to confront more and more governmental laws and industry self-regulatory codes that require them to disclose their financial relationships with HCPs and others. In the course of studying this movement, speaking with life sciences companies, and listening to presentations from representatives of groups like the European Federation of Pharmaceutical Industries and Associations ("EFPIA") and Eucomed, which represent the European pharmaceutical industry and medical device industry, respectively, we have been struck by the frequent use of one word to describe this movement – and that word is journey. We have used it ourselves, and we have heard others use it to describe how the life sciences industry is on a journey to more transparency.

According to dictionary.com, journey is defined as "a traveling from one place to another, usually taking a rather long time; trip." It is certainly true that, as a general proposition, the life sciences industry is traveling from one place to another with respect to transparency. If we look into the past, we can see that industry was at a place where there was limited, or perhaps

[1] We are aware that the correct spelling is "Believing," not "Believin'". However, because the theme of this paper is the journey that the life sciences industry is on towards global transparency, we chose to honor the spirit of the band Journey's signature hit, "Don't Stop Believin'," both with the paper's title and the intentional misspelling contained therein. As Neil Schon, guitarist for Journey, has noted, his band's biggest hit has become "this national anthem, world anthem. It's really wild. If somebody plays it, no matter where, everybody sings it." Neil Schon, Bio, JOURNEYMUSIC.COM, http://www.journeymusic.com/pages/bio (last visited Aug. 5, 2014). Thus, we thought there was a relevant parallel between the world-wide popularity of "Don't Stop Believin'" and the world-wide movement – albeit not necessarily a universally popular one – of the journey toward more transparency for life sciences companies.

even no, transparency concerning its financial interactions with HCPs. Now, as a result of governments enacting laws that impose reporting obligations or industry groups developing self-regulatory codes with similar requirements, the life sciences industry is well on its way toward more transparency. It is too early to predict where the transparency journey will end; in that regard, it seems somewhat impossible to define what "complete" or "full" transparency would even mean in this context. Nonetheless, the trend and the movement is obvious, and it is accelerating: there will be more transparency and disclosure reporting, in more places around the world, more often.

Although the life sciences industry is on the road toward greater transparency, the trip is not proceeding at the same pace in all regions. It is also occurring at a different rate between the pharmaceutical industry and the medical device industry. As to regional differences, in the United States and France, both pharmaceutical and medical device companies are already reporting pursuant to federal laws.

In contrast to this government-driven, legislative approach, the pharmaceutical industry in Europe has taken an active role in developing a self-regulatory system of transparency. In June 2013, EFPIA, which is comprised of thirty-three national European member associations and forty pharmaceutical companies, adopted the "EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" ("Disclosure Code"). EFPIA's proactive decision to implement an industry-driven solution was in response to the legislation that had been enacted in some European nations including, most prominently, France. As explained more fully below, the Disclosure Code, which was slightly amended and approved again by EFPIA in June 2014, requires EFPIA members to publicly disclose, in 2016, many of their 2015 financial interactions with HCPs and

healthcare organisations ("HCOs"), primarily at the individual – as opposed to aggregate – level. By adopting this Disclosure Code, EFPIA intended to provide a consistent, uniform approach to transparency reporting for the pharmaceutical industry across Europe and, in doing so, demonstrate to European governments that there is no need for them to enact their own transparency laws. The journey to transparency is at a similar stage for the pharmaceutical industry in Australia. There, the pharmaceutical industry group, Medicines Australia, is working on developing a self-regulatory transparency reporting system that would require individual-level reporting in 2016.

In other places around the world, like Latin America, Africa, and the Middle East, the journey toward transparency is not as advanced, as those regions have not exhibited the same approach as Europe, either in the form of laws or industry self-regulatory codes. Thus, the journey's end in those regions is further into the future. Similarly, with the exception of Japan, where both pharmaceutical and medical device industry groups have self-imposed reporting requirements for their members, Asia does not have comparable laws or industry codes.

The medical device industry lags the pharmaceutical industry in adopting disclosure codes. In that regard, Eucomed, though generally supportive of concepts like transparency, integrity, and ethical conduct, has not adopted EFPIA-like reporting requirements. That is not to say that Eucomed eventually will not do so; but it is not presently at that point on its transparency journey.

This paper will review the history of the transparency movement and touch upon some of the key signposts and markers on the journey toward global transparency.

The Legislative Journey in the United States and Parts of Europe

This paper will start with the legislative journey in the United States because that is where the transparency movement began and, as a result, the rest of the world has been influenced by the United States' approach.[2] In the United States, much of the recent discussion about transparency reporting has centered on federal law. On March 23, 2010, the United States enacted the Patient Protection and Affordable Care Act ("PPACA"), which is a broad, wide-ranging healthcare reform law. Of particular importance to the transparency journey is one part of PPACA: Transparency Reports and Reporting of Physician Ownership or Investment Interests (section 6002 of PPACA) ("US Sunshine Act"). In short, the US Sunshine Act requires pharmaceutical companies and medical device companies to report to the Centers for Medicare & Medicaid Services ("CMS"), which is part of the federal government's Department of Health & Human Services, any direct or indirect payment or other transfer of value to a covered recipient or any payment provided to a third party on behalf of a covered recipient during a calendar year. First reports under the US Sunshine Act were filed in 2014, covering data from August 1, 2013 to December 31, 2013. However, before examining the federal reporting requirements that were created in the US Sunshine Act, it is important to go further back in time, as the journey toward transparency actually began at the U.S. State level.

State Reporting Laws

For a number of years, several states have required life sciences companies to report on various aspects of their financial relationships with HCPs. It is important to emphasize that the US Sunshine Act does not prohibit states from requiring that manufacturers disclose information that is not covered by the federal law. However, if a State's law requires a manufacturer to

[2] Countries outside of the United States have not necessarily followed or adhered to the approach taken by the United States; rather, some countries, including, for example, the Netherlands, have explicitly noted that they had looked to what the United States had done in developing their own transparency reporting systems.

disclose or report the same information that must now be reported under the US Sunshine Act, that portion of the State's law is preempted. Thus, life sciences companies must comply with both the federal reporting requirements and any applicable State reporting requirements that survive preemption.

While space does not allow a detailed analysis of each State's provisions, we will highlight the more important aspects of the disclosure laws in Minnesota, Vermont, the District of Columbia, West Virginia, and Massachusetts.

The transparency journey in the United States began in Minnesota in 1993, when it became the first State to require pharmaceutical companies to report interactions with healthcare practitioners.[3] For several years, Minnesota law required wholesale drug distributors to annually report 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 with a genuine research project. The passage of the US Sunshine Act altered how Minnesota implemented its transparency requirements, as the Minnesota government instructed companies that they did not have to file reports covering calendar years 2012 and 2013.[4]

In 2014, the Minnesota Legislature and Board of Pharmacy clarified the State's reporting requirements. As a result, effective July 1, 2014, drug manufacturers must annually report the same information identified above, but only with respect to payments to physician assistants, dental therapists, veterinarians, and nurse practitioners because those recipients are not covered

[3] MINN. STAT. § 151.47(1)(f) (2013). (In 2013 the Minnesota Board of Pharmacy sought to repeal the section that required pharmaceutical manufacturers to report certain payment made to practitioners; however, 151.47, subd. 1(f) was not repealed but only modified.)

[4] July 9, 2014, Memorandum from the State of Minn. Bd. of Pharm. on Payments to Practitioner Reporting, http://www.phcybrd.state.mn.us/Payments/MemopaymentJuly%202014.pdf.

by the US Sunshine Act. In contrast, payments made to, for example, physicians, are no longer reportable because that information must be submitted to the federal government under the US Sunshine Act. On that point, the State of Minnesota's Board of Pharmacy explained in a July 9, 2014, memorandum that it "[a]cknowledged the federal Physician Payments Sunshine Act pre-emption of state law, meaning that payment made to physicians, as defined by the federal law, will not have to be reported. The intent was to have the Board continue to collect data on payment made to other practitioners[.]"[5] In that memorandum, the Board of Pharmacy also noted that it would provide instructions later in 2014 about how companies are to report the required information.[6]

In 2002, Vermont became the second State to embrace transparency, as the Vermont Prescribed Products Disclosure Law requires pharmaceutical and medical device manufacturers to annually report to Vermont's Office of the Attorney General 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. In essence, Vermont's law is a gift ban, with certain permissible expenditures and gifts that must be disclosed.

In Vermont, pharmaceutical and medical device manufacturers are allowed to make the following expenditures, but they must be reported: 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

[5] *Id.*
[6] *Id.*

market value. Vermont law also permits pharmaceutical and medical device manufacturers to give the following types of gifts, but they too must be reported: 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, 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.

The District of Columbia entered the transparency arena in 2004. There, pharmaceutical manufacturers and labelers of prescription drugs that employ, direct, or utilize marketing representatives in the District must report annually "the nature, value, purpose, and recipient" of marketing and advertising expenditures.[7] 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, and 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 contractors who engage in advertising or promotional activities performed in the District or directed to District residents, including all forms of payment to employees.

2004 also saw West Virginia's entry into the transparency movement with respect to pharmaceutical companies. In West Virginia, pharmaceutical manufacturers and labelers of

[7] D.C. CODE §§ 48-833.01-.03 (2010).

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.[8] Companies are not required, however, 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.

In 2008, the transparency journey moved northeast to Massachusetts. Massachusetts requires pharmaceutical and medical device manufacturers to disclose annually 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.[9] 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 on 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.

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

[9] MASS. GEN. LAWS ch. 111N, § 6.

As noted previously, despite the passage of the US Sunshine Act, individual states remain free to pass their own reporting requirements and transparency measures so long as they do not duplicate the substantive provisions of the federal law. To date, only Connecticut has adopted such a law. In Connecticut, pharmaceutical and medical device companies are required to report payments or transfers of value made to advanced practice registered nurses ("APRN") – who are registered in Connecticut – on a quarterly basis, with the first report being due no later than July 1, 2015.[10] Companies must submit their reports to the Commissioner of Consumer Protection in the same form and manner as the US Sunshine Act.[11] There are two other significant points to note about Connecticut's reporting system: 1) there is no minimum threshold for reporting; and 2) companies are not required to report transfers of value made indirectly to an APRN through a third party in connection with an activity or service in which the manufacturer is unaware of the APRN's identity.

Although other states have not joined Connecticut in passing disclosure laws following the enactment of the US Sunshine Act, the life sciences industry should monitor legislative and regulatory activities in all fifty states to determine whether any additional jurisdictions will seek to implement their own unique reporting requirements.

Reporting Under the US Sunshine Act

Historical Background & Process for First Reports in 2014

For the past several years, the primary focus of the life sciences industry has been federal level reporting. Before delving into the details of federal reporting, it is helpful to take a step back to place this movement into context by asking a threshold question: Why did the federal

[10] 2014 Conn. Pub. Acts 14-217, pg. 93. (Feb. Sess.), *available at* http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=5597&which_year=2014 (last visited Aug. 13, 2014).

[11] *Id.*

government decide to require life sciences companies to report on their financial interactions with the medical profession? While there are many different ways to answer that question, one of the more concise responses was provided by Senator Charles Grassley, one of the co-authors of the US Sunshine Act, who explained:

> Disclosure brings about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine. The lack of transparency regarding payments made by the pharmaceutical and medical device community to physicians has created a culture that this law should begin to change substantially. The reform represented by the [US Sunshine Act] is in patients' best interests.[12]

Similarly, on its website CMS has acknowledged that collaboration between the life sciences industry and HCPs is beneficial, but that it also can raise concerns about conflicts of interest. Despite being careful to point out that a financial relationship, standing alone, does not signify an inappropriate relationship, CMS explains that disclosure of the details of such relationships is nonetheless necessary to "[e]ncourage transparency of reporting financial ties; [r]eveal the nature and extent of relationships; [p]revent inappropriate influence on research, education, and clinical decision-making; [a]void conflicts of interest that can compromise clinical integrity and patient care; and [m]inimize risk of increased health care costs."[13] CMS has also noted that

> Open Payments[14] is a national disclosure program that promotes transparency by publishing the financial relationships between the medical industry and healthcare providers (physicians and hospitals) on a publicly accessible website developed by CMS. This public website … will be organized and designed to increase

[12] Feb. 1, 2013, Memorandum from Senator Chuck Grassley Regarding the Release of the Sunshine Act, http://www.grassley.senate.gov/news/news-releases/physician-payments-sunshine-act-regulations-released.

[13] CMS.GOV, *About Open Payments*, OPEN PAYMENTS (Last Updated Oct. 21, 2013, 10:41 AM), http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/About-Open-Payments.html.

[14] Open Payments is the name of the national disclosure system that has been established by CMS pursuant to the US Sunshine Act.

> access to and knowledge about these relationships and to provide information to enable consumers to make informed decisions.[15]

The US Sunshine Act contemplated that companies would begin to capture data on January 1, 2012, for reporting in March 2013, following the issuance by CMS of final regulations by October 1, 2011. However, CMS repeatedly pushed that deadline back. On December 19, 2011, CMS published in the Federal Register long-awaited draft regulations, which were not finalized until February 1, 2013, taking effect in April 2013.[16]

CMS ultimately determined that data collection for the first reporting period would run from August 1, 2013, until December 31, 2013. In early February 2014, CMS announced that the registration and data submission process would run from February 18, 2014, to March 31, 2014. During that time, companies were required to register in CMS's Enterprise Portal and submit corporate profile information, along with aggregate data submission reports. Those reports, which provided information on payments and other transfers of value to covered recipients at the aggregate level, were due on March 31, 2014.[17] This February 18, 2014 through March 31, 2014 period is also referred to as Phase 1 of CMS's two-phased approach to initial reports under the US Sunshine Act.

