PORZIO LifeSciences

Like Beauty and Art, Transparency is in the Eye of the Beholder

WHITE PAPER

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"The numbers show why we ought to have sunshine. A patient who's interested should be able to search for her doctor and see whether there are payments that she'd like to consider."

"Of course, just because you take money it doesn't mean you are corrupt, but it is a risk and it should be openly declared so that others can access it."

"A better informed patient has more confidence in the relationships between doctor and company. They are more likely to understand the value of these relationships in the development of better medicines and devices, including a doctor's or patient's participation in … clinical trials."

"The backbone of any physician-patient relationship is trust. Where there could be perceived conflicts, where this is not public, where this is confidential or clandestine for whatever reason, [i]t can really start to erode that."

In prior White Papers, we extensively analyzed the data revealed by the transparency reports required by the US Sunshine Act and the Disclosure Code of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). Although we will discuss similar data in this year's White Paper, we decided to take a step back to examine whether the global transparency movement can be considered a success. Of course, in order to do that, we need to take a further step back to attempt to define how success can be measured in this context, especially when evaluated against the broad array of purposes underlying the Sunshine laws and self-regulatory industry codes.

The above statements, from the co-author of the US Sunshine Act, United States Senator Charles Grassley; British doctor and author of *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*, Ben Goldacre; Chief Executive of Medicines Australia, the industry

group representing the Australian pharmaceutical industry, Milton Catelin; and Canadian physician and transparency advocate Andrew Boozary, respectively, help to provide different perspectives and context that will guide us on our journey of exploration into the success of the global transparency movement. Because although it is easy to reference the number of laws or industry codes that have been adopted around the world, the number of companies that reported in a jurisdiction or the amounts they reported, or a particular country's "consent rate," a simple recitation of that data does not provide truly meaningful insight into whether the transparency movement has been successful.

On that point, in today's world we are awash in Big Data. The global transparency movement is no different than many other aspects of life in the 21st century, as statistics and data are used to support competing points of view about the financial relationships between the life sciences industry, healthcare professionals ("HCPs"), and healthcare organizations ("HCOs"). In that regard, one could take the view articulated by statistician W. Edwards Deming, who stated that, "[i]n God we trust. All others must bring data." Of course, a person who blindly relies only upon statistics and numbers might be surprised to learn that President Hillary Clinton is *not* meeting with Prime Minister David Cameron to discuss why the United Kingdom is such an important part of the European Union, both presently and in the future.

Conversely, others may ascribe to the sentiment expressed by Sendil Mullainathan, a Professor of Economics at Harvard, who observed that "[t]he problem with data is that it says a lot, but it also says nothing. 'Big data' is terrific, but it's usually thin. To understand why something is happening, we have to engage in both forensics and guess work." The views of Mr. Deming and Professor Mullainathan are not necessarily inconsistent or opposing, but they offer different perspectives on how data can and should be viewed and used. In this paper, we will

attempt to "bring data," but we will not do so with such a myopic focus that we miss the larger context. Rather, we will engage more deeply to try to ascertain what the data says about the global transparency movement, an endeavor that calls for both forensics and guess work. Our ultimate goal is to present a fair, balanced view of the success of transparency initiatives and to evaluate where the movement may be headed next.

To do so, we will focus primarily on the transparency experience of four countries: the United States, the United Kingdom, Australia, and Canada. Although we will touch upon additional countries and other transparency developments, we chose those four countries because they represent a mix of legislative-based, industry code-based, and to-be-established reporting requirements and encompass all of the key issues involved in the global transparency movement.

United States

The US Sunshine Act requires "applicable manufacturers," that is, pharmaceutical and medical device companies that satisfy certain statutory requirements, to report any direct or indirect payments or other transfers of value ("TOVs") to a "covered recipient" on an annual basis. "Covered recipients" are physicians and teaching hospitals. Applicable manufacturers are required to submit their reports on-line to the Centers for Medicare and Medicaid Services ("CMS"), which is part of the federal government's Department of Health & Human Services ("HHS"). There are three different types of reports that a company may have to submit: 1) a General Payments Report, which includes payments and TOVs to a covered recipient; 2) a Research Payments Report, which encompasses all payments and TOVs made in connection with an activity that meets the definition of research and that is subject to a written agreement or research protocol; and 3) a Physicians Ownership and Investment Interest Report, which includes any ownership or investment interests held by a physician or an immediate family member in an

applicable manufacturer. In turn, CMS makes all of the data reported by companies publicly available on its Open Payments website.

Applicable manufacturers first reported under the US Sunshine Act in 2014, but in that year they only had to report five months of 2013 data. Since 2015, applicable manufacturers have annually reported twelve months of data, and the total amount reported has increased every year. For 2014 data, companies reported $7.86 billion, which increased to $8.09 billion for 2015 data, and then to $8.18 billion for 2016 data. The total amount reported thus far under the US Sunshine Act, which includes 2013 data, is $24.94 billion.[1]

With respect to the categories of payments, for General Payments, companies reported $2.68 billion for 2014 data, $2.68 billion for 2015 data, and $2.80 billion for 2016 data. As to Research Payments, companies reported $4.07 billion for 2014 data, $4.45 billion for 2015 data, and $4.36 billion for 2016 data. Lastly, for Physicians Ownership and Investment Interest Reports, companies reported $1.11 billion for 2014 data, $961.62 million for 2015 data, and $1.02 billion for 2016 data. Since reporting began in 2014, 2,078 companies have reported on 906,000 physicians and 1,220 teaching hospitals, publishing 40.77 million total records.[2]

As promised in the beginning of this paper, we have brought data. A lot of it, in terms of millions of records that have been published, billions of dollars of reported payments, and thousands of reporting companies and nearly a million recipients in the United States.[3] But what does all that data mean? Has the US Sunshine Act been successful? And how should success be measured? In trying to answer those questions, it is helpful to consider the statements of Senator

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[1] *The Facts About Open Payments Data*, OPENPAYMENTSDATA.CMS.GOV, https://openpaymentsdata.cms.gov/summary (last visited July 27, 2017).

[2] *Id.*

[3] We certainly recognize that the US Sunshine Act does not prohibit States and localities from requiring that manufacturers disclose information that is not covered by the federal law and that several States have such reporting requirements. We have extensively addressed those State requirements in prior White Papers, and have chosen to focus solely on the US Sunshine Act this year.