Phase 2 of CMS's approach ran from June 1, 2014 through June 30, 2014, and there were two steps within Phase 2. Step 1 of Phase 2 required companies to complete their corporate and authorized officer registration; delegate specific user roles; perform test submissions; and fix errors. During Step 2 of Phase 2, which ended on June 30, 2014, companies were required to

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[15] CMS.GOV, *About Open Payments*, OPEN PAYMENTS (Last Updated Oct. 21, 2013, 10:41 AM), http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/About-Open-Payments.html.

[16] *See* Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Ownership or Investment Interests, 42 C.F.R. § 403.900 (2013) ("Transparency Reports and Reporting of Ownership or Investment Interests").

[17] Because the aggregate reports were a one-time phenomenon, we will not delve into all of the details of those reports.

submit detailed, individual-level 2013 payment data and attest to the accuracy of the payment data submission.

The review and dispute process feature of Open Payments began on July 14, 2014, and ends on August 27, 2014. The review, dispute, and correction process enables covered recipients to review and initiate disputes regarding the data reported about them by companies, **before** CMS makes the information public by September 30, 2014.

In the future, companies will be required to submit their annual reports – covering data for the full preceding calendar year – by March 31. In turn, CMS will make that information available to the public by the end of June each year.

The Details of Federal Level Reporting

Although earlier in the paper we referred to pharmaceutical and medical device companies as having an obligation to report under the US Sunshine Act, the Act and regulations provide a detailed definition of what types of entities have such an obligation. Specifically, "applicable manufacturers" and "group purchasing organizations" ("GPOs") must report. An "applicable manufacturer" is an entity that is operating in the United States[18] and falls within one of the following categories: 1) it is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological, or medical supply is solely for use by or within the entity itself or the entity's own patients; 2) it is an entity under common ownership[19] with an entity

[18] Operating in the United States means that the entity has a physical location within the United States or otherwise conducts activities in the United States, either directly or through a legally-authorized agent. Patient Protection and Affordable Care Act ("PPACA"), 42 U.S.C. §1320a-7h(e)(2) (2010); *see also* Transparency Reports and Reporting of Ownership or Investment Interests, 42 C.F.R. § 403.902 (2013).

[19] "Common ownership" refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own(s) 5% or more total ownership of the two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. Transparency Reports and Reporting of Ownership or Investment Interests, 42 C.F.R. § 403.902 (2013).

from category 1 and it provides assistance or support[20] to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. A GPO is an entity that operates in the United States and purchases, arranges for, or negotiates for the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities, but not solely for use by the entity itself. This includes an entity that purchases a covered product for resale or distribution.

Applicable manufacturers and GPOs must report on payments or transfers of value[21] that they make to "covered recipients." Under the US Sunshine Act and the implementing regulations, the definition of "covered recipients" includes physicians and teaching hospitals. Physicians are defined as doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, but the definition does not include residents. Teaching hospitals are hospitals that receive graduate medical education funding and certain other types of funding. On its website, CMS provides a full list of affected teaching hospitals that are subject to reporting by applicable manufacturers and GPOs.[22]

There are three distinct reports that companies might have to file depending on their financial interactions with covered recipients: 1) a General Payments Report, which includes payments and transfers of value given to a covered recipient; 2) a Research Payments Report, which includes all payments and transfers of value made in connection with an activity that

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[20] "Assistance and support means to provide a service or services needed to produce, prepare, propagate, compound, convert, market, promote, sell, or distribute a covered drug, device, biological, or medical supply." *Id*.

[21] A payment or transfer of value include direct or indirect payments or other transfers of value to a covered recipient or any payment provided to a third party on behalf of a covered recipient (e.g., honorarium, food, travel cost, textbooks, scientific reprints). PPACA, 42 U.S.C. §1320a-7h(e)(10)(A) (2010). A company does not have to report on an individual payment to a covered recipient that is less than $10 unless transfers to the recipient for the year exceed $100 in the aggregate. PPACA, 42 U.S.C. §1320a-7h(e)(10)(B)(i) (2010).

[22] CMS.GOV, *Teaching Hospitals*, OPEN PAYMENTS (Last Updated Aug. 8, 2014, 4:54 AM), http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Teaching-Hospitals.html.

meets the definition of research and that is subject to a written agreement or research protocol; and 3) Physicians Ownership and Investment Interest Report, which covers any ownership or investment interests held by a physician or immediate family member in an applicable manufacturer or GPO. Each of the three reports has its own template that has been promulgated by CMS, and each must be submitted to CMS via the CMS's web-based reporting system.

For the General Payments report, companies must report, among other things, the following information:

- Name of the recipient;
- Primary business address;
- Specialty for physicians;
- National Provider Identifier for physicians;
- State license number and State of licensure of the recipient (for physicians);
- Amount of the transfer of value;
- Date of transfer of value;
- Form of payment (cash or cash equivalent; in-kind items or services; stock, stock option or any other ownership interest; dividend, profit or other return on investment);
- Nature of the payment, which is the reason for the payment;[23] and
- Product involved.

[23] A company must select one of the following options as to the nature of the payment: consulting fee; compensation for services other than consulting, including serving as faculty or a speaker at an event other than continuing education; honoraria; gift; entertainment; food and beverage; travel and lodging (including the City, State, Country); education; charitable contribution; royalty or license; current or prospective ownerships or investment interest; compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program; compensation for serving as faculty or as a speaker for an accredited or certified continuing education program; grant; or space rental or facility fees (teaching hospitals only).

In the Research Payment report, companies must disclose the payments or transfers of value[24] that they made in connection with research services subject to either a written agreement or research protocol. Such services may include costs associated with patient care, time spent by healthcare professionals treating patients and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies. However, the aggregate payment amount should not include any payments for activities that are separate or capable of being segregated from the written agreement or research protocol. When reporting on research payments, companies must disclose, among other things, the following information:

- Name of the research entity, individual, or entity receiving payment;
- Total aggregate amount of research payment;
- Name of research study;
- Date of payment;
- Name(s) of any related covered drug, device, biological, or medical supply and the National Drug Code; and
- An indication if the study is eligible for delayed publication.[25]

As noted previously, CMS will make all the information that is reported pursuant to the US Sunshine Act available to the public. That publication will occur by September 30 of this year for the 2013 data, and then by June 30 every year going forward. However, for Research Payments, companies have the option to "delay publication" by CMS of the information they report.

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[24] This includes payments and transfers of value related to pre-clinical, Phases I-IV clinical studies, and investigator-initiated research. Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9482 (Preamble) (Feb. 8, 2013).

[25] Companies have the option to include contextual information and the clinicaltrial.gov identifier. Transparency Reports and Reporting of Ownership or Investment Interests, 42 C.F.R. § 403.904(f)(1)(vii) (2013).

Publication for research payments can be delayed in the following circumstances: 1) payment is related to the research/development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply; or 2) payment is related to an investigation regarding a new product. When a company opts to delay publication of the information in its Research Payments report, CMS will not publicly disclose the information until the earlier of either: 1) the date of approval, licensure, or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration ("FDA"); or 2) four calendar years after the date the payment or other transfer of value was made.

The Physicians Ownership and Investment Interest Report requires applicable manufacturers and GPOs to report to CMS all ownership and investment interests[26] held in the manufacturer or GPO by a physician or immediate family member[27] of a physician. For these reports, companies must disclose the following information:

- Name of physician;
- Specialty, NPI, and state license number of physician;
- Physician primary business address;
- Indication of whether ownership or investment interest is held by the physician or a family member;
- Dollar amount invested by the physician or family member;

[26] Ownership or investment interests include stock; stock options; partnership shares; LLC memberships; loans; bonds; or other financial instruments secured with an entity's property or revenue. The interest to be reported can be direct or indirect, but ownership or investment interests in a publicly traded security or mutual fund are excluded from reporting. Transparency Reports and Reporting of Ownership or Investment Interests, 42 C.F.R. § 403.902 (2013).

[27] "Immediate family member" includes the following: spouse; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother-, or sister—in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. *Id*.

- Value and terms of each ownership/investment interest; and
- Direct and indirect payment or other transfers of value provided to a physician holding ownership or investment interest, or on behalf of a physician holding such an ownership or investment interest.

Despite the broadness of the reporting requirements under the US Sunshine Act, there are several exceptions. As noted previously, payments that are less than $10 do not have to be reported unless the aggregate amount paid or transferred to the physician exceeds $100, in which case all payments must be reported. Other exclusions from reporting include:

- Product samples intended for patient use;
- Educational materials distributed for the benefit of patients or intended for patient use;
- Loans of covered devices, not to exceed 90 days, to permit evaluation by a covered recipient;
- Services/items covered under a warranty;
- Transfer of anything of value to a covered recipient when that recipient is a patient, research subject, or is participating in data collection and not acting in his or her professional capacity;
- Discounts, including rebates;
- In-kind items used to provide charity care;
- Dividends/profit, ownership, or investment interest in a publicly traded security/mutual fund;

- Payments for the provision of health care to the applicable manufacturer's employees under a plan provided by any manufacturer that offers a self-insured plan;
- Payments provided to a covered recipient if the payment is solely for non-medical professional services;
- Payments or other transfers of value provided as compensation for speaking at a continuing education program (so long as several conditions are met);[28]
- Payments for a civil or criminal action or an administration proceeding;
- Any indirect payment or transfer of value where the manufacturer is unaware of the identity of the covered recipient; and
- A payment or transfer made solely in the context of a personal, non-business related relationship.

There are four other points key to the US Sunshine Act. First, an applicable manufacturer or GPO must attest that the information being submitted in its reports is accurate, timely, complete, and correct. This is the final step in the submission process, and it is mandatory. If a reporting company fails to attest, CMS will not consider the data that was submitted to have been officially reported. Companies must specifically designate an "attester," who can be the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other officer of the applicable manufacturer or GPO, to verify the information submitted.

Second, companies have the option to submit an assumptions statement during the attestation process. Such a statement is voluntary and will not be made available to the public.

[28] CMS has published proposed amendments to its regulations that would remove this exception and require the reporting of such payments and transfers of value relating to compensation for speaking at continuing education programs. Proposed Rule, Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, etc., 79 Fed. Reg. 40,383-385 (July 11, 2014).

The assumptions statement allows companies to explain the assumptions that they made, and methodologies they employed, in reporting payments and other transfers of value. The assumptions statement has to be submitted in a free-form text field and cannot exceed 4,000 characters.

Third, the US Sunshine Act and implementing regulations provide for a review and dispute period before CMS makes reported data available to the public. During the forty-five day review period, covered recipients may log into a secure website to review data about them that was submitted by applicable manufacturers or GPOs. They may also initiate a dispute with the applicable manufacturer or GPO via the secured website. If the dispute is resolved during the review period, or if it is resolved during the fifteen-day correction period that follows the review period, CMS will publish the corrected data. However, if a dispute about what an applicable manufacturer or GPO has reported to CMS about a particular covered recipient cannot be resolved within the fifteen-day correction period, CMS will publicly post the originally submitted data, but mark it as disputed.

For 2014 reporting – which involves data covering August 1, 2013 through December 31, 2013 payments and transfers of value – the review and dispute period runs from July 14, 2014 through August 27, 2014. The correction period begins on August 28, 2014, and ends on September 11, 2014. CMS will publicly release the information reported by applicable manufacturers and GPOs by September 30, 2014.

Fourth, 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.

As might be expected, the journey to transparency under the US Sunshine Act has not been without a few bumps and detours. For example, Senator Grassley and Senator Herbert Kohl, the other co-author of the US Sunshine Act, repeatedly expressed their disappointment with CMS's inability to meet deadlines. The pharmaceutical industry also expressed frustration with various aspects of the Open Payments program and the roll-out of the reporting requirements. For example, in June 2014 – in the midst of the initial reporting earlier this year – PhRMA wrote a letter to CMS to "express our concerns with the experiences that many of our members have had thus far with respect to registration and submission of data to [CMS] pursuant to the Open Payments Program."[29] In addition to recounting some of the difficulties that PhRMA members had with trying to register and submit data, PhRMA pointed out that its members had "spent an unreasonable amount of time and resources working through these issues[.]"[30] As a result of these difficulties, PhRMA requested an extension for all manufacturers to complete their submissions. CMS was unmoved by the request and did not extend the June 30, 2014 deadline.

Physicians are another group that has experienced problems with the Open Payments program. On July 28, 2014, a group of medical societies, along with PhRMA and other industry groups, sent a letter to CMS "to identify certain pressing issues related to implementation of the [US Sunshine Act]."[31] In the hope of working collaboratively with CMS to ensure the ultimate

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[29] June 13, 2014, Memorandum from PhRMA to CMS Regarding Phase Two Registration and Submission.

[30] *Id*.

[31] July 28, 2014, Memorandum from Physician Organizations and Pharmaceutical Industry Trade Groups to CMS. Numerous news articles have also chronicled some of the issues and complaints that physicians have about

success of the Open Payments program, the groups focused on three main areas of concern: 1) providing necessary context; 2) increasing outreach and education to physicians; and 3) simplifying physician registration.