Charles Grassley, one of the co-authors of the US Sunshine Act. After the final implementing regulations for the US Sunshine Act had been issued, but prior to the first round of reports, in February 2013 Senator Grassley 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.[4]

In 2014, on the eve of the public release of the data from the first reports, Senator Grassley commented:

> From day one, the [US Sunshine Act] database will be helpful in shining light on a part of medicine most people haven't had the time or opportunity to consider. Eventually, the database will become a valuable resource for all of us with a stake in our country's health care system. This includes individual consumers, insurance companies, and taxpayers who pay for Medicare and Medicaid.
>
> Transparency shouldn't stop doctors from receiving a payment if they want to. It should empower consumers to learn whether their doctors take payments and if so, why, and whether that matters to them. The patient who is prescribed a drug that might be beneficial yet risky will be able to learn whether the prescribing doctor accepted drug company money to study the risks. The information might not change the outcome, but it's something a patient might like to know. That's the idea behind the [US Sunshine Act].[5]

After CMS revealed the Sunshine Act data in 2015, Senator Grassley proclaimed:

> CMS has worked and continues to work to fulfill the Sunshine Act and also has taken action to make Medicare payment data more transparent. There's a strong public interest in knowing where this money goes and why. Consumers, researchers, and other members of the public benefit from disclosure. The

[4] Press Release, The Office of US Senator Charles Grassley, *Physician Payments Sunshine Act Regulations Released* (February 1, 2013), https://www.grassley.senate.gov/news/news-releases/physician-payments-sunshine-act-regulations-released.

[5] Press Release, The Office of US Senator Charles Grassley, *Grassley on the Physician Payments Sunshine Act Data Set to Launch* (September 29, 2014), https://www.grassley.senate.gov/news/news-releases/grassley-physician-payments-sunshine-act-data-set-launch.

> Sunshine Act is working as intended to shine light on part of the health care system that many of us didn't know much about before.[6]

In 2016, following the release of 2015 data by CMS, Senator Grassley commented:

> The purpose of the Sunshine Act was to disclose drug and medical device company payments to doctors and teaching hospitals to the public. With the information available publicly, patients, doctors and researchers are able to access the data. Researchers and journalists increasingly find ways to analyze the information. Just this week, in addition to the CMS report, the news site ProPublica released an analysis of payment information at hospitals by region and hospital ownership. Transparency in the health care system increases public understanding of how a complex system works.[7]

Most recently, following the public release of 2016 data on June 30, 2017, Senator Grassley stated:

> There have been attempts to get rid of the sunshine requirements. The numbers show why we ought to have sunshine. A patient who's interested should be able to search for her doctor and see whether there are payments that she'd like to consider. Researchers and reporters are able to mine the data for patterns and trends. Transparency adds value just about wherever it's applied. I've been asked whether it's possible to measure the success of the sunshine database. We know that doctors continue to receive the research payments they use for patient benefit, just as they did before sunshine. There's no way to know how many questionable payments were never made because someone didn't want to disclose them. If sunshine has deterred questionable payments while letting doctors continue to act for patient benefit, then it's a success.[8]

Senator Grassley's statements reveal four main purposes of the US Sunshine Act: 1) transparency to shed light on industry's payments to physicians and teaching hospitals; 2) transparency for the benefit of patients; 3) transparency for the analysis of data that can be performed by researchers, reporters, and others; and 4) transparency to deter questionable

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[6] Press Release, The Office of US Senator Charles Grassley, *Grassley Welcomes Release of More Sunshine Act Data* (June 30, 2015), https://www.grassley.senate.gov/news/news-releases/grassley-welcomes-release-more-sunshine-act-data.

[7] Press Release, The Office of US Senator Charles Grassley, *Grassley Welcomes Latest Data on Drug, Device Company Payments to Doctors, Teaching Hospitals* (June 30, 2016), https://www.grassley.senate.gov/news/news-releases/grassley-welcomes-latest-data-drug-device-company-payments-doctors-teaching.

[8] Press Release, The Office of US Senator Charles Grassley, *Grassley Welcomes Latest Physician Payments Sunshine Act Data, Highlights Value of Transparency* (June 30, 2017), https://www.grassley.senate.gov/news/news-releases/grassley-welcomes-latest-physician-payments-sunshine-act-data-highlights-value.

payments and improve accountability. We will evaluate the success of the Act in achieving each of its stated goals.

First, there is the notion that it is important for industry to be transparent and open about its financial relationships with physicians and teaching hospitals. From that perspective, there can be little doubt that the US Sunshine Act has achieved its objective. One need look no further than the sheer number of companies that have reported, the millions of records that have been published, the hundreds of thousands of recipients that have been identified, and the billions of dollars that have been disclosed to confirm that the life sciences industry has disclosed significant details and information about its financial relationships with physicians and teaching hospitals. Thus, the US Sunshine Act can be considered a success if the only metric is whether companies have revealed data about those relationships.

The second purpose, transparency for the benefit of patients, is not so easily measured. In several statements, Senator Grassley explained that patients *may* want to know whether their physicians have received financial support from the life sciences industry. Further, Senator Grassley noted that such information *may* affect patient choices about their healthcare. There are several complications when evaluating whether or not this purpose has been fulfilled.

First, there is the question whether patients are even aware of the publicly available data. We always suspected that the answer was "no," a suspicion that has recently been supported by empirical evidence in the form of a study that was released earlier this year in the *Journal of General Internal Medicine* titled, "Public Awareness of and Contact With Physicians Who Receive Industry Payments: A National Survey."[9] In this article, the authors explained that their study "is the first nationally representative study" examining how aware Americans are of the

[9] Genevieve Pham-Kanter et al., *Public Awareness of and Contact with Physicians who Receive Industry Payments: A National Survey*, 32 J. GEN. INTERN. MED. 767 (2017).

prevalence of industry payments to HCPs.[10] Their objectives were to determine the percentage of the American patient population exposed to HCPs who receive industry payments and to investigate Americans' awareness of such industry payments to HCPs. The authors did this through a cross-sectional survey conducted in September-October 2014 involving 3,542 adults.[11]

For the respondents who could be matched to a specific physician, the authors found that 65% of the patients had seen a physician who had received an industry payment during the prior 12 months. However, only 12% of the survey respondents knew that payment information about their HCPs was publicly available, and only 5% actually knew whether their own HCP had received industry payments. The authors acknowledged a number of limitations to their study, including that they only examined General Payments and not Research Payments, but concluded that "[p]atients' contact with physicians who receive industry payments is more prevalent than physician-based measures of industry contact would suggest. *Very few Americans know whether their own doctor has received industry payments or are aware that payment information is publicly available*."[12] (emphasis added) Although this is only one study,[13] its conclusion suggests that to the extent the US Sunshine Act was intended to benefit patients by providing them with information about relationships that their HCPs might have with industry, it has not fulfilled that objective, though the reason it has not done so might be because patients do not even know that such payment information is available.

The American public's lack of awareness of the US Sunshine Act payment data is not the only problem when measuring whether the law has been successful from a patient's point of

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10 *Id*. at 767, 771.

11 *Id*. at 768.

12 *Id*. at 767.