As to the first point regarding context, the letter observes that CMS had not provided any information about "how context will be provided to the general public when Sunshine data is made available in September." Stressing the significance of explaining the meaning of the data to the public, the letter suggests that failing to provide an appropriate context for all the information about payments and interactions could lead to confusion and misinterpretation. With respect to educating physicians, the letter acknowledges that CMS had hosted multiple webinars and created a fact sheet about Open Payments. However, the letter points out that the information had not always been provided in a timely manner and that many physicians were still unaware of the various requirements of the US Sunshine Act. Lastly, as to physician registration, the letter describes the registration process as "cumbersome and overly personal," and complains that it placed a "significant burden on physicians, who already have extremely busy schedules." In sum, the organisations signing the letter concludes:

> We urge you to consider our request to provide details on the context that will be included in the data release, increase educational efforts and outreach, and simplify physician registration requirements. These actions are consistent with the intent of the Sunshine Act, and will increase awareness and understanding among the physician community.

Although the United States has made significant progress on its journey to transparency, it is far from over. As explained above, at the federal level, the review and dispute period is

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the Open Payments program. *See, e.g., Doctors Using CMS' Open Payments Site Report Long Waits, Errors*, HEALTHBEAT, (Published July 22, 2014), http://www.ihealthbeat.org/articles/2014/7/22/doctors-using-cms-trial-open-payment-site-report-long-waits-errors; Ed Silverman, *Sunshine … Or Clouds? Drug Makers Grapple With Transparency Law*, THE WALL STREET JOURNAL (Published June 5, 2014), http://blogs.wsj.com/pharmalot/2014/06/05/sunshine-or-clouds-drug-makers-grapple-with-transparency-law/; Robert Lowes, *Deadline to Check Industry Payments to Docs Fast Approaching*, MEDSCAPE, (July 25, 2014), http://www.medscape.com/viewarticle/828942.

ongoing at the time of publication of this paper, and CMS has already proposed some changes to the existing requirements. It is expected that CMS will continue to amend and revise the system in the future.

Not only will there be changes to the system, but there are a number of questions that cannot yet be answered, primarily relating to the public release of the information. Some questions include: 1) How will the public react to all of this information? 2) How will the media react to the publication of the information? 3) How will HCPs react to all of this information being made public, and will it affect their relationships with life sciences companies, as well as with their patients? 4) How will legislators respond to the public release of information? In that regard, will federal legislators seek to enact amendments or changes to the US Sunshine Act in light of what the reported data reveals? Will states seek to supplement the requirements of the US Sunshine Act and require more reporting for industry? 5) Will there be an increase in enforcement actions based on what is revealed by the data? These are just a few of the many questions and issues that the life sciences industry will have to grapple with in the United States as the journey to transparency continues.

European Transparency Laws

Our journey next takes us east, across the Atlantic Ocean, where we start by examining the most well-known transparency disclosure law in Europe. In December 2011, France enacted the 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").[32] Like the US Sunshine Act, the French Sunshine Act was part of larger healthcare reform law, and it requires broad disclosure by pharmaceutical and medical device companies of agreements with and benefits provided to

[32] LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé (the "French Sunshine Act").

HCPs and various entities. Similar to the experience in the United States, there was also some delay in the French government's issuance of an implementing decree: the French Sunshine Act required the decree to be in effect by August 1, 2012, but the final decree was not issued until May 21, 2013.[33] The Ministry of Health and Social Affairs also published a Circular, dated May 29, 2013, that provides additional guidance about certain portions of the final decree.[34] Moreover, on December 3, 2013, the Ministry issued an Order that outlines some of the requirements and specifications associated with the French reporting system.

The final decree imposes two main types of disclosure requirements on pharmaceutical and medical device companies: 1) all agreements, except for commercial sales agreements of goods and services, that they have with specified individuals and entities; and 2) certain benefits given to those individuals and entities. Specifically, companies must disclose the existence of agreements with and benefits provided to the following:

1) Healthcare professionals (e.g., physicians, nurses, but the disclosure requirements do not apply to the reporting company's employees);
2) Associations of healthcare professionals and associations of students for relevant occupations;
3) Students for relevant occupations;
4) User associations of the health system (public or private);
5) Health facilities;
6) Foundations, learned societies, and consulting companies or organisations in the health sector;
7) Publishing companies: press, radio, television, and on-line media;
8) Editors of prescription and dispensing software; and
9) Legal entities contributing to the initial training of healthcare professionals.

For agreements, companies must reveal the following:

- the identity of the parties to the agreement:

[33] Décret n° 2013-413 du 21 mai 2013 portant approbation de la charte de l'expertise sanitaire prévue à l'article L. 1452-2 du code de la santé publique (France) (the "May 21, 2013 Decree").
[34] Circular No. DGS/PF2/2013/224 of May 29, 2013 (France) (regarding the application of Article 2 of LOI n 2011-2012 of December 29, 2011 increasing the safety for health purposes of drugs and healthcare products).

- For healthcare professionals: name, professional address, qualifications, title, specialty, and registration number with the relevant professional board;
- For healthcare students: name and educational institution;
- For legal entities, like associations, health institutions, etc.: name, corporate purpose, and registered address;

- the date the agreement was signed;
- the subject matter of the agreement (which can be phrased in such a way as to protect confidential and trade secret information);
- if the agreement involves a promotional or scientific event, the program of the event.

As to benefits, companies must disclose all benefits that they provide, whether direct or indirect, in kind or in cash, to the aforementioned recipients if the benefits are equal to or exceed ten euros, inclusive of VAT. Benefits worth less than ten euros do not have to be disclosed. In disclosing benefits, companies must identify the recipient and the recipient's personal information in the same manner as for agreements (e.g., name, address, title); the amount of each benefit; the date and nature of each benefit; and the time period (either the first six months of a year or the latter six months) during which the benefit was received.

The Circular elaborated upon the definition of benefits, as it provides that benefits include in-kind benefits like donations of equipment, invitations, hospitality expenses, or payment for trips. Moreover, benefits include commissions, discounts, rebates, or repayment of expenses. As to the indirect aspect of benefits, the Circular makes clear that benefits include money or in-kind support given to family members of a covered recipient or groups of which the recipient is a member.[35]

Like the reporting process in the United States, companies must report this information about benefits and agreements to the French government via a web portal: https://www.entreprises-transparence.sante.gouv.fr/flow/login.xhtml#. Also similar to the United States, the information that companies report to the French government is made publicly

[35] *Id.*

available in France. Although that public disclosure has not yet occurred in the United States, it has in France, as the French government made the information available in June 2014 via the following website: www.transparence.sante.gouv.fr. The website is called the Public Transparency Database – Health (Base de donnes publique Transparence – Sante), and it was created with the intention of making all reportable information publicly available in one central location. The Pubic Transparency Database allows the public to search the reported information by company or by recipient. Additionally, the website contains sections that explain what the website was designed for and the surrounding regulatory framework, as well as a section with common questions and answers. The information on the database will be updated twice a year and will remain publicly available for five years.

In terms of the timing of reports in France, companies must report the pertinent information on agreements to the public authority within fifteen days of the signing of the agreement.[36] In contrast, for benefits, the relevant information must only be submitted bi-annually: by August 1 for benefits provided from January to June of a calendar year, and by February 1 for benefits provided from July through December of the preceding calendar year.

France is the most well-known European country to take a legislative approach to transparency, but it is not the only one. Portugal joined the transparency movement in February 2013 with the publication of Decree-Law n. 20/2013 of February 14,[37] which was an amendment to the Medicinal Products Act, and with its publication of Decree-Law n. 128/2013 in September

[36] However, in February 2014 a proposed decree was released that would, among other things, change that reporting deadline for agreements. Rather than having to report within fifteen days of signing the agreement, companies would have to report their agreements every six months on the same schedule that is in place for reporting of benefits.

[37] Decreto-Lei n.° 20/2013 de 14 de Fevereiro, www.dre.pt/pdf1s/2013/02/03200/0079900912.pdf (in Portuguese).

2013.[38] As with the United States and French laws, the Portuguese statutory amendments addressed a wide range of topics relating to many aspects of drug safety, but also established new reporting requirements for several actors in the healthcare field. Specifically, pharmaceutical companies must report to Infarmed (the Portuguese National Authority of Medicines and Health Products, which is a government agency accountable to the Health Ministry) on the grant of any financial support provided to patient organisations. Significantly, the amendments also require patient organisations, scientific associations, and health professionals (including doctors, dentists, pharmacists and nurses), to submit to Infarmed information about subsidies, grants, and other financial support that they receive from pharmaceutical companies if such support exceeds twenty-five euros. As with the United States and France, the information is submitted via a website established by the government: https://placotrans.infarmed.pt/Login.aspx.

Slovakia and Romania have also entered the transparency fray, with Slovakia adopting a disclosure law in September 2011 and Romania doing likewise in February 2014. 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 topics beyond transparency and reporting.[39] Under Slovakia's Sunshine Act, companies must annually submit a report to the Ministry of Health providing the value of advertising and marketing expenses and non-monetary benefits provided directly or indirectly to HCPs at the individual level. The report

[38] Decreto-Lei n.º 128/2013, de 5 de Setembro, http://www.infarmed.pt/portal/page/portal/infarmed/legislacao/legislacao_farmaceutica_compilada/titulo_iii/titulo_iii_capitulo_i/035-g2_dl_128_2013_vf.pdf (in Portuguese).

[39] Zákon, o liekoch a zdravotníckych pomôckach a o zmene a doplnení niektorých zákonov, 362/2011 Z.z. [Collection on Drugs and Medical Aids, Act no. 362/2011] (Slovakia), *available at* http://jaspi.justice.gov.sk/jaspiw1/jaspiw_mini_fr0.htm (last visited Aug. 13, 2014).

must also include the name and address of the recipients and the value of the expenditure or benefits, and the Ministry must publish a report of that information on its website.

Romania's law requires pharmaceutical and medical device companies to declare to the Ministry of Health and the National Medicines Agency all sponsorship activities and any other costs for doctors, nurses, professional organisations, and patient organisations.[40] Recipients of such benefits also have reporting obligations. The Romanian law charged the Ministry of Health and the National Agency for Medicines and Medical Devices with the responsibility to more fully develop the reporting system.

Denmark is another European nation that is far along on its journey to transparency. Although it has had governmentally-imposed disclosure requirements for several years, in 2014 it added more reporting requirements. Currently, healthcare professionals are required to obtain permission from the Danish Health and Medicines Authority before they can establish a relationship with or collaborate with a pharmaceutical company.[41] In turn, pharmaceutical companies must annually report to the Danish agency all doctors, dentists, or pharmacists with whom they have collaborated. Although pharmaceutical companies must provide certain information about the doctors, dentists, and pharmacists with whom they have worked (e.g., name, address, dates of collaboration), they are not required to list any information concerning any financial compensation or benefits that were provided to those healthcare professionals.

This system, which identifies relationships between industry and professionals but does not provide for any financial transparency, has been modified by legislation that the Danish

[40] The Medicinal Product of Law nr. 95/2006, Art. 7991 (2014), on healthcare reform (Romania).

[41] Bekendtgørelse af lov om apoteksvirksomhed [The Danish Pharmacy Act], *https://www.retsinformation.dk/Forms/r0710.aspx?id=120537* (in Danish) (last visited Aug. 13, 2014).

Parliament passed and that was enacted into law in May 2014.[42] This law, which takes effect on November 1, 2014, extends the above-described disclosure obligations of the pharmaceutical industry to the medical device industry as well. In addition, the legislation imposes a new, primary reporting obligation on HCPs – not life sciences companies – as they will have to disclose the amount of fees they receive for research (e.g., clinical research); fees for education/speaking; fees for consultancy (e.g., advisory boards); fees for market research; events; and other sponsorships and transfers of value. The Danish Health and Medicines Authority will publicly disclose the reported individual data on its website.

The European Pharmaceutical Industry Accelerates the Journey to Transparency

One of the biggest developments in the global transparency movement over the past several years in Europe is the aggressive steps that EFPIA has taken to impose reporting requirements on its members in the form of its Disclosure Code. EFPIA's hope is that an effective self-regulated system of disclosure will discourage additional European governments from enacting their own transparency laws, which would undoubtedly be unique and different from existing laws in other countries.

Before examining EFPIA's push to enact a consistent self-regulatory disclosure system across Europe, it is important to point out that there is a global pharmaceutical organisation that is involved in the transparency discussion. The International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") is a global, non-profit, non-governmental organisation that represents the research-based pharmaceutical industry, including the biological

[42] Lov om ændring af lægemiddelloven, lov om medicinsk udstyr, apotekerloven, sundhedsloven og lov om markedsføring af sundhedsydelser [Act to amend the Medicines Act, the Act on medical equipment, pharmacies Act, Health Act and the marketing of healthcare] (Denmark), https://www.retsinformation.dk/Forms/R0710.aspx?id=163281#Not1 (in Danish) (last visited Aug. 13, 2014).

and vaccine sectors. Members of IFPMA include national and regional pharmaceutical industry associations, as well as pharmaceutical companies.

Because of its commitment to high ethical standards, IFPMA adopted a code in 1981 to outline principles to govern its members.[43] That code has been updated numerous times since then, most recently in March 2012. The IFPMA Code governs the promotion of pharmaceutical products to HCPs and applies to all pharmaceutical products, including prescription, generic, and over-the-counter medicines promoted to HCPs by member companies worldwide. Significantly, the IFPMA Code does not include disclosure or reporting requirements. However, that does not mean that IFPMA does not support transparency in the relationships between industry and HCPs.

For example, in January 2014, IFPMA was one of five global healthcare organisations that established and signed a Consensus Framework for Ethical Collaboration.[44] The other organisations are the International Alliance of Patients' Organisations, International Council of Nurses, International Pharmaceutical Federation, and the World Medical Association. The Consensus Framework is premised on four principles: 1) Putting patients first; 2) Supporting ethical research and innovation; 3) Ensuring independence and ethical conduct; and 4) Promoting transparency and accountability.[45]

The Consensus Framework embodies a shared commitment among the signatories to improve global health and ensure that patients receive appropriate care. It is significant to note that the Framework is not a binding document, nor does it have an enforcement mechanism. Moreover, the Consensus Framework does not create new standards or supersede existing codes

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[43] *IFPMA Code of Practice 2012 (EN)*, IFPMA.ORG, http://www.ifpma.org/ethics/ifpma-code-of-practice/ifpma-code-of-practice.html (last visited Aug. 13, 2014).

[44] Jan. 13, 2014, News Release, Putting patients first: five global healthcare organisations sign Consensus Framework for Ethical Collaboration, IFPMA, IAPO, ICN, FIP & WMA, http://ifpma.org/fileadmin/content/News/2014/EN-News_Release_-_Consensus_Framework_-_13_Jan_2014.pdf.

[45] International Alliance of Patients' Organizations, *Consensus Framework for Ethical Collaboration*, (Published Jan. 2014), http://www.ifpma.org/fileadmin/content/Publication/2014/Consensus_Framework-vF.pdf.

or guidelines; rather, it reinforces already existing commitments and is intended to complement codes and guidelines that are already in place. In that regard, the Framework declares that

> [p]artners are encouraged to develop their own self-regulatory codes and principles for ethical collaboration and interactions and ensure their effective implementation. Systems to monitor and report breaches of the set standards should be established to support ethical practices and ensure accountability both at the institutional and individual levels. These may include, for example, public statements detailing collaborative agreements and external review mechanisms.

In contrast to IFPMA, which does not have disclosure requirements in its Code, EFPIA has created such reporting obligations for its members. EFPIA has three separate codes: 1) EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions With, Healthcare Professionals ("EFPIA HCP Code");[46] 2) EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations ("EFPIA PO Code");[47] and 3) the aforementioned Disclosure Code.[48] These 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 of EFPIA's national industry association members[49] must have in their own national codes, though national associations can include stricter or more rigorous standards in their codes.

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[46] *EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with Healthcare Professionals*, EFPIA.EU, http://transparency.efpia.eu/codes-of-conduct, (last visited Aug. 13, 2014). The EFPIA HCP Code was most recently amended in June 2014. It does not contain reporting or disclosure requirements but instead covers and regulates other aspects of the pharmaceutical industry's interactions with HCP.

[47] *EFPIA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations*, EFPIA.EU, http://transparency.efpia.eu/codes-of-conduct, (last visited Aug. 13, 2014).

[48] *EFPIA Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To Healthcare Professionals And Healthcare Organisations*, EFPIA.EU, http://transparency.efpia.eu/the-efpia-code-2, (last visited Aug. 13, 2014).

[49] EFPIA's national member associations are based in the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, and the United Kingdom.

Although the adoption of the Disclosure Code was a watershed moment in the global transparency movement, it is important to remember that the EFPIA PO Code also contains reporting requirements, which took effect in 2012. The EFPIA PO Code was initially approved in 2007 and was most recently amended in June 2011. Pursuant to the provisions of the EFPIA PO Code, companies must make publicly available a list of patient organisations to which they provide financial 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 on a PO-specific basis. For significant non-financial support that cannot be assigned a meaningful monetary value, the description must describe clearly the non-monetary benefit the patient organisation receives.

In addition, each company must make publicly available a list of patient organisations 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 organisation over the reporting period.

EFPIA, however, revolutionized its approach to transparency – and greatly accelerated the trend toward global transparency – at its 2013 Annual Meeting when it adopted the Disclosure Code. In a July 2, 2013, press release announcing the adoption of its Disclosure Code,[50] Richard Bergstrom, the Director General of EFPIA, declared that

> [t]his is an important step for our industry, as we demonstrate our commitment to transparency and secure the trust of the patients our industry serves. This code is EFPIA's delivery on the guiding principles set forth last Autumn, in which we

[50] July 2, 2013, Press Release, Pharmaceutical Companies to Disclose All Financial Relations with Healthcare Professionals, EFPIA, http://www.efpia.eu/mediaroom/109/43/Pharmaceutical-Companies-to-Disclose-All-Financial-Relations-with-Healthcare-Professionals.

> committed to working together with relevant stakeholders to establish a clear approach to transparency of financial transactions and other declarations of interest.
>
> We know that by making this a success, we can improve the relationship between industry, HCO's and HCP's in a way that ultimately benefits the people that all three of these stakeholders aim to serve – patients.

(emphasis in original)

EFPIA's intent is evident from the Preamble of the Disclosure Code, which declares that it

> believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. EFPIA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest.
>
> Consequently, professional and industry associations, including EFPIA and its member associations, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

Although we will delve into the details of the Disclosure Code *infra*, it is important to first highlight some of the proactive steps that EFPIA has taken to publicize its commitment to transparency and to educate its members, non-member pharmaceutical companies, the public, HCPs, and other key actors about its Disclosure Code. In October 2013, EFPIA announced that over thirty of its member companies had submitted commitment letters, signed by their CEOs or other high-level officers, that expressed both their support for increased transparency of industry interactions with the medical profession and their commitment to the Disclosure Code.[51] In that

[51] Oct. 31, 2013, Press Release, Signing Off: EFPIA Member Companies Submit Letters Agreeing to Advance Transparent Relationships with the Medical Profession, EFPIA, http://transparency.efpia.eu/mediaroom/21/19/Signing-Off-EFPIA-Member-Companies-Submit-Letters-Agreeing-to-Advance-Transparent-Relationships-with-the-Medical-Profession. All of the commitment letters are published on EFPIA's website. *Transparency and Industry Interactions with the Medical Profession - Commitment Letters published*, EFPIA.EU (Published Oct. 22, 2013), http://transparency.efpia.eu/mediaroom/20/19/Transparency-and-Industry-Interactions-with-the-Medical-Profession-Commitment-Letters-published.

press release, EFPIA also reiterated its commitment to transparency and why it was being proactive on this issue:

> It is essential that the industry interact regularly with healthcare professionals and organisations. As the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patients' behaviour and management of diseases. This plays a big part in informing the pharmaceutical industry's efforts to improve patient care and treatment options – and is essential to improving patient outcomes. A healthy working relationship between the pharmaceutical industry and HCPs/HCOs is in the best interests of patients. Of course, it is only fair to compensate HCPs and HCOs for the valuable insights and time they offer.
>
> But we recognise and understand the desire for greater transparency of these relationships. This commitment of EFPIA member companies is a significant indicator of our industry's response to growing expectations for transparency. That is the motivation behind the EFPIA Code. This is something that we see as a common need and goal. We've made huge progress and I am optimistic about the next steps as we move ahead – because sometimes simply reaching that first decision and coming together as a group to take action is actually the most difficult step.[52]

On May 27, 2014, EFPIA announced the launch of an on-line and social media campaign to further publicize the Disclosure Code.[53] Among other things, EFPIA's campaign includes a new website, www.pharmadisclosure.eu, and a new Twitter handle, @Pharma2015_16. The new website provides updates on developments related to the Disclosure Code, including how it is being implemented by the various EFPIA national member associations. In announcing the new campaign at a Brussels launch event, Mr. Bergstrom stated:

> We as an industry have said we will be absolutely transparent about our relationships with healthcare professionals and organisations. But we have only just begun to communicate with the three million medical professionals in Europe about how this will be put into practice. The launch of this campaign continues

[52] Oct. 31, 2013, Press Release, Signing Off: EFPIA Member Companies Submit Letters Agreeing to Advance Transparent Relationships with the Medical Profession, EFPIA, http://transparency.efpia.eu/mediaroom/21/19/Signing-Off-EFPIA-Member-Companies-Submit-Letters-Agreeing-to-Advance-Transparent-Relationships-with-the-Medical-Profession

[53] May 27, 2014, Press Release, Pharmaceutical industry launches online and social media campaign to raise awareness of new financial disclosure codes, EFPIA, http://transparency.efpia.eu/mediaroom/23/19/Pharmaceutical-industry-launches-online-and-social-media-campaign-to-raise-awareness-of-new-financial-disclosure-codes.

> the conversation using dynamic channels to optimise the reach and connectivity with those who need to know and act on the changes taking place.[54]

On June 6, 2014, EFPIA released its annual report, which is titled, "The Power of one: a commitment to collaboration."[55] In his Foreword to the report, Mr. Bergstrom references the Disclosure Code and its purpose and rationale, and also defends the relationships between industry and the medical profession:

> Healthcare professionals (HCPs) and healthcare organisations (HCOs) have valuable working relationships with the industry necessary to advance medicines research and development. Doctors and healthcare organisations offer invaluable insights into patient behaviour and disease management, which can help inform the pharmaceutical industry's efforts to improve patient care and treatment options.
>
> Of course, doctors should be compensated for their time and the expertise they share – but this could become clearer. That's the aim of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations which launched this year, requiring EFPIA member companies to disclose financial and other transfers of value (i.e. speaking fees for a congress) made to HCPs and HCOs. The aim is to illuminate the relationship between industry and HCPs/HCOs so patients can have full confidence in the system.[56]

In addition to chronicling news and developments on www.pharmadisclosure.eu, EFPIA has continued to post additional materials about the Disclosure Code on its own website. For example, EFPIA has posted two videos about transparency: 1) "Introducing the EFPIA Disclosure Code", and 2) "The EFPIA Disclosure Code in the Netherlands".[57] Moreover, EFPIA has created the following documents that provide basic information about the Disclosure Code: 1) "EFPIA Code – 10 Facts for Healthcare Practitioners"; 2) "EFPIA Code – Answering Your

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[54] Press Release, This is the beginning of a conversation, PHARMADISCLOSURE.EU, http://pharmadisclosure.eu/news/launch-of-pharmadisclosure-eu-doctors-and-industry-collaborate-for-better-trust/ (last visited Aug. 13, 2014).

[55] June 6, 2014, Press Release, EFPIA Publishes Annual Review 2013, EFPIA, http://www.efpia.eu/mediaroom/174/44/EFPIA-Publishes-Annual-Review-2013.

[56] *The Power of One: a commitment to collaboration - 2013 Annual Review and forward look*, EFPIA (Published Jun. 6, 2014), http://www.efpia-annualreview.eu/.

[57] Video Wall, EFPIA.EU, http://www.efpia.eu/media/video-wall (last visited Aug. 13, 2014).

Questions"; 3) "EFPIA Code – 10 Key Messages"; and 4) "Introducing the EFPIA Disclosure Code". EFPIA has also circulated Frequently Asked Questions documents to its members to provide additional guidance and clarification about the Disclosure Code.

As to the substantive requirements of the Disclosure Code, companies must publicly disclose, for the first time in 2016, their 2015 transfers of value[58] to HCPs[59] and HCOs.[60] The Disclosure Code provides that company disclosures must be made on an annual basis, with each reporting period covering a full calendar year. Companies are required to make their disclosure within six months following the end of the preceding reporting period, and the information that is disclosed must remain in the public domain for three years, unless a shorter time is required under local law or a recipient revokes previously-granted consent relating to a specific disclosure. Companies are required to document all transfers of value that must be disclosed and to maintain such records for at least five years, unless a shorter period is required under local law.

To assist companies with their disclosure obligations, EFPIA adopted a template – a multi-colored, multi-column, and multi-row XL spreadsheet – that provides a structure by which

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[58] The definition of transfer of value is: "Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value." *Disclosure Code*, EFPIA.EU, http://transparency.efpia.eu/the-efpia-code-2, (last visited Aug. 13, 2014).

[59] The definition of HCP is: "Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products." *Id.*

[60] The definition of HCO is: "Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services." *Id.*

all the information must be reported.[61] The Disclosure Code requires that companies make their disclosure in one of two ways: 1) on their own website; or 2) on a central platform, which could be developed by the national member association. The disclosures themselves must be made in the local language, though companies are encouraged to also make the disclosures in English if that is not the local language.

In terms of what information must be disclosed, companies must report, on the individual level, their transfers of value provided to HCPs and HCOs in the following categories: 1) donations and grants[62] (for HCOs only); 2) contributions to costs related to events[63] (including registration fees; travel and accommodation, to the extent permissible; and, for HCOs only, sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event); and 3) fees for service and consultancy.[64] Unlike the approach seen in many of the previously discussed laws, companies do not have to report the details of every single transaction that they have with a HCP or HCO; instead, they are permitted to aggregate all their transfers of value to a HCP or HCO on a category-by-category basis, so long as they are able to provide itemized disclosure upon the request of the recipient or the relevant authorities.