13 Another recently published study similarly suggested that "[w]hile arguments in favor of payment disclosure laws have focused on the value of transparency and informing consumers of health services, it is unclear how many patients will actively use the [CMS Open Payments] website." Alison R. Hwong et al., *The Effects of Public Disclosure of Industry Payments to Physicians on Patient Trust: A Randomized Experiment*, J. GEN. INTERN. MED. (forthcoming 2017), *available at* https://link.springer.com/article/10.1007/s11606-017-4122-y.

view. Another problem is context. Specifically, since the beginning of US Sunshine Act reporting, a major concern articulated by both industry and physicians was how the data would be received by the public. Both industry and physicians expressed unease that without the proper context, the data could be easily misinterpreted, resulting in the public being confused and potentially misled about how and why industry interacts with physicians.

One could argue that this concern has not become a reality because the American public seems largely unaware of the existence of US Sunshine Act data, but it is nonetheless a serious problem. In that regard, if a patient knew about the US Sunshine Act payment information and went to CMS's Open Payments website to search for his or her physician, the patient would still have difficulty evaluating what the financial relationship between his or her physician and industry meant. On its website, CMS explains that it

> **does not identify which financial relationships are beneficial or which may cause conflicts of interest.**
>
> ….
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> Sharing information about financial relationships alone is not enough to decide whether they're beneficial or improper. Just because there are financial ties doesn't mean that anyone is doing anything wrong. Transparency will shed light on the nature and extent of these financial relationships and will hopefully discourage the development of inappropriate relationships. Given the complexity of disclosure and the importance of discouraging inappropriate relationships without harming beneficial ones, CMS has worked closely with stakeholders to better understand the current scope of the interactions between physicians, teaching hospitals, and industry manufacturers.[14]

(emphasis in original)

Thus, it is clear that although a patient searching the Open Payments website for information about his or her physicians can find data about payments, he or she still will not have a true understanding of what the payments were for or why industry and physicians work

[14] *Open Payments Data in Context*, CMS.GOV, https://www.cms.gov/OpenPayments/About/Open-Payments-Data-in-Context.html (last visited July 28, 2017).

together. Gaining that understanding would require more research and study, a time-consuming task that the average patient may not be willing to perform. Accordingly, the patient will be left only with data, not an understanding of how or why his or her physician has a financial relationship with industry.

Assuming that a patient goes online to the Open Payments website and reviews the Sunshine data, the next question, which we will raise but cannot conclusively answer, becomes: what does the patient think if his or her physician has received payments? While it is easy to imagine some patients being concerned about that and wondering whether the physician has been "bought" by industry, it is equally easy to imagine other patients welcoming that information under the belief that the physician must be important, valued, or a key opinion leader if he or she is working with manufacturers.

A simple hypothetical can help to illuminate this point. According to data disclosed under the US Sunshine Act, Doctor A is listed as having consulted with and performed research activities for three different pharmaceutical companies, receiving a total of $600,000. Patient X and Patient Z are both treated by Doctor A and learn about those payments. Patient X reacts negatively to this, believing that Doctor A is a captive of industry who will simply push prescriptions that he does not truly support, and is only doing so because of the financial payments he received. Conversely, Patient Z is thrilled to learn that Doctor A is so well-regarded and valued by industry that multiple companies chose to work with him. Unlike Patient X, Patient Z feels that Doctor A is a true expert in the field and is reassured that Doctor A will be providing the best treatment possible. Is this situation an over-simplification? Perhaps. But the reactions of Patient X and Patient Z are both plausible, and should be considered in evaluating the value of the US Sunshine Act data from a patient perspective.

A recent study from the *Journal of General Internal Medicine*, "The Effects of Public Disclosure of Industry Payments to Physicians on Patient Trust: A Randomized Experiment,"[15] sheds some insight on this topic. The purpose of the authors' study was to determine how viewing the online public disclosures of payments to HCPs affected patients' trust ratings for HCPs, the medical profession, and the pharmaceutical and medical device industries. Study participants were randomized to view HCPs who received no payments, "low payments" ($250-$300), or "high payments" (greater than $13,000), and then assign trust ratings based on what they observed. The authors found that HCPs who received "high payments" received lower trust ratings than physicians who received no payments. The authors concluded that

> [d]isclosure of industry payments to physicians affected perceptions of individual physician honesty and fidelity, but not perceptions of competence. Disclosure did not affect trust ratings for the medical profession or the pharmaceutical and medical device industry.[16]

Similarly, the authors of "Public Awareness of and Contact With Physicians Who Receive Industry Payments: A National Survey" raise several important points on this topic. With regard to US Sunshine Act data, they explain that

> [s]ome patients will want to initiate conversations with their doctors, whereas others may view industry ties as unimportant relative to other considerations. In other areas of health care quality, such as cardiac surgery outcomes reporting, transparency initiatives appear to have had little effect on consumer decisions, yet have had interesting effects on providers.[17]

It is fair to say that if a reason for the US Sunshine Act was to make available to patients information about their physicians' ties to industry, it has succeeded, in that the information is available. However, more substantively, if the goal is to actually educate the American public about this issue, then that goal has not been achieved. According to research, most Americans

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15 Hwong et al., *supra* note 13.
16 *Id*.
17 Pham-Kanter et al., *supra* note 9, at 773.

do not know about the US Sunshine Act data, and even fewer seem to know if their physicians have received payments. Moreover, it is unclear how patients react to that information, or what impact, if any, it has on their healthcare decisions. Consequently, it is difficult to argue convincingly that the US Sunshine Act has truly impacted patients and their healthcare decisions.

The third articulated purpose of the US Sunshine Act data, and perhaps one that could be characterized as a secondary purpose, is to allow researchers and reporters to investigate the data and identify trends and patterns. There can be little doubt that researchers and reporters have taken advantage of the treasure trove of information provided by US Sunshine Act data. Every year CMS's release of the payment information is greeted with numerous news articles that often cast either, or both, industry and physicians in a negative light. For purposes of this paper, it is not necessary to review that coverage in any depth, but it is worth highlighting ProPublica, since Senator Grassley specifically cited that independent, non-profit newsroom in his 2016 statement.[18]

ProPublica has developed a "Dollars for Docs" database that contains information from CMS data to enable users to search for physicians and sort information in a variety of ways.[19] ProPublica also has published numerous articles about industry payments to physicians, including those featuring findings that there is an association between payments and higher rates of brand name prescribing, and that the drugs most aggressively promoted to physicians typically are not cures or medical breakthroughs.[20]

The question that we wish to raise about such findings, as well as similar ones from other researchers and reporters, is whether the existence of an association between payments and

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[18] Press Release, The Office of US Senator Charles Grassley, *supra* note 6.

[19] *Dollars for Docs*, PROPUBLICA, https://projects.propublica.org/docdollars/ (last visited July 28, 2017).