Despite the Disclosure Code's preference for reporting at the individual level, there are two instances in which companies will report at the aggregate level. The first instance is when

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[61] *Id*. With respect to the template, the Disclosure Code provides: "for consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in Schedule 2 for reference, reflecting the requirements of this Code. Deviations from this Schedule should only be acceptable where legal requirements justify that this Code is not transposed in full – therefore, within a given country, only one template shall apply." EFPIA's national member associations have nearly universally adopted the EFPIA template without changes; one significant exception, however, is the United Kingdom. The United Kingdom's draft template will be discussed *infra*.

[62] The definition of donations and grants is: "those donations and grants (either cash or benefits in kind) within the scope of Article 11 of the HCP Code." *Id*.

[63] The definition of events is: "All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "Event") organised or sponsored by or on behalf of a company. (Article 10 of the HCP Code)." *Id.*

[64] Fees and expenses are to be disclosed as two separate amounts.

certain information cannot be disclosed at the individual level for legal reasons. Because the Disclosure Code is a voluntary form of self-regulation and is not a law, and because of the data privacy protections afforded to European Union citizens under the governing European Union Directive and national laws, companies must, as a general proposition, obtain the consent of a recipient in order to publicly disclose the individual information called for in the Disclosure Code.[65] In instances where companies are not able to obtain such consent, they must disclose the amounts attributable to such transfers of value on an aggregate basis. Such aggregate disclosures must identify, for each reported category, the number of recipients covered by the disclosure (on both an absolute basis and as a percentage of all recipients) and the aggregate amount attributable to all such transfers of value.

The second instance when companies can report at the aggregate level is for research and development transfers of value.[66] That is, companies are required to report all of their transfers for research and development in a calendar year, which includes costs related to events that are clearly related to research and development activities, as a single aggregate number.

One potential difficulty associated with reporting these various transfers of value concerns cross-border situations; for example, when a company is based in Country X but makes a transfer of value to a HCP from Country Y to attend an event in Country Z. The Disclosure Code addresses that topic by explaining that

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[65] On the issue of consent, the Disclosure Code includes a footnote that states: "When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the Recipients' consent to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure."

[66] Research and development transfers of value are defined as: "Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the HCP Code)." *Disclosure Code*, EFPIA.EU, http://transparency.efpia.eu/the-efpia-code-2 (last visited Aug. 13, 2014).

> [d]isclosures shall be made pursuant to the national code of the country where the Recipient has its physical address. If a Member Company is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the Member Company shall disclose such Transfer of Value in a manner consistent with the national code to which the Recipient is subject.

Another key feature of the Disclosure Code is its requirement that companies make their "methodology" public. This concept is similar to the assumptions document that companies have the option to submit under the US Sunshine Act. Unlike the US Sunshine Act, the Disclosure Code mandates that all companies prepare and make public the methodology that they utilized in preparing their disclosure reports. Specifically, the Disclosure Code provides:

> Each Member Company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category[.] The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

The Disclosure Code includes specific exclusions, as the following transfers of value do **not** have to be disclosed: 1) transfers that are solely related to over-the-counter medicines; 2) transfers that are not explicitly identified in the Code, including, for example, items of medical utility, meals/drinks,[67] and medical samples; or 3) transfers that are part of ordinary course purchases and sales of medicinal products by and between a member company and an HCP or HCO. Companies are not obligated to disclose any of these types of transfers of value.

The Disclosure Code also requires EFPIA's national member associations to include sanctions for violations of the disclosure provisions, with such sanctions to be proportionate to the nature of the violation. Despite suggesting that a combination of publication and fines would

[67] Unlike the legislation in the United States and France, EFPIA does not require companies to report on meals. Rather, Section 10.05 of the EFPIA HCP Code prohibits member companies from providing any meals to HCPs unless the value of the meal does not exceed the monetary threshold set by each national member association in its local code.

be the most effective sanction, the Disclosure Code ultimately delegates the responsibility to national member associations to decide the most appropriate sanction scheme.

As originally adopted in June 2013, the Disclosure Code called for EFPIA's national member associations to formally transpose the disclosure requirements into their own national codes by December 31, 2013. (That language remains in the version of the Disclosure Code that was approved by EFPIA in June 2014.) National member associations were expected to incorporate the provisions of the Disclosure Code into their own national codes in full, except when the Disclosure Code's provisions conflicted with governing national laws or regulations. In such instances, EFPIA indicated that it would tolerate deviations from the provisions of the Disclosure Code, but only to the degree needed for compliance with the controlling national legislation.[68]

The EFPIA approach to transparency, as embodied by its Disclosure Code, holds tremendous potential for achieving some degree of uniformity across Europe, although it is impossible to achieve absolute consistency for two primary reasons. First, the various laws that were discussed previously take precedence in those countries over the industry's self-regulatory approach, and those laws contain reporting requirements that differ from the Disclosure Code.

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[68] In countries with transparency laws, the national member associations have pursued a largely similar course with respect to their implementation of the Disclosure Code. For example, to fulfill its EFPIA-related obligations, the French industry group simply incorporated the French Sunshine Act's requirements into its Code. Thus, members of the French industry group do not have to submit one report to the French government and then a second report to the industry group; instead, their compliance with the French law is sufficient to satisfy their industry group obligations. *See*, LES ENTREPRISES DU MEDICAMENT ("LEEM"), http://www.leem.org/ (last visited Aug. 13, 2014). Likewise, the Danish industry group's Code requires its members to comply with the governing Danish legislation. *See*, *The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals 2014*, THE ETHICAL COMMITTEE FOR THE PHARMACEUTICAL INDUSTRY IN DENMARK,, http://www.enli.dk (last visited Aug. 13, 2014).

Second, in transposing the Disclosure Code into their national codes, EFPIA's national member associations have taken slightly different approaches to some issues.

Almost uniformly, national member associations have adopted the categories of transfers of value that must be reported (e.g., consultancy fees and expenses; contributions to costs of events, etc.) at the individual level and the aggregate reporting circumstances (e.g., research and development transfers of value; absence of recipient consent to publish information at the individual level). While it is beyond the intended scope of this paper to analyze in detail all of the national codes and identify all of the variations among them, we will highlight some key discrepancies focusing on the following topics: 1) platform of disclosure; 2) language of disclosure; and 3) consent.

As discussed previously, the Disclosure Code calls for companies to make their disclosures public either on their own websites or on a central platform developed by the national member association. From that EFPIA provision, we have identified six different approaches taken by national member associations:

1. Disclosures to be made on the member company's website (Finland, Spain, Switzerland, Slovenia);
2. Disclosures to be made on the national member association website (Greece, the Netherlands);
3. Disclosures to be made on either the company's website or the national member association's website (Sweden, Turkey, Latvia, Croatia, Serbia);
4. Disclosures to be made on the company's website linked to the national member association's website (Bulgaria, Lithuania);
5. Disclosures to be made on the national member association's website linked to the company website (Romania); and
6. Not yet identified in the national Code (Ireland).[69]

Similarly, national member associations have made different decisions about the language in which the report must be submitted. On that point, the Disclosure Code provides

[69] This is intended to be a representative, not exhaustive, listing of how certain national member associations have addressed this topic.

that reports must be in the local language, but encourages companies to submit reports in English. On that issue, we have identified five different approaches taken by national member associations:

1. Local language only (Finland, Greece, Bulgaria, Romania);
2. Local language and English both required (Russia, Czech Republic, Lithuania);
3. Local language required and English encouraged (Norway, Spain, Sweden, Turkey, Latvia, Slovenia);
4. Other (Switzerland requires English and, whenever possible, German, French and Italian; Belgium requires Dutch and French and encourages English); and
5. Not yet identified in the national Code (Italy).[70]

One of the most critical factors to the success of EFPIA's self-regulatory system is consent. Because the Disclosure Code does not have the force of law, and because of the data privacy protections afforded to European citizens, companies must generally obtain the consent of recipients of their transfers of value in order to be able to legally publish the information. The Disclosure Code recognizes the possibility that recipients may not consent to such disclosure, in which case companies must report on those transfers in the aggregate. However, aggregate reporting will likely not be sufficient to convince governments and legislators to refrain from regulating this area. That is, the global movement, as evidenced by the US Sunshine Act, the French Sunshine Act, and the other European legislation, calls for the disclosure of individual level information so that the public can have as much insight as possible into the relationship between industry and individual HCPs. If a significant number of recipients refuse to consent to the public disclosure of the transfers of value they receive, and companies are thereby forced to report mainly at the aggregate as opposed to individual level, not only would that undermine EFPIA's stated purpose in adopting the Disclosure Code, it would make it rather difficult for the

[70] This is intended to be a representative, not exhaustive, listing of how certain national member associations have addressed this topic.

pharmaceutical industry to convince governments and legislators that their self-regulatory approach is effective and consistent with the global transparency movement.

The need for HCPs to understand what EFPIA is trying to achieve with its Disclosure Code, and to support that effort and achieve a high percentage of consent for disclosure among all HCPs, is one of the primary motivations for EFPIA's publicity efforts. As noted *supra*, EFPIA's efforts include the creation of various materials and videos to share with HCPs, as well as hosting meetings and events designed to educate the medical community about the Disclosure Code. At the May 27 event in Brussels, for example, Mr. Bergstrom commented that "[w]e as an industry have said we will be absolutely transparent about our relationships with healthcare professionals. But we have only just begun to communicate with the three million medical professionals in Europe about how this will be put into practice[.]"[71] He also noted that the launch of www.pharmadisclosure.eu was just "the beginning of the conversation[.]"

At that same event, however, some of the concerns of HCPs were highlighted. For example, Powel Sztwiertnia, General Director of INFARMA, the Polish national member association of EFPIA, discussed a survey his organization conducted of Polish HCPs, which found that they were broadly supportive of the principle of transparency but had major concerns and anxiety about the publication of their names and the amounts of the payments they received.[72] In addition to those general concerns and anxieties, Robert Schaefer, Senior Project Manager at the European Society for Medical Oncology, discussed the wide range of disclosure and conflict of interest rules that HCPs are subject to, which are often conflicting and inconsistent.

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[71] *This is the beginning of a conversation*, *supra*, http://pharmadisclosure.eu/news/launch-of-pharmadisclosure-eu-doctors-and-industry-collaborate-for-better-trust/ (last visited Aug. 13, 2014).

[72] *Id.*

In that vein, Mr. Schaefer, in an article posted on www.pharmadisclosure.eu, elaborated on HCP concerns and observed that:

> while [HCPs] are in favour of the greater transparency that will flow from disclosure of the number, duration and amount of payments they receive from pharmaceutical companies, there are concerns that, taken with increased mandatory disclosure requirements at a national level and other self-regulatory requirements to disclose, doctors may face a conflict between different codes, policies and regulations.
> …
>
> The combination of a rising tide of mandatory and self-regulatory disclosure requirements, coupled with a huge variety of different approaches and perceptions of 'risk' is increasing the bureaucratic overhead and may very well have the opposite of the desired effect, resulting in a "cacophony of disclosure" that generates more heat than light.
> …
>
> The EFPIA disclosure code has the potential to affect healthcare professionals in a number of ways; influencing patient perceptions; undermining doctor's independence; impacting on tax status and attracting unfavourable press coverage, to name but a few. In the face of this, some healthcare professionals may choose not to work with the industry or to attend sponsored medical conferences and may instead look for low-cost alternatives that may not always meet the highest educational standards.
>
> Such negative impact can be avoided if the code is appropriately implemented. This calls for a concerted effort to manage patient perceptions, to educate professionals about the new requirements and to increase public awareness and understanding of the value the relationship between the industry and healthcare professionals holds for patients. Transfers of value should always be put in the correct context, allowing for a proper assessment of their relevance, significance and proportionality.[73]

Mr. Schaefer is not the only person to express concerns on www.pharmadisclsoure.eu about how the implementation of the Disclosure Code will affect the medical profession. In that regard, Michel Ballieu, the CEO of the European CanCer Organisation, was the focus of a recent article in which he stressed that the movement toward transparency should not be achieved at the

[73] Robert Schaefer, *It Will Happen, So it is Better to Get Ready Now*, PHARMADISCLOSURE.EU, http://pharmadisclosure.eu/news/it-will-happen-so-it-is-better-to-get-ready-now/ (last visited Aug. 13, 2014).

expense of HCPs.[74] More specifically, he stated that "the move to financial disclosure [must] be done in such a way that it does not affect the reputation of healthcare professionals and healthcare organisations that are the recipients of those payments[.]" To that end, Mr. Ballieu has called for the pharmaceutical industry and medical associations to work together on a communications campaign to educate the public and explain to European citizens the importance of the relationship between industry and medical professionals to the development of better patient care. Mr. Ballieu's point is similar to the one that was expressed by industry and medical societies in the United States in their July 28, 2014, letter to CMS that called for the federal government to explain the "context" of the financial relationships that must be reported under the US Sunshine Act to ensure that the public does not misunderstand or misinterpret what the reported information represents concerning the relationship between industry and the medical profession.

In short, the importance of consent to the ultimate success of the Disclosure Code cannot be overstated. Some national member associations have provided suggested language for their members to use in obtaining consent. The Irish industry group provides the following language:

> Notwithstanding any obligations of confidentiality which [name of pharmaceutical company] may have toward [name of healthcare professional or healthcare organisation], [name of healthcare professional or healthcare organisation] hereby agrees that [name of pharmaceutical company] shall be entitled to disclose details of all direct and indirect transfers of value, whether in cash, in kind or otherwise which are made to or for the benefit of [name of healthcare professional or healthcare organisation] – whether for promotional purposes or otherwise – in connection with the development and sale of prescription medicinal product exclusively for human use and such other information as will enable [name of pharmaceutical company] to comply with its obligations under the IPHA Code.[75]

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[74] Michel Ballieu, *Explain the Value of the Relationship, Not the Value of the Transaction*, PHARMADISCLOSURE.EU, http://pharmadisclosure.eu/news/explain-the-value-of-the-relationship-not-the-value-of-the-transaction/ (last visited Aug. 13, 2014).

[75] *Code of Practice for the Pharmaceutical Industry* (Ed. 8.0), IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION (Published Jan. 2014), www.ipha.ie.

The industry group in the United Kingdom does not offer suggested language like its Irish counterpart, but it does mirror the Disclosure Code's footnote on consent, as it encourages its members to

> include in a contract involving a transfer of value provisions regarding the consent of the recipient to its disclosure. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure. Companies must ensure that they have appropriate arrangements in place to lawfully disclose information about transfers of value.[76]

The Italian code requires companies to maintain appropriate documentation about recipient consent for at least three years,[77] and the Slovenian code provides that if a HCP revokes his or her consent to disclosure, he or she must reimburse the company for the transfer of value at issue.[78] The Greek code also contains stringent provisions surrounding consent, as it first notes that "[a] condition for the disclosure is the written consent of the recipient[,]" but then goes on to state that if the recipient denies consent the company may not contract with him or her.[79] Consent is also a point of emphasis for the German industry group, as it stresses on its website that federal German law requires express consent as a pre-requisite to publication. The German group is expected to promulgate standard contracts addressing consent for use by its members.[80]

Although EFPIA's Disclosure Code, as implemented by its national member associations in their own national codes, requires first reports in 2016 to cover 2015 data, there are two countries, the Netherlands and the United Kingdom, where reporting has already taken place

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[76] *Code of Practice for the Pharmaceutical Industry*, ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY ("ABPI") ("ABPI Code") (Published Jan. 1, 2014), http://www.abpi.org.uk/Pages/default.aspx.

[77] *Codice Deontologico Farmindustria* [Code of Ethics], FARMINDUSTRIA, (Published July 2, 2014) (Italy), https://www.farmindustria.it/ (in Italian).

[78] *Code on Disclosures of Transfers of Value From Pharmaceutical companies to Healthcare Professionals and Healthcare Organisations*, FORUM OF INTERNATIONAL RESEARCH AND DEVELOPMENT PHARMACEUTICAL COMPANIES, EIG ("FIRDPC") (Published July 4, 2014), http://www.firdpc.com/en/.

[79] *Disclosures of Transfers of Value by Pharmaceutical Companies to Healthcare Organisations*, SFEE (April 2014), www.sfee.gr.

[80] VFA DIE FORSCHENDEN PHARMA-UNTERNEHMEN [RESEARCH-BASED PHARMACEUTICAL COMPANIES], http://www.vfa.de/de/home.html (last visited Aug,. 13, 2014).

pursuant to industry association rules. The Dutch industry association, Nefarma, working in conjunction with several other key actors in the healthcare field, has required its members to report on their financial interactions – at the individual level – since 2013 (covering 2012 data). By way of background, in 2009, the Dutch Minister of Health requested that the pharmaceutical industry develop a mechanism to disclose financial relationships between industry members and Dutch HCPs because the Dutch government preferred a system of self-regulation over legislation.[81] This request was 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 HCPs. As a result of the request, the Dutch pharmaceutical industry worked with HCPs and other key actors in a cooperative manner to develop a self-regulatory system that addressed the issues and concerns of all stakeholders, ultimately developing disclosure rules for pharmaceutical companies.

As noted above, companies submitted their first reports under the Dutch disclosure system in 2013 to cover 2012 data, and filed their second set of reports in 2014 to cover 2013 data. In May 2014, the Dutch industry group adopted an updated Code of Conduct for Pharmaceutical Advertising that incorporates the disclosure rules, which had been separate from the prior version of the Code of Conduct, into the Code itself.[82]

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[81] Michel A. Dutrée, *Nefarma Leads the Way on Transparency*, PHARMADISCLOSURE.EU, http://pharmadisclosure.eu/news/nefarma-leads-the-way-on-transparency/ (last visited Aug. 13, 2014). Moreover, the Explanatory Notes to the Dutch Code of Conduct for Pharmaceutical Advertising explain that "[a]lthough transparency with regard to relations with pharmaceutical companies is part of the professional principles of a healthcare professional, there is a need within society to actively disclose the information on the financial relations between the parties. The then Minister of Public Health, Welfare and Sport, Ab Klink, urged the [pharmaceutical industry] … in May 2009 to draft standards for the Dutch equivalent of the [US] Sunshine Act. The [US] Sunshine Act requires the disclosure of payments made by the pharmaceutical industry to physicians and scientists in the United States."

[82] *Foundation for the Code for Pharmaceutical Advertising – Code of Conduct for Pharmaceutical Advertising*, THE DUTCH FOUNDATION FOR THE CODE FOR PHARMACEUTICAL ADVERTISING ("CGR"), http://www.cgr.nl/en-GB/Gedragscode-Geneesmiddelenreclame (last visited May 15, 2014).

Under the Dutch code, companies are required to disclose their "financial relations"[83] resulting from the following types of agreements: 1) service agreements with HCPs; 2) sponsorship agreements with groupings of HCPs and associations of professionals/institutions; and 3) support for patient organisations.[84]

Unlike EFPIA's Disclosure Code, which does not set a minimum threshold for reporting, the Dutch system requires that companies report their financial relations with a recipient only if the total sum in a calendar year exceeds 500 euros. The Explanatory Notes to the Dutch Code of Conduct for Pharmaceutical Advertising offers the following justification to support that threshold:

> This limit links up with the opinion issued by the Dutch Council for Public Health and Healthcare (Radd voor de Volksgezondheid en Zorg) in 2008 in its report "Pharmaceutical Industry and the Use of Medicinal Products, the Balance between Public and Corporate Interests." In addition, this limit does justice to the principle of proportionality from the point of view of the protection of the privacy of the healthcare professionals concerned and between the administrative work caused by the rules of conduct on the one hand and the interest of the disclosure of financial relations on the other hand. This limit does not, however, mean that financial relations representing a lower value could not be disclosed. Healthcare professionals can also disclose their financial relations with suppliers of care products other than medicinal products, such as medical aids.

The substance of the mandated disclosure depends upon the nature of the financial relation. For a service agreement, the company must provide the nature of the agreement;[85]

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[83] The Code defines financial relations in the following manner: "direct or indirect financial compensation in cash or in kind or otherwise provided by an authorisation holder to healthcare professionals, groupings of healthcare professionals and/or entities in which healthcare professionals participate or by which they are employed based in and/or practicing in the Netherlands or to a patient organisation based in the Netherlands."

[84] The inclusion of reporting as to patient organisations is a new change to the Dutch system. Such relations must be disclosed as from January 1, 2015.

[85] Agreements have been classified as follows: 1) Service provision - consultancy, which includes general individual consultancy work, such as writing articles/scientific lectures commissioned by a third party; 2) Service provision - advisory board, which includes participation in an advisory board; 3) Service position - speaker, which encompasses acting as a speaker/giving a presentation; 4) Service provision, research not subject to the Medical Research Involving Human Subjects Act; 5) Service provision – other, which covers other forms of services not specifically addressed by one of the other categories; 6) Sponsoring an event not organised by the reporting company; and 7) Sponsoring – other, which includes innovative and/or quality-enhancing activities aimed as directly

personal information of the healthcare professional who actually perform the services (irrespective of whether that professional was also the recipient of the amount paid), including: name, specialization; work address; the total amount paid to the professional; and the name, registered address and/or registration number of the association or institution that employs the HCP. For sponsorship agreements, the company must disclose the name, registered addresses and/or registration number of the recipient entity, along with the amount paid to the group during the calendar year. For support of patient organisations, companies must report the name, registered address, and/or registration number of the patient organisation, as well as the sums paid to it during the calendar year.

The Dutch Code further requires that the financial relations that are disclosed must be recorded in a written agreement between the parties that identifies the data that will be disclosed and the manner, and by whom, the information will be disclosed. Companies are also required to provide all recipients with an annual overview of the data to be disclosed, and they must submit their reports to the central register that has been established by the Dutch pharmaceutical group within three months of the end of the calendar year.

The central register is www.transparantieregister.nl. The register is publicly available and can be searched by HCP, but it cannot be searched by company. Thus, if a person were interested in learning how much (fictional) "Dr. Mary Jones" received from Nefarma member companies, that person could search for Dr. Mary Jones and see how much support was given to her. However, a person interested in learning how much (fictional) "Pharma Company Z" spent on Dutch healthcare professionals cannot perform a similar company-based search on the website.

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or indirectly improving patient care or advancing medical science and which not funded in any other regular manner.

Shortly after the first reports were submitted in 2013, the Dutch industry group issued a press release to tout its success in achieving a system that provided greater transparency into the relationships between the pharmaceutical industry and the medical profession.[86] The press release pointed out that the Dutch system actually provided more transparency than the scheme promulgated in the United States and also stressed that the Netherlands was leading the way in Europe with respect to self-regulation and that other countries, including the United Kingdom, were looking to the Dutch scheme as a model.

Not only did the press release trumpet the development of the Dutch transparency system, it also provided data about the financial information that had been disclosed by companies. According to the press release, more than fifty pharmaceutical companies submitted reports. Combining the reports from all of the reporting pharmaceutical companies revealed the following: 1) there were approximately 7,600 financial relationships reported involving more than 2,100 physicians and 1,200 institutions and associations; and 2) the total reported value of those relationships was more approximately 32 million euros.

As pointed out above, one of the unanswered questions in the United States is how will the media react to the publication of the data under the US Sunshine Act. There was a similar concern in the Netherlands, but although there were numerous articles about what was disclosed in the transparency register, there was only one negative article.[87] Moreover, in 2014, there was only one newspaper article, and it merely pointed out there was no significant change in the 2013 data, which revealed a total reported value of financial relations of approximately 33 million

[86] Apr. 2013 Press Release, *Transparantie* [*Transparency*], STICHTING CODE GENEESMIDDELEN RECLAME ("CGR"), http://cgr.nl/getattachment/Nieuws/Nieuwsbrieven/2013/Nr-2-2013-Transparantieregister/CGR-nieuwsbrief-2-2013.pdf.aspx (in Dutch).

[87] Dutrée, *supra*, http://pharmadisclosure.eu/news/nefarma-leads-the-way-on-transparency/.

euros. While the life sciences industry desires a similar media reaction to the publication of the Open Payments data, it certainly is expecting a harsher response.

Like their Dutch counterparts, members of the Association of the British Pharmaceutical Industry ("ABPI") disclosed their relationships with HCPs for the first time in 2013. Under the Code that was in effect at the time, the ABPI required companies to disclose the support they provided to HCPs in several categories, including payments for consulting services and sponsorship of healthcare professionals to attend events sponsored by third parties. Unlike Dutch pharmaceutical companies, however, members of the ABPI were not required to report on the individual level but rather only in the aggregate, and they also were not required to identify the names of the particular professionals that they support.

In an April 5, 2013, press release, the ABPI announced that, based on the disclosures of its members, it estimated that the pharmaceutical industry spent approximately £40m in 2012 on such support.[88] Nearly one year later, the ABPI announced that its members spent approximately £38.5m on such support in 2013.[89] Commenting on that 2013 data, Stephen Whitehead, the ABPI Chief Executive, stated:

> One eighth of the world's most popular prescription medicines were developed in the UK as a result of collaboration with healthcare professionals. We know that our responsibility for medicines extends beyond sale and purchase and it would be wrong for us to develop medicines in isolation. The industry works hand in hand with healthcare professionals to ensure that our discoveries and innovations bring the best possible outcomes for patients, and working in partnership has helped the industry listen to clinical expertise and develop medicines which can be life-saving for patients.
>
> Individual disclosure is an important step we are now preparing for. The changes are part of the industry's commitment to enhance transparency around these

[88] Apr. 5, 2013, Press Release, *Pharmaceutical industry takes the lead on transparency*, ABPI, http://www.abpi.org.uk/media-centre/newsreleases/2013/Pages/050413-a.aspx.

[89] Apr. 4, 2014, Press Release, *Pharmaceutical industry takes another stride towards greater transparency of financial relationships with healthcare professionals*, ABPI, http://www.abpi.org.uk/media-centre/newsreleases/2014/Pages/030414.aspx.

> relationships, and are a response to recognising, and wanting to address, the high expectations of stakeholders in this area. We hope this will allow us to foster greater trust between the medical community, industry and patients.

As to Mr. Whitehead's point about preparing for individual disclosure, the ABPI did transpose EFPIA's disclosure provisions, including individual-level reporting beginning in 2016 to cover 2015 data, into its Code of Practice for the Pharmaceutical Industry ("2014 ABPI Code"), which is administered by the Prescription Medicines Code of Practice Authority ("PMCPA").[90] The existing aggregate reporting requirements remain in place in the 2014 ABPI Code until they are superseded by the individual level requirements that are based on the EFPIA system.