[20] *Dollars for Doctors: How Industry Money Reaches Physicians*, PROPUBLICA, https://www.propublica.org/series/dollars-for-docs (last visited July 28, 2017).

prescription is necessarily a bad thing. Watchdog groups and industry critics would certainly answer that it is, contending that industry's payments influence physicians to prescribe certain drugs against their best medical judgment. On the other hand, industry supporters and many physicians would assert that even if there is an association between payments and prescriptions, that is not necessarily a negative result; rather, the relationships between industry and physicians help to educate physicians about drug developments and the benefits of various medicines, and they also create opportunities for physicians and industry to collaboratively develop new treatments, medicines, and devices to improve patient health.

Moreover, industry supporters and physicians would likely also highlight other studies that offer a more nuanced version of whether there is a correlation between industry payments and prescription rates. For example, *Cancer* recently published a study titled, "The lack of a relationship between physician payments from drug manufacturers and Medicare claims for abiraterone and enzalutamide."[21] One of the authors of that study, Benjamin Davies, MD, wrote an article for *Forbes* in which he explained that, in the wake of studies showing that physicians who received industry payments prescribed branded drugs more frequently than generic versions, he and his colleagues researched the specific issue of branded variation (that is, drugs that do not have a generic version) in the context of prostate cancer drugs.[22] In describing what he and his fellow researchers found, Dr. Davies explained:

> we found very little correlation between payments to physicians and the amount of drug they dispense. **In fact, the median amount of prescribed drugs was exactly the same between those doctors who received money from the pharmaceutical companies and those that did not.** You can read the paper to

[21] Jathin Bandari et al., *The lack of a relationship between physician payments from drug manufacturers and Medicare claims for abiraterone and enzulatamide*, CANCER (forthcoming 2017), *available at* https://www.ncbi.nlm.nih.gov/pubmed/28749536.

[22] Benjamin Davies, *Can Pharma Influence Physician Prescribing? Unleashing New Data Using Prostate Cancer Drugs*, FORBES (August 4, 2017, 12:30 PM), https://www.forbes.com/sites/benjamindavies/2017/08/04/can-pharma-influence-physician-prescribing-unleashing-new-data-using-prostate-cancer-drugs/#1ae09418628c.

> get a feel for some of the other nuances of our findings but suffice it to say no strong relationship was seen. Within this narrow spectrum of prostate cancer drugs, pharma payments did not seem to make a difference at all to prescribing habits of doctors.[23]

(emphasis in original)

Another consideration about the effects of disclosure laws was identified in recent research from the University of Michigan's Ross School of Business. In a paper titled, "'Let the Sun Shine In': The Impact of Industry Payment Disclosure on Physician Prescription Behavior,"[24] the authors examined whether industry disclosure of financial payments has an effect on physician prescribing behavior. To do so, the authors analyzed prescriptions written by Massachusetts physicians over a four year period, following the introduction of a disclosure law in Massachusetts, compared to prescriptions written in New York and Connecticut, where there were no such requirements. The authors concluded that the Massachusetts disclosure law "resulted in a decline in the prescription of branded drugs in Massachusetts."[25] Further, the authors found that "the prescription of generic drugs in all three drug classes also declines as a result of the disclosure …."[26] The authors explained that the results "suggest that the disclosure law was effective in reducing the total number of prescriptions and possibly in driving physicians to subscribe away from branded drugs to generics."[27] However, the authors also acknowledged that

> the results support the notion that the change in prescription behavior was driven by self-monitoring among physicians to curb "over-diagnoses," rather than a change in how firms deliver payments. While on the one hand, this may be seen as a "good" outcome i.e., lower prescriptions especially of branded drugs are likely to reduce health care costs, there could be "bad" aspects in that self-

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23 *Id.*

24 Tong Guo et al., *Let the Sun Shine in: The Impact of Industry Payment Disclosure on Physician Prescription Behavior*, SSRN.COM (2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2953399.

25 *Id.* at 2-3.

26 *Id.* at 3.

27 *Id.*

> monitoring may shift physicians from "over diagnosis" to "under prescribing," leading perhaps to worse health outcomes. Thus, the contribution of this paper is in establishing *what* happened and proposing some explanations for *why* it happened, setting the stage for further investigation by researchers and policy makers into the benefits and costs of the legislation.[28]

(emphasis in original)

We do not reference this paper, and the concern it raises about physicians' under-prescribing, to try to undermine the various studies and papers that find an association between industry payments to physicians and prescription rates. Instead, we raise this point to highlight that disclosure laws like the US Sunshine Act create risks that may lead to unintended consequences, like physicians under-prescribing drugs, that may result in a decline in public health, which is clearly not the intent of the US Sunshine Act.

As the authors of the Michigan Ross study observed, there is much more that needs to be studied and researched in this area. To the extent that the success of the US Sunshine Act is measured by the opportunity the data affords to researchers, reporters, and policymakers for such analysis, it is a clear success. Only time will tell what additional patterns and trends will be identified. Ideally, those trends and patterns will help policymakers and legislators determine if the US Sunshine Act is helping to improve the public health, and whether there are changes that can be made to the law to ensure that patients are receiving the best possible care.

To examine the final purpose of the US Sunshine Act, let's return for a moment to Senator Grassley's most recent statement on the Open Payments data. In June 2017, he raised the very question of whether "it's possible to measure the success of the sunshine database."[29] To answer that, he first pointed out that "[w]e know that doctors continue to receive the research

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[28] *Id*. at 4.

[29] Press Release, The Office of US Senator Charles Grassley, *supra* note 8.

payments they use for patient benefit, just as they did before sunshine."[30] Senator Grassley then suggested a potential but unmeasurable argument for the success of the US Sunshine Act, stating: "[t]here's no way to know how many questionable payments were never made because someone didn't want to disclose them. If sunshine has deterred questionable payments while letting doctors continue to act for patient benefit, then it's a success."[31]

Senator Grassley's conditional statement of how to measure success is essentially impossible to prove. How would one prove the negative - that a questionable payment was not made due to the existence of the US Sunshine Act - other than by having a physician or company make such an admission? We have yet to come across such evidence, and we doubt that we ever will. But we submit that it is more important to focus on Senator Grassley's underlying point, namely, that the US Sunshine Act can be considered a success if it has served a broadly deterrent effect and helped to reduce potential conflicts of interest in the relationships between industry and physicians.

Answering that question again depends on one's perspective. Because overall payments have increased each year, and because some studies correlate payments with prescriptions, industry critics argue that the US Sunshine Act has not had its intended effect. They can buttress their argument by citing to the opioid epidemic,[32] or government investigations and prosecutions

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[30] *Id*. In previous years, Senator Grassley had also explained that "[t]ransparency shouldn't stop doctors from receiving a payment if they want to." Press Release, The Office of US Senator Charles Grassley, *supra* note 5. On that topic, some critics may argue that the US Sunshine Act has not been successful because the amounts reported by companies have increased every year, and many of those critics would presumably favor outright prohibitions or severe restrictions on industry payments to physicians rather than just disclosure of such relationships. However, banning, restricting, or even reducing the amount of payments from industry to physicians was not the intent of the Sunshine Act. Accordingly, the annual increases in the amounts disclosed, standing alone, is neither necessarily surprising nor negative.

[31] *Id*.

[32] On July, 13, 2017, Senator Grassley issued a press release titled, "Medicare Opioids Report Underscores Need for Grassley-Blumenthal Expanded Sunshine Payments Bill". Press Release, The Office of US Senator Charles Grassley, *Medicare Opioids Report Underscores Need for Grassley-Blumenthal Expanded Sunshine Payments Bill* (July 13, 2017), https://www.grassley.senate.gov/news/news-releases/medicare-opioids-report-underscores-need-grassley-blumenthal-expanded-sunshine. In that press release, Senator Grassley referenced a

of life sciences companies under anti-bribery and price fixing laws, as evidence that industry has continued to behave improperly and, therefore, the US Sunshine Act has not had a sufficient deterrent effect on questionable activities. Conversely, industry defenders respond that such conduct is aberrational and not representative of industry as a whole, and argue that it is not fair to portray all of industry in a negative light due to the isolated conduct of a few bad actors. At the same time, industry supporters agree that the US Sunshine Act has not had a deterrent effect on company behavior because the very reason industry is interacting with physicians is for the benefit of patient care, not for any improper purpose. Consequently, the disclosure of payments would never impact their decisions on providing financing to physicians.

At a minimum, it is clear that the US Sunshine Act has fulfilled Senator Grassley's intention that it "help[] … shin[e] light on a part of medicine most people haven't had the time or opportunity to consider." What that light reveals about the life sciences industry's relationship with physicians is a lot of data. What that data means very much depends on who is looking, what their perspective is, and what they are looking for. The ultimate value of the Sunshine Act to the public remains an open question. Recent studies support anecdotal evidence that the vast majority of American patients are unaware of the Open Payments data. Similar studies question the impact of such data on the decisions of even the small minority of informed patients. Mining the data to support enlightened policy-making appears to be years away, if possible at all. The data has been collected, organized, and presented for public scrutiny. The long-term success of the US Sunshine Act will depend on our collective ability to use the data for the public good.

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recent HHS report about the use of opioids by Medicare Part D beneficiaries and explained that the report supported the need for an expansion of the US Sunshine Act's reporting requirements to nurse practitioners and physician assistants. *Id*. Senator Grassley introduced such legislation, the Provider Payment Sunshine Act, S.308, in February 2017. *Id.*

EFPIA

There has been a very different transparency experience in Europe, which has been driven more by self-regulatory industry codes than laws. Nonetheless, over the past few years, several countries have adopted transparency laws, including France, Portugal, Slovakia, Denmark, Romania, Greece, and, most recently, Belgium.[33] Companies subject to those Sunshine laws have had to comply with widely varying, inconsistent reporting obligations. Meanwhile, in the face of those Sunshine laws, the pharmaceutical industry, the medical device industry, and the generic and biosimilar industry have responded in distinctive ways, each taking a unique approach to self-regulatory transparency.[34]

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[33] We extensively chronicled those transparency laws, most of which only apply to the pharmaceutical industry, in our prior White Papers and will not focus on them here. D. JEFFREY CAMPBELL, ESQ. & BRIAN P. SHARKEY, ESQ., A MILESTONE MOMENT (OR A DEAD JELLYFISH) FOR THE GLOBAL TRANSPARENCY MOVEMENT 65-67 (2016) [hereinafter 2016 WHITE PAPER]; CAMPBELL & SHARKEY, READY OR NOT, FULL SPEED AHEAD FOR THE GLOBAL TRANSPARENCY MOVEMENT 29-32 (2015) [hereinafter 2015 WHITE PAPER]; CAMPBELL & SHARKEY, DO START BELIEVIN': THE LIFE SCIENCES INDUSTRY'S JOURNEY TO GLOBAL TRANSPARENCY 22-28 (2014) [hereinafter 2014 WHITE PAPER]; CAMPBELL & SHARKEY, THE ONGOING GLOBAL TRANSFORMATION IN LIFE SCIENCES TRANSPARENCY 2-8 (2013) [hereinafter 2013 WHITE PAPER]; CAMPBELL & SHARKEY, THE TREND TOWARDS GLOBAL TRANSPARENCY: A CHALLENGING NEW WORLD FOR THE LIFE SCIENCES INDUSTRY 15-21 (2012) [hereinafter 2012 WHITE PAPER]. However, it is significant to note that there have been recent, important changes to some of the existing laws. For example, in France, the reporting requirements, which apply to both pharmaceutical and medical device companies, were altered so that the reporting of agreements, amounts identified in and paid pursuant to agreements, and benefits are all due on the same schedule: September 1 for items from the first six months of a year and March 1 for the last six months of the preceding year. In addition, in Portugal, the existing transparency reporting requirements were extended to the medical device industry in February 2017.

[34] We will focus on the approach taken by the pharmaceutical industry in this Paper. In our prior White Papers, we analyzed the approach to transparency taken by MedTech Europe, which represents the medical device and in vitro diagnostic industries in Europe, and Medicines for Europe, which represents the generic and biosimilar industries in Europe. *See* CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2015 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2014 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2013 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2012 WHITE PAPER, *supra* note 33.

In short, MedTech Europe has determined that the best way to approach these matters is to prohibit its member companies, as of January 1, 2018, from providing financial or in kind support directly to HCPs to attend third party organization events (with certain exceptions.) Further, MedTech Europe will require its member companies, beginning in 2018 for 2017 data, to report information about grants and donations that they provide to HCOs.

Medicines for Europe has adopted disclosure requirements for its members. The first set of reports are due in 2018 and cover 2017 data. In last year's White Paper, we detailed the similarities, and differences, between EFPIA's and Medicines for Europe's transparency reporting requirements. *See* CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 33, at 61-65.

The pharmaceutical industry association, EFPIA, has been the most aggressive and proactive in this space. It adopted its Disclosure Code in 2013 in an effort to provide a consistent, uniform approach to transparency reporting across Europe, and to demonstrate to European governments that transparency laws were not necessary because industry's self-regulation would shed appropriate light on its relationships with HCPs and HCOs. As the Director General of EFPIA recently explained:

> Discovering, developing and delivering new medicines to patients is challenging. It often requires collaboration and dialogue, with patients, with healthcare professionals and with healthcare organisations. The transparency of these relationships is vital to build understanding and ensure confidence. That is why EFPIA and its members have committed to disclosing annually transfers of value to health professionals and healthcare organisations.[35]

In short, the Disclosure Code requires member companies to report certain transfers of value that they make to HCPs (e.g., sponsorships and consultancy fees and expenses) and HCOs (e.g., sponsorships, consultancy fees and expenses, donations and grants) at the individual level, and to report all the amounts that they spend on research and development in a given country in the aggregate as one lump sum figure. EFPIA's national member associations transposed EFPIA's Disclosure Code provisions into their own national codes. The first year of data collection was 2015 and the first reports were released in 2016.[36]

In last year's White Paper, we examined those 2016 reports and tried to determine how effective EFPIA's self-disclosure system was, particularly in terms of how much data was reported at the individual level.[37] That is, because EFPIA's Disclosure Code is a voluntary form of self-regulation, and because the European Union ("EU") affords significant data protection

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35 Press Release, EFPIA, *Pharmaceutical companies continue to drive transparency and underline industry investment in Europe's Healthcare* (June 20, 2017), https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/20-june-2017-pharmaceutical-companies-continue-to-drive-transparency-and-underline-industry-investment-in-europe-s-healthcare/.