With few minor differences, the 2014 ABPI Code's individual level disclosure provisions were largely identical to the EFPIA provisions. However, on July 14, 2014, the PMCPA announced it had launched a consultation on proposed changes to the ABPI Code of Conduct.[91] According to a summary of the proposed changes to the ABPI Code, some of the proposals relate to the revised EFPIA Disclosure Code; some of the proposals relate to the revised EFPIA HCP Code; and some proposals relate to the ABPI's standard review, as "well as the usual tidying up."[92] In terms of the proposals relating to individual disclosures, the ABPI Code would clarify relevant definitions and would require companies to report as transfers of value certain expenditures that they make in connection with services provided to the National Health Service, and other organisations, that are linked to the use of specific medicines.[93] Furthermore, after studying whether to create a central reporting platform or to have companies report the

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90 ABPI Code, http://www.pmcpa.org.uk/thecode/Pages/default.aspx.

91 July 14, 2014, Press Release, *Consultation on proposals to amend the 2014 ABPI Code*, PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY ("PMCPA"), http://www.pmcpa.org.uk/media/Pages/Consultation-on-proposals-to-amend-the-2014-ABPI-Code-of-Practice.aspx.

92 *Proposals for Amendment of The ABPI Code*, ABPI (Published July 11, 2014), http://www.pmcpa.org.uk/media/Documents/Code%20Proposals%20for%20public%20consultation.docx.

93 *Id.*

information on their own websites, the ABPI and PMCPA decided to pursue the former approach, as a proposed amendment to the ABPI Code states: "There will be a central platform for disclosure in the UK which companies must use."[94]

While most of the amendments are only minor changes and do not markedly differ from EFPIA's Disclosure Code, one proposed amendment about HCO reporting is a significant change from the EFPIA approach. As discussed *supra*, the EFPIA Disclosure Code states that transfers of value to HCPs and HCOs "may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to the (i) the relevant recipient, and/or (ii) the relevant authorities." The proposed ABPI Code would be different because only payments to HCPs could be aggregated; payments to HCOs would not be allowed to be aggregated and would have to be reported on a per activity basis.[95]

In view of the different reporting requirements for HCOs, as well as some other deviations from the EFPIA Disclosure Code, the PMCPA has developed a draft template that reflects those differences.[96] The PMCPA has acknowledged that there are differences between the UK template and the EFPIA template, though they are limited to "those changes necessary to reflect requirements of the ABPI Code and to provide the data in a form suitable for the ABPI searchable database."[97]

Among other things, the UK draft template differs from the EFPIA template because it requires the following information, which the EFPIA template does not: information about the

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94 *Id.*

95 *Id.* at Amendment 68, Clause 21.7. (The proposed language in the Code reads: "Different categories of transfers of value to individual health professionals can be aggregated on a category by category basis, provided that itemised disclosure would be made available upon request to the relevant recipient or the relevant authorities. *Payments to healthcare organisations are required to be disclosed on a per activity basis*.") (emphasis added).

96 *See UK Template – DRAFT for Consultation as of 14/7/14*, PMCPA (Published July 14, 2014), http://www.pmcpa.org.uk/media/Documents/ABPI%20Draft%20for%20Consultation%20UK%20Disclosure%20Template%2014july14.pdf.

97 Consultation on proposals to amend the 2014 ABPI Code of Practice, *supra*, http://www.pmcpa.org.uk/media/Pages/Consultation-on-proposals-to-amend-the-2014-ABPI-Code-of-Practice.aspx.

HCP's specialty and role; additional information in the Principal Practice Address section of the report (including institution name and e-mail address); a local register ID or third party database ID; a column for joint working; and the addition of benefits in kind to HCOs in the Donations/Grants column. Furthermore, the UK template reflects that HCO payments are reported at the activity level as opposed to the aggregate level; on that point, unlike the EFPIA template that lists as examples HCO1, HCO2 (as aggregate spend amounts without listing each payment made to a HCO), the UK template lists HCO1, **Payment 1**, HCO1 **Payment 2**, HCO2, Payment 1, to reflect that every transfer of value to every HCO must be reported at the individual, as opposed to aggregate, level.

The PMCPA has outlined the following timetable for the new Code:

- July 11 – proposals for Code changes sent to ABPI members, non-members that have agreed to comply with the Code, and posted on the PMCPA website;
- September 5 – the consultation period closes;
- October 7 – the ABPI Board of Management is to agree to final proposals;
- November 20 – proposals for changes to the Code to be presented to the ABPI Half-Yearly General Meeting; and
- January 1 (2015) – the new Code to come into operation.

A Longer Journey for the Medical Device Industry

In contrast to the aggressive approach that EFPIA and its national member associations have pursued in developing a self-regulatory reporting system, Eucomed, which represents the medical device industry in Europe, has not imposed reporting requirements on its members.[98] Eucomed represents approximately 25,000 designers, manufacturers and suppliers of medical

[98] As noted *supra*, medical device companies are required to report in certain countries, like the United States and France, as a result of laws.

technology used in the diagnosis, prevention, treatment, and amelioration of disease and disability.[99]

Eucomed is committed to high ethical standards for its members and works to ensure that they act according to the highest ethical and professional standards when working with HCPs. In that regard, Eucomed's Code of Ethical Business Practices governs many aspects of the relationship between its members and HCPs, but it does not mandate reporting of the financial interactions between its members and HCPs.[100]

By way of additional background, in September 2012, Eucomed issued a White Paper titled, "Transparency and Disclosure: Interactions between Industry and Healthcare Professionals (HCP)".[101] Eucomed acknowledged in that paper the spread of the transparency movement and cited the laws passed in France and Slovakia, as well as the transparency reporting systems in the United States, Australia, and Japan. Nonetheless, Eucomed expressed the view that if a country were to pursue reporting requirements, whether through legislation or a voluntary industry code, several important factors and issues must be evaluated and accounted for before adopting such a scheme. For example, Eucomed's White Paper recommends that companies should only have to report on payments made above "a reasonable threshold per year per HCP," and that reporting should take place only once a year, to reflect the payments made during the previous calendar year, rather than multiple times during the course of a given year. It remains to be seen whether EFPIA's active engagement in the transparency movement will

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99 *About Us*, EUCOMED.ORG, http://www.eucomed.org/about-us (last visited Aug 13, 2014).

100 *Code of Ethical Business Practice, Eucomed Guidelines on Interactions with Healthcare Professionals*, EUCOMED.ORG, http://www.eucomed.org/key-themes/ethics (last visited Aug. 13, 2014).

101 *Transparency and Disclosure: Interactions between Industry and Healthcare Professionals (HCP)*, EUCOMED.ORG (Published September 20, 2012), http://www.eucomed.org/publications/download/105/file/20120920_transparency_position_final.pdf (Published in the form of a White Paper).

motivate Eucomed to act in a similar fashion, or if the EFPIA experience will lead Eucomed in a different direction.

Eucomed's approach is consistent with most other medical device associations around the world. For example, Mecomed, which is the Middle East's Medical Devices & Diagnostics Trade Association, has its own Code of Business Practice, which was last amended in March 2012.[102] While that Code governs many aspects of industry interactions with HCPs, and generally supports the principle of transparency, Mecomed also declines to impose reporting requirements on its members.

The Pacific Rim

In Australia, the pharmaceutical industry is represented by Medicines Australia, which promulgates and implements the Medicines Australia Code of Conduct ("Australia Code").[103] The Australian journey to transparency stretches back decades, as the Australia Code, first established in 1960, has been revised numerous times and is currently in its 17th Edition as of January 2013.[104] Under that most recent edition, companies are required, for the first time, to report on the aggregate fees they pay to HCPs who provide services, including, for example, preparing promotional materials and participating in advisory boards. Although companies are required to submit a number of details about their payments, the names of the consultants do not have to be identified. Moreover, the current Australia Code requires member companies to submit reports that provide detailed financial information about educational meetings and symposia that they sponsor, as well as payments made to speakers to attend and present at

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[102] *Code of Business Practice: Mecomed Guidelines on Interactions with Healthcare Professionals*, MECOMED, http://www.mecomed.org/media/PDFs/code.pdf.

[103] *Medicines Australia's Code of Conduct, Edition 17*, MEDICINES AUSTRALIA, http://medicinesaustralia.com.au/files/2010/01/20130328-PUB-Edition17-FINAL.pdf (last visited Aug. 13, 2014).

[104] *Id.*

education meetings, but the names of the individual recipients of such sponsorship and payments do not have to be identified.

Because of its commitment to increasing transparency, Medicines Australia began working on that issue before the 17th Edition even took effect. In August 2012, Medicines Australia created a Transparency Working Group to develop measures and policies that would further enhance transparency of payments and other transfers of value.[105] The guiding mission of the Transparency Working Group, which was comprised of members from Medicines Australia, the generics sector, physicians' groups, colleges, and consumer groups, was to enable patients to be better informed about the financial relationships between HCPs and the industry. In July 2013, the Transparency Working Group released a report containing a model and some recommendations for individual level transparency reporting.

As part of its process to amend the Australia Code, Medicines Australia had a Code Review Panel examine the Transparency Working Group's paper and recommendations, as well as a host of other issues. The Panel met on an essentially monthly basis since August 2013 to further develop and refine Medicines Australia's transparency system.

Ultimately, on July 2, 2014, Medicines Australia announced that it had submitted an application to the Australian Competition and Consumer Commission ("ACCC") for approval of the next edition of its Code, Edition 18.[106] As discussed below, the new Code, which was approved unanimously by the members of Medicines Australia, for the first time includes individual level reporting. Medicines Australia expects the ACCC authorisation process to take

[105] *Issues & Information - Transparency Working Group*, MEDICINESAUSTRALIA.COM, http://medicinesaustralia.com.au/issues-information/transparency-working-group/ (last visited Aug. 13, 2013).

[106] July 2, 2014, Press Release, *MA submits new transparency reforms to ACCC*, MEDICINE AUSTRALIA, http://medicinesaustralia.com.au/2014/07/02/ma-submits-new-transparency-reforms-to-accc/.

approximately six months and, if authorised by the ACCC, the new Code will take effect in January 2015, with the new transparency system starting in October 2015.

In announcing this watershed moment in Australia's journey to transparency, Medicines Australia Chief Executive, Dr. Brendan Shaw, declared:

> "Medicines Australia's member companies are taking the lead in setting new standards of transparency in Australia's health sector with this new Code[.] … Interactions between healthcare professionals and pharmaceutical companies are essential for ensuring that patients have the best care. They ensure healthcare professionals have up to date and comprehensive information about medical developments. This new Code sets new standards in the transparency in these interactions which is unprecedented in the Australian health sector. While the **journey** of delivering greater transparency isn't easy, these new transparency measures are an important step forward for industry, healthcare professionals and importantly Australian patients.
>
> …
>
> Medicines Australia's members support a strong industry code that evolves with changing community expectations. We have consulted with a wide range of stakeholders in the development of the new code, including consumer and medical groups, some of whom actively participated through representation on the Code Review Panel. … Medicines Australia looks forward to other industry sectors following this lead towards greater transparency."

(emphasis added)

The Introduction to the 18th Edition of the Australia Code reflects Dr. Shaw's comments about the significance of transparency:

> The Australian medicines industry collaborates with healthcare professionals in Australia to deliver up-to-date information about the safe, effective and appropriate use of the medicines they prescribe, dispense, administer or recommend.
>
> The industry also engages healthcare professionals to obtain feedback and learn from their experiences in using medicines in a practical setting. This open dialogue is critical in enhancing the quality use of medicines, building shared knowledge and identifying future needs that can be met through research and development.

> It is important that the community continues to trust and have confidence in the relationships between pharmaceutical companies and their doctors, pharmacists, nurses and other healthcare professionals. In response to community feedback, Medicines Australia has led the collaboration with healthcare professional organisations and patient groups to develop a strong and pragmatic framework, included in this 18th edition of the Code, that will deliver further transparency around payments and other financial relationships between pharmaceutical companies and individual healthcare professionals.
>
> These new transparency measures are an important step forward for industry, healthcare professionals and, importantly, for Australian patients.[107]

In terms of the substantive requirements of the 18th Edition of the Australia Code, it includes some elements similar to the US Sunshine Act (e.g., review and dispute process; corporate declaration requirement); other features that are reminiscent of EFPIA (e.g., obtaining consent; not having to report on meals); some components that are similar to France (e.g., bi-annual reporting); and others that are unique to Australia (e.g., no reporting for research and development). Before delving into the details of those new individual level reporting requirements, it is important to emphasize that the aforementioned aggregate reporting requirements will remain in place until the new system takes effect. In that regard, the 18th Edition of the Australia Code notes that

> [i]n Edition 18 of the Code the reporting requirements for Health Consumer Organisation support remain unchanged. For all other types of reporting, the reporting requirements will follow those of Edition 17 until 30 September 2015. From 1 October 2015 the enhanced transparency reports come into effect, providing greater transparency on important interactions between Member Companies and Australian healthcare professionals. [108]

With respect to the mechanics of reporting, the 18th Edition of the Australia Code requires that each member company place its transparency report about HCPs on its own

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[107] *Introduction, Code of Conduct, 18th Edition,* MEDICINES AUSTRALIA, http://medicinesaustralia.com.au/files/2010/01/20140701-Draft-Edition-18-Code-version-30-June-2014-final-no-mark-up.pdf.