36 CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 33.

37 *Id.*

rights to its citizens under the governing EU Directive[38] (and soon-to-be effective Regulation[39]) and national laws, companies must, as a general matter, obtain the consent of an HCP in order to publicly disclose the individual level information called for in the Disclosure Code. If a recipient does not consent, the company must report that financial information in the aggregate, along with the information of any other HCPs who did not consent.

Consequently, the "consent rate," that is, the percentage of HCPs who consented to having their payment information disclosed at the individual level, reported by individual companies, or by national member associations reflecting all of the reports of their member companies, has become for some observers a key measure of success of EFPIA's transparency initiative. However, we are skeptics. For the reasons we outline below, we do not view "consent rates" as the ultimate augur of the success of EFPIA's Disclosure Code.

Before addressing that topic, however, we must emphasize that a myopic focus on "consent rates" as the key indicator of success of EFPIA's Disclosure Code fails to consider the immense amount of data that has been publicly disclosed pursuant to that Code. As a direct result of the EFPIA Disclosure Code, companies have reported billions of Euros (and other currencies) in interactions with HCPs and HCOs. But for the existence of the Disclosure Code, none of this data would be available for public review. Moreover, the public dialogue over the meaning and significance of the data would be absent, pre-empted by ignorance and secrecy. As a matter of fairness, any evaluation of the success of the EFPIA Disclosure Code must take into account the fact that the Code has brought forth enormous amounts of data that were previously

[38] Directive 95/46, of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281).

[39] Regulation 2016/679, of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC, 2016 (L 119).

not exposed for public review. To borrow one of Senator Grassley's rationales for adopting the US Sunshine Act, the EFPIA Disclosure Code must be considered successful from the perspective that it has helped to shine a light on an area of medicine that most people have not had the time or opportunity to consider.

Our analysis of HCP consent rates is driven not by a view that that metric is the paramount measure of the success of the EFPIA Disclosure Code, but by the central role it has taken in this debate. In initiating a consideration of the importance of consent rates, it is helpful to ponder a few consent-related questions and a few problems with the use of "consent" as a barometer of success. First, which company do you think is the most transparent: Company A, which has a 90% HCP consent rate, but reports 50% of the value of its TOVs at the individual level; Company B, which has an 80% consent rate, but reports 60% of the value of its TOVs at the individual level; or Company C, which has a 70% consent rate, and reports 70% of the value of its TOVs at the individual level. There is no correct or incorrect answer – it is a matter of perspective and personal opinion, but it does raise doubts about whether transparency can be truly measured by the rate at which HCPs consent to having pharmaceutical companies disclose the transfers of value provided to them at the individual level.

Second, is it fair for the pharmaceutical industry's transparency initiative to be considered a success – or a failure – based on whether or not HCPs consent to allowing their information to be published? The data protection laws in the EU establish that it is the right of the HCP to grant or withhold consent. Thus, it is actually HCPs – not companies – that control the consent rate. Critics counter that companies should take the position, as some have, that they will not work with HCPs unless they consent. The benefits, and drawbacks, of that approach raise a plethora of other issues, but for now it is sufficient to note that an argument can be advanced that it is

unfair to judge the success of EFPIA's voluntary transparency initiative based on the decisions and actions of others that are outside the control of the pharmaceutical industry.

Layered on top of these philosophical questions are other very practical ones. First is the threshold issue of how one calculates a "consent rate," and whether it is even possible to get an accurate consent rate. In that regard, the consent rate that is often referenced cannot, in most cases, be accurately calculated based upon the data provided in the EFPIA disclosure reports. On that point, one would reasonably expect the consent rate to be calculated by dividing the number of individual physicians who consented to disclosure by the total number of individuals reported (consenting HCPs + non-consenting HCPs = total number of HCPs). However, due to the structure of the EFPIA reporting template, when data is reported in the aggregate it is not always possible to get a true count of the total number of unique HCPs reported on by a company.

For example, if Company A's report identifies "10" as the number of HCPs reported in the aggregate for each of the four categories of reportable spend,[40] one can only say with certainty that there are between 10 and 40 unique HCPs reflected on that report. In other words, the 10 HCPs who received Registration Fees but were reported in the aggregate could be the same 10 HCPs who received the other three categories of spend. However, it could be that the 10 HCPs who were included within "10" in each of the four reporting categories are unique, whereby the company actually had 40 non-consenting HCPs, not 10. Or the number of unique, non-consenting HCPs could be somewhere in the range between 10 and 40.

When this issue is considered at the national level, the problems are magnified. An individual physician who gives his or her consent to Company A may decide to not provide

[40] The four categories, and corresponding columns, on the EFPIA template, are: Registration Fees; Travel & Accommodation; Fees for Service and Consultancy; and Related Expenses for Fees for Service and Consultancy.

consent to Company B. There is no requirement in any of the industry codes or data protection laws that prevents an HCP from giving consent to one, or more, of the companies with whom he or she worked, but declining to give consent to others. In that sense, an HCP has the ability to "cherry pick" his or her consent among companies. That possibility of cherry-picking means that it is not possible, with any degree of certainty, to calculate a national HCP consent rate because it is impossible to know how many HCPs provided consent to some but not all of the companies with whom they worked. On that point, if Dr. M provided consent to Company A but refused consent to Company Y and Company Z, is Dr. M considered a consenting or non-consenting HCP in calculating the HCP consent rate? Accordingly, between the structural issues of the EFPIA template and the possible cherry-picking of consent by HCPs among companies, it is impossible to ascertain a reliable national HCP consent rate.

United Kingdom

In spite of the incalculability of a true consent rate, the metric remains a focus of debate for some stakeholders and observers. With respect to the United Kingdom, for a number of years member companies of the local EFPIA member association, the Association of the British Pharmaceutical Industry ("ABPI"), disclosed the aggregate 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. Under this aggregate reporting approach, companies did not identify the names of the particular HCPs they had supported. However, once EFPIA adopted its Disclosure Code, the ABPI transposed those requirements into its own local code, and member companies reported their 2015 data, at the individual level, in

2016. We chronicled those reports, and the media reaction to the revealed data, in last year's White Paper.[41]

On June 30, 2017, the ABPI issued a press release titled, "Significant increase in healthcare professionals disclosing partnerships with the pharmaceutical industry."[42] The press release included 3 bullet points at its outset concerning the data revealed by the ABPI member companies:

- An estimated 65% of healthcare professionals consent to disclose payments and benefits in kind – and they receive 60% of the (non-R&D) payments made to healthcare professionals;
- 82% of payments and benefits in kind not related to research and development is disclosed on a named, individual healthcare professional and organizations basis;
- Three quarters (74%) of payments and benefits in kind are related to industry's work with healthcare professionals and organizations to research and develop new medicines.[43]

As to the consent rate, the ABPI emphasized that the 65% rate was an increase from last year's 55% rate.[44] As to the overall amount of spend, companies reported £454.5m, an increase of 25% from last year. Spend for research and development increased from last year's £254m to £338.1m. The remaining £116.5m was broken down as follows:

- Registration fees – £3.5m;
- Sponsorship agreement with HCOs/3rd parties – £21.1m;
- Travel and accommodation – £10m;

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41 Last year's White Paper also examined the data, and reaction to the data, from the first round of reports for many other EFPIA countries. CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 33.

42 Press Release, ABPI, *Significant Increase in Healthcare Professionals Disclosing Partnerships with the Pharmaceutical Industry* (June 30, 2017), http://www.abpi.org.uk/media-centre/newsreleases/2017/Pages/SIGNIFICANT-INCREASE-IN-HEALTHCARE-PROFESSIONALS-DISCLOSING-PARTNERSHIPS-WITH-THE-PHARMACEUTICAL-INDUSTRY.aspx.

43 *Id.*

44 We will discuss the ABPI's 2016 consent rate *infra*.

- Donations and grants – £29.4m;
- Fees for service and consultancy – £39.9m;
- Expenses related to consultancy fees – £9.6m; and
- Joint Working – £2.9m.[45]

A total of 115 companies reported, and the average amount reported per company was £4m. Companies that reported more than £5m invested, on average, 75% on research and development. In the ABPI's press release outlining this data, Mike Thompson, the group's Chief Executive, stated:

> We have seen a significant step change in behaviour in the past year which we welcome wholeheartedly and should be applauded.
>
> Increasingly doctors, nurses and other healthcare professionals are doing the right thing in disclosing their collaborations with industry. I am by no means complacent however – we can and we should be achieving greater transparency. We remain committed to achieving a 100% consent rate in relation to the vital work that the industry does with HCPs and HCOs for the benefit of patients. Greater commitment to this ambition from the NHS, Royal Colleges and professional bodies gives me hope that, collectively, we will achieve this.
>
> The industry's commitment to research and development in order to bring the newest, most effective medicines to patients in this country is also indicated in these figures today.
>
> With more than £300 million spent in 2016 on partnerships with HCPs and HCOs on the scientific discovery of life-changing medicines last year, the industry remains committed to really making a difference to the lives of patients and their families in the UK.[46]

The ABPI also issued a second press release on June 30 from of a representative of the Academy of Medical Royal Colleges.[47] In that press release, the representative observed that he

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45 *Id.*

46 *Id.*

47 Press Release, ABPI, *Declaring Conflicts of Interest* (June 30, 2017), http://www.abpi.org.uk/our-work/news/Pages/Declaring-Conflicts-of-Interest.aspx.

was pleased that the consent rate improved by 10% from 2015 data to 2016 data and expressed his hope that it would continue to improve.[48]

As with the first round of reporting last year, the press once again covered the ABPI's release of the data reported by its member companies.[49] Some of the coverage objectively reported the data that the ABPI announced, focusing on the amount spent by particular companies or the amounts reported for specific HCPs.[50] However, some press articles were more critical of the data and the ABPI's transparency initiative, with an article from *The Telegraph*, titled, "Big pharma cash and hospitality to doctors rises as one in three refuses to reveal earnings,"[51] being a good example of that approach. This article focused on the fact that the overall amount reported for 2016 rose more than £116m from 2015, and observed that NHS England[52] has taken the position that companies should only work with HCPs who consent and refuse to work with HCPs who do not consent to having their information published. The article included a statement from a NHS England spokesperson, who declared:

> The public rightly expect the highest standards of behaviour in the NHS and an increase in health professionals declaring these payments would be welcomed.

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48 *Id*.

49 *See, e.g.*, Georgina Campbell, *Oxford doctor gets £128,000 payout from drug groups*, THE OXFORD TIMES (July 1, 2017), http://www.oxfordtimes.co.uk/news/15384554.Oxford_doctor_gets___128_000_payout_from_drug_groups/; Nigel Hawkes, *More doctors are disclosing payments from drug companies*, THE BMJ (June 30, 2017), http://www.bmj.com/content/357/bmj.j3195; *More healthcare professionals happy to disclose pharma partnership details, says ABPI*, EPM MAGAZINE (June 30, 2017), http://www.epmmagazine.com/news/more-healthcare-professionals-happy-to-disclose-pharma-partn/; James Paton, *Drugmakers' Payments to U.K. Health Groups and Doctors Climb 25%*, BLOOMBERG (June 30, 2017), https://www.bloomberg.com/news/articles/2017-06-30/drugmakers-payments-to-u-k-health-groups-doctors-climb-25; Richard Staines, *More UK doctors disclosing pharma fees, but a third still anonymous*, PHARMAPHORUM (July 3, 2017), https://pharmaphorum.com/news/abpi-hails-step-change-doctors-disclosing-pharma-payments/; Jo Stephenson, *Pharma payments to nurses increase to at least £3m*, NURSING TIMES (July 5, 2017), https://www.nursingtimes.net/news/reviews-and-reports/pharma-payments-to-nurses-increase-to-at-least-3m/7019320.article.

50 *Id*.

51 Henry Bodkin, *Big pharma cash and hospitality to doctors rises as one in three refuses to reveal earnings*, THE TELEGRAPH (June 30, 2017), http://www.telegraph.co.uk/news/2017/06/30/big-pharma-cash-hospitality-doctors-rises-one-three-refuses/.

52 NHS England is an independent organization established by Parliament, independent from Government, that is charged with the stewardship of the National Health Service. Each year, the Government sets out its expectations of NHS England, and the funding it receives, in the form of a mandate that is put before Parliament.

> The NHS is determined to be a world leader on managing any potential conflicts of interest and our new strengthened guidance, which came into force earlier this month, makes clear what behaviour is and is not acceptable so appropriate action can be taken if wrongdoing is found.[53]

The article also quoted industry critic Dr. Ben Goldacre, who opined that

> [a]ll the same old problems remain[.] It is ridiculous that doctors working in the NHS are allowed to take money from pharma companies and withhold that fact from patients and members of the public. Of course, just because you take money it doesn't mean you are corrupt, but it is a risk and it should be openly declared so that others can access it.[54]

The Telegraph article also asserted that transparency advocates have begun to call for a law similar to the US Sunshine Act. In addition to presenting critical points of view about the ABPI's data, the article included a statement from Mr. Thompson, the ABPI's Chief Executive, who highlighted the increase in the consent rate and characterized the 2016 data as a "milestone for us on a journey towards transparency."[55]

Several other press articles quoted Mr. Thompson as he attempted not only to explain the benefits and purposes of the ABPI's transparency initiative, but also to put the reported data in an appropriate, overall context. For example, in another article, one that noted that industry critics were advocating for a disclosure law like the US Sunshine Act, Mr. Thompson stressed that HCPs had consented at a higher rate than in the first year of reporting.[56] In another article that detailed the amounts that the pharmaceutical industry reported for transfers of value to nurses, Mr. Thompson explained that there was no "bad practice" involved with industry's relationship with HCPs but rather the relationship is "something to celebrate."[57] He elaborated that

> [t]his is not about us clamping down on bad practice – actually we don't think there is any bad practice. But in a sense the only way you can prove that is – in

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53 Bodkin, *supra* note 51.
54 *Id*.
55 *Id*.
56 Staines, *supra* note 49.
57 Stephenson, *supra* note 49.

> the end – by having this level of transparency. If there is anything that was a bit funny then getting to a position where it is all transparent is the surest way of ensuring it doesn't happen. We're very proud of what we do and proud about the healthcare professionals we work with – these are amazing people, they have fantastic insights. I think patients would be incredibly pleased that the expertise they have is being brought to bear to try and bring better medications through to patients in the future[.][58]

He also commented on the issue of consent, stressing that "[w]e require the consent of healthcare professionals to disclose this data so the Data Protection Act means that if they chose not to do it, it means there is absolutely nothing we can do[.]"[59]

The ABPI data, and the reaction to it, provides a number of subjects for us to further analyze. First, there is the consent rate issue. As we touched upon earlier, for the first two years of EFPIA and ABPI reporting, much of the perceived success, or lack of success, has been filtered through the prism of a particular country's consent rate. The facile analysis essentially is that the higher the consent rate is, the more successful the transparency initiative is, and the lower the consent rate is, the less successful the transparency initiative. We submit that this is a gross over-simplification, for many reasons.

First, as noted previously, the right to consent or refuse to consent belongs to the individual HCPs, so it is not fair to judge how transparent *industry* is by focusing only on whether or not *HCPs* consent. There can be many reasons why an HCP would not consent to having the transfers of value that he or she received published at the individual level. From a cultural perspective, while some European countries are open about and accustomed to sharing this type of information, others are far less so. Frankly, many individuals are not comfortable publicly disclosing their salary information. And when we try to explain this reporting paradigm to individuals who are not involved in this field, the most common, and very logical, response

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58 *Id.*

59 *Id.*

that we get is something along the lines of, "why would doctors ever voluntarily consent to having this information published?"

Putting aside the fact that the consent rate measures the decisions of HCPs, not the pharmaceutical companies, and putting aside the fact that the pharmaceutical industry has voluntarily chosen to pursue transparency, an initiative that has not been replicated by other industries, another key problem with using the consent rate as an absolute measurement of success is the fact that consent rates can be calculated in different ways. As noted previously, due to the structure of the EFPIA reporting template, as transposed by local industry groups, it is impossible to glean a true consent rate per company from the disclosure reports, much less a national consent rate from the amalgamated reports of member companies.

This problem was brought into focus by the 2016 ABPI reporting experience. In June 2016 the ABPI declared that its members had a 70% consent rate for 2015 data. However, in March 2017, the ABPI announced that the consent rate was actually 55%, not 70%. Specifically, the ABPI issued a press release titled, "Pharmaceutical Industry Disclosure UK: six month figures show increase in research spend and lower than estimated number of healthcare professionals disclosing payments from industry."[60] The ABPI explained that in January 2017, it had reviewed the data in its disclosure database and had determined that there was a slight increase in spending on research and development over that originally reported, and a "lower than originally estimated rate of healthcare professionals willing to disclose."[61] As a result, the ABPI had RAND Europe analyze the disclosed data in January 2017 to identify any changes from when the data was first examined in June 2016. That analysis revealed that there had been

[60] Press Release, ABPI, *Pharmaceutical Industry Disclosure UK: six month figures show increase in research spend and lower than estimated number of healthcare professionals disclosing payments from industry* (March 27, 2017), http://www.abpi.org.uk/media-centre/newsreleases/2017/Pages/Pharmaceutical-Industry-Disclosure-UK-six-month-figures-show-increase-in-research-spend-and-lower-than-estimated-number-of.aspx.

[61] *Id.*

little change in the amounts of spend, as the total amount disclosed by all companies increased from £340.3m to £363m, with the largest increase being in the area of research and development, which increased from £229.3m to £254m. The other categories of spend had minimal, if any, increases.

But the more significant aspect of the review was that the ABPI was forced to re-calculate the consent rate from what it had announced in July 2016 – 70% – downward to 55%. Specifically, the ABPI revealed that

> *RAND Europe's analysis has highlighted differences between companies in how they recorded information relating to the percentage of HCPs that did not give their consent to publish details of payments or benefits in kind they received. The data from the companies is accurate, but recorded in different ways, which makes calculating industry-level information from the amalgamated data difficult.* Correcting for this has resulted in a lower than originally calculated estimate of the overall HCP consent rate. At launch, it was estimated that around 70% of the HCPs receiving a payment or benefit in kind from industry in 2015 gave their consent to publish their details in relation to this. However, following recalculation to correct for inconsistencies in how the data was recorded, this figure is around 55%.[62]

(emphasis added)

The press release included the following statement from the Chief Economist of RAND Europe:

> *There were differences in how individual companies had interpreted the data request, which led to inconsistencies in the dataset.* The impact of correcting these inconsistencies means that the proportion of healthcare professionals consenting to be named in the dataset in June 2016 was typically 55 per cent. The analysis showed no change to this figure for January 2017.[63]
> (emphasis added)

In addition to discussing the re-calculation of the consent rate, Mr. Thompson of the ABPI reiterated the group's commitment to transparency and disclosures at the individual level. He reasoned that

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62 *Id.*
63 *Id.*

> [i]t is important for us to review and audit the *Disclosure UK* data in light of the greater transparency that we are trying to achieve and continually work to improve the information we are making publicly available. Our intent is to ensure that 100% of UK healthcare professionals who receive a payment or benefit in kind for the invaluable work they do with pharmaceutical companies in developing medicines and improving patient treatment gives their consent for us to publish their details. We will continue to work with the NHS, particularly in the light of their new conflicts of interest guidance which advocates disclosing on our database, to make this a reality. In the meantime, we are working with our European colleagues to ensure that there are fewer possibilities for data inconsistencies in the future.[64]

The statements from RAND Europe's President and Mr