[108] The 18th Edition of the Australia Code contains a summary of changes to reporting and applicable deadlines.

website, and Medicines Australia will provide hyperlinks to each company's report from its website. (As discussed below, there is a different approach for reporting sponsorship of third party educational events.) The initial HCP reports – which cover the period from October 1, 2015 through April 30, 2016 – must be published on member company websites by August 31, 2016. The reporting cycle covers a six-month period (except for the initial report, which covers seven months), and reports must be posted four months after the close of the period. Thus, the second reports pursuant to the new system would cover data from May 1, 2016 through October 31, 2016, and must be posted by February 28, 2017. The third reports cover data from November 1, 2016 through April 30, 2017, and must be posted by August 31, 2017.

A broad range of activities are encompassed within the scope of the 18th Edition of the Australia Code, as companies must report the following transfers of value they provide to HCPs:[109]

- Fees paid to HCPs in return for speaking at an educational meeting or event.
- Sponsorship of a HCP to attend an educational event. Specific reportable items in regard to sponsorships include any airfare, accommodation, or registration fees directly in association with the meeting, whether held inside or outside of Australia.
- Fees paid to HCP consultants in Australia, or to their employers on their behalf, for specific services rendered by them. Such services include, but are not limited to: all consultancy services provided in relation to educational meetings; preparation of promotional materials or product position papers; assistance with training; or any other advice to the company. Reportable items include all payments in respect to consulting

[109] HCPs are defined in the Australia Code's glossary in the following manner: "a healthcare professional registered to practice in Australia who in the course their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia."

fees, accommodation and airfares (both within and outside Australia) associated with the provision of consulting services.

  - **Significantly, such services do not include payments to consultants in relation to research and development work, including the conduct of clinical trials**.[110] This is an important exception to reporting, and one that is different than the reporting schemes in place in other areas of the world.

- Fees paid to HCPs in their role as Advisory Board members. Specific reportable items include all payments with respect to Advisory Board sitting fees and accommodation and airfares (both within and outside Australia) associated with the activities of the Advisory Board.
- Fees paid to HCPs for the purpose of market research. Such fees must be reported when the company knows the identity of the HCP. Reporting is not required where the company contracting the marketing research is not involved in the selection of the participating HCPs and is not aware of the identities of the participating HCPs.
- Payment of an educational grant or sponsorship to a specific HCP.

When an HCP requests that payment for any of the above categories be made to a third party, companies are required to disclose such payments for the individual HCP; however, the report should identify that the payment was made to a third party.

There are also a number of items and activities that are exempted from reporting, including:

- Transfers of value only have to be reported that are related to prescription medicines. Companies that have separate divisions that do not supply prescription medicines for

[110] Research and development is defined in the Australia Code's glossary as follows: "any early-stage research, such as target discovery, drug discovery, mechanism of action or proof of concept studies; pre-clinical research, such as toxicological studies; and human clinical trials."

human use (e.g., animal health divisions) are only required to report transfers of value in relation to the human use prescription medicines.

- Companies do not have to report transfers of value made to their employees who are HCPs.
- Hospitality (food and beverages) does not have be reported. In an approach that is similar to EFPIA, the cost of any meal (including drinks) provided by a company must be below the defined limit included in the Code ($120 for food and beverages, exclusive of GST).
- Venue costs are not reportable (e.g., room and/or AV equipment hire), and neither are airport ground transfers, taxis, and parking fees.

According to the 18th Edition of the Australia Code, companies must report the aforementioned transfers of value pursuant to a template provided in the Code's Guidelines, but those Guidelines are not yet publicly available. In the template, companies will be required to report all individual transfers of value for each HCP, indicating the following information:

- Date of the event or provision of service;
- HCP's name;
- Type of HCP (e.g., medical practitioner, pharmacist, nurse practitioner);
- HCP's principal practice address;
- Description of the service (e.g., speaker, Advisory Board, etc.);
- Description of the event (e.g., company sponsored meeting in Australia, independent meeting held in Australia, independent meeting held overseas, etc.);
- Whether the payment was made to the HCP or a third party;

- The amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

Moreover, the most senior executive officer[111] of the member company must provide to Medicines Australia a signed and dated declaration that the company has published the required information on its company website. The declaration must be provided to Medicines Australia within seven calendar days following publication of each report.

Because this is a self-regulatory transparency system, the 18th Edition of the Australia Code is similar to EFPIA in that it requires consent as a pre-requisite for publication of information about individual HCPs. Specifically, companies must comply with governing Australian privacy legislation regarding reporting of HCP data and must establish a means to ensure informed consent and maintenance of records in accordance with that legislation. However, when a recipient of a transfer of value cannot be identified for legal reasons (e.g., lack of consent), the amount attributable to such transfers must be reported on an aggregate basis. Companies must identify the number of such recipients, as well as the aggregate amount attributable to such recipients.

Before publishing information pursuant to this system, companies must provide HCPs for whom they have reportable information the opportunity to review the data and submit corrections to that information. The period provided for review and verification/correction will be at least six weeks. The information that is ultimately disclosed on company websites must remain there for 2 years from the date of first publication.

[111] The Glossary to the Australia Code defines "senior executive officer" as follows: "'senior executive officer' means the most senior executive officer of the member whether described as Managing Director, Chief Executive Officer, General Manager, Regional Director or otherwise …. For a non-member company this means the most senior executive responsible for the company's prescription medicines business".

Lastly, as pointed out previously, the 18th Edition of the Australia Code has created a different reporting system for sponsorship of third party educational meetings and symposia (e.g., financial sponsorship of a third party educational event; monetary contribution to support the conduct of grand rounds, clinic meetings or journal club meetings; purchase space for providing a trade display at an educational event). Beginning on October 1, 2015, the following requirements apply to company reporting of such events organized by third parties:

- Companies must complete the table set forth in the Code's appendix for each six-month period of November 1 through April 30 and May 1 through October 31.
- Companies must provide the completed table to Medicines Australia within four months from the end of each six-month period.
- The initial report will cover seven months – October 1, 2015 through April 30, 2016 – but subsequent reports will follow the six-month reporting cycle.
- Medicines Australia will make publicly available on its website the completed reports provided by each member company within 2 months from when the reports are submitted to Medicines Australia.

Australia is not the only country in the Pacific Rim where transparency has taken hold. In Japan, disclosure requirements have been implemented by both the Japan Pharmaceutical Manufacturers Association (“JPMA”) via the “JPMA Guidelines on Transparency on Corporate Activities with Medical Institutions and Healthcare Professionals,” and the Japanese Federation of Medical Devices Association ("JFMDA") via its "Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations," in

2011 and 2013, respectively.[112] As to the latter organization, the JFMDA is an outlier compared to other medical device industry groups around the world, like Eucomed and Mecomed, because it imposed reporting requirements on its members while other similar groups have not.

Both Guidelines in Japan impose similar transparency requirements upon their members. Under both sets of 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 annually for the preceding fiscal year. Under both sets of Guidelines, there are five categories of payments that must be disclosed: 1) research and development expenses; 2) academic research support expenses; 3) manuscript writing, consulting, speaking services; 4) provision of information related expenses; and 5) other expenses, including hospitality provided to healthcare professionals.

In adopting its Guidelines, which closely track the JPMA's Guidelines, the JFMDA explained that it felt the need to embrace transparency; specifically, it espoused the principle previously articulated by EFPIA, Medicines Australia, Nefarma, and others involved in the transparency movement:

> The industry-academia collaboration which is indispensable for proper usage of medical research, development, implementation as well as post-market improvement, is based on agreements and contracts with medical institutions and people involved in medical care. There have been cases where financial compensation are made in regard to those activities. Companies have been working to increase the transparency of these dealings by obeying the relevant regulations such as the Pharmaceutical Affairs Law but also by voluntary compliance with industry guidelines such as the Code of Ethics, the Charter of Corporate Behavior, the Promotion Code of the Medical Devices Industry, and

[112] *Transparency Guideline for the Relation between Corporate Activities and Medical Institutions*, JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION ("JPMA"), HTTP://WWW.JPMA.OR.JP/ENGLISH/ISUUES/PRACTICE.HTML (last visited Aug. 13, 2014); *See also*, *The Code of Ethics/ The Promotion Code*, THE JAPAN FEDERATION OF MEDICAL DEVICES ASSOCIATIONS ("JFMDA") (Revised Mar. 25, 2005), http://www.jfmda.gr.jp/e/promotioncode/.

> the Fair Competition Code of the Medical Devices Industry. However, as these collaborations increase, the chances arise for medical institutions and related healthcare professionals to become deeply involved in a specific company or product and there is concern over the possibility that this can affect fair and impartial conduct.
>
> In Europe, the US and other countries as well as Japan, there is a growing demand for more transparency. The Japan Pharmaceutical Manufacturers Association (JPMA) published its Guidelines for Transparency of Relationships between Corporate Activities and Medical Institutions and with the trend in the medical world to put out a policy on conflict of interest in industry collaboration, the JFMDA, in light of the importance of securing transparency, has formulated these guidelines.[113]

Conclusion

As the journey that this paper has taken nears its end, it is helpful to summarize some of the key stops we have made along the way. First, from a global perspective, the transparency movement is well-advanced in the United States, Europe, Australia, and Japan. The movement has not spread as quickly in other parts of the world, like Latin America, Africa, the Middle East, and most parts of Asia. However, life sciences companies are well-advised to continue to monitor these regions because transparency measures can spring up anywhere, often without notice.

For example, according to press accounts from earlier this year, the Drug Regulatory Authority of Pakistan, which is a governmental body, has announced an initiative to increase transparency in interactions between health care providers and the pharmaceutical industry.[114] Meanwhile, in Canada a few prominent physicians are trying to start a transparency movement, as earlier this year they wrote a letter to the editor in The Globe and Mail entitled, "Big pharma's

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[113] *Formulation of "Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations"*, THE JAPAN FEDERATION OF MEDICAL DEVICE ASSOCIATIONS ("JFMDA"), http://www.jfmda.gr.jp/promotioncode/pdf/120524_clear_02_e.pdf (last visited Aug. 13, 2014).

[114] *Drug regulator's initiative 'to increase transparency'*, THE EXPRESS TRIBUNE (Published Apr. 22, 2014), http://tribune.com.pk/story/698607/drug-regulators-initiative-to-increase-transparency/.

relationship with your doctor needs some U.S.-style sunshine."[115] In addition, these doctors have started a group called OpenPharma.[116] Among other things, this group advocates that the Canadian federal government enact legislation requiring full disclosure of payments to physicians, with such information to be made available on a website with open access for the public. In addition, the group is calling for provincial governments to have all drug companies with products listed on governmental formularies publicly report any transfers of value to HCPs.

A third development that demonstrates the unknown future of the journey towards transparency occurred in Scotland, where a Scottish physician, Dr. Peter J. Gordon, essentially single-handedly began a transparency movement by availing himself of the Scottish public petition process.[117] In September 2013, Dr. Gordon submitted Public Petition No. PE01493, titled, "A Sunshine Act for Scotland." In his petition, Dr. Gordon urged the Scottish government to create a Sunshine Act that would include a searchable record of all payments to healthcare workers from industry. The Scottish Public Petitions Committee has taken evidence and conducted hearings on the petition and requested various entities, including within the Scottish government, to respond to points raised by Dr. Gordon. The petition is presently pending, but its mere existence, along with the possibility that it could ultimately lead to the enactment of a Sunshine Act in Scotland, exposes not only the unpredictability of the transparency movement but also the need for life sciences companies to remain abreast of developments around the world that could affect them.

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[115] Andrew Boozary and Joel Lexchin, *Big pharma's relationship with your doctor needs some U.S.-style sunshine*, THE GLOBE AND MAIL (Last updated Mar. 26, 2014, 12:41 PM EDT), http://www.theglobeandmail.com/globe-debate/big-pharmas-relationship-with-your-doctor-needs-some-us-style-sunshine/article17676871/?cmpid=rss1.

[116] *Transparency: To Protect the Patient-Doctor Relationship*, OPEN PHARMA, http://openpharma.ca/ (last visited on Aug. 13, 2014).

[117] *PEO01493: A Sunshine Act for Scotland*, THE SCOTTISH PARLIAMENT, http://www.scottish.parliament.uk/GettingInvolved/Petitions/sunshineact (last visited on Aug. 13, 2014).

In addition to keeping track of potential new transparency hot spots around the world, life sciences companies must also be cognizant of what is happening with laws and industry codes that are already in place. The upcoming publication in the United States of the data disclosed pursuant to the US Sunshine Act will be a major moment in the transparency movement. Earlier we outlined some of the important questions that cannot be resolved until after the information is released, and it will also be interesting to observe how other areas of the world react and possibly respond to the experience in the United States. Along the same lines, although reporting under the EFPIA system will not occur until 2016, data collection begins in 2015 and EFPIA, along with its national member associations, members, and allies, will be busy in the interim trying to publicize its Disclosure Code so that it proves successful. If EFPIA's self-regulatory approach fails to meet its objectives, it is likely that more European governments will intervene and enact some type of transparency legislation. On the other hand, if the EFPIA program succeeds, it will undoubtedly influence how other industry groups, both pharmaceutical groups in other regions of the world and medical device groups like Eucomed, approach transparency.

In sum, the journey to transparency is proceeding throughout the world, albeit at varying rates in different regions and among the medical device and pharmaceutical industries. We cannot predict where the journey to transparency will ultimately lead, but we can state with certainty that the transparency movement is gaining strength and that we will continue to see more – not less – transparency in more places, creating more reporting obligations and compliance challenges for life sciences companies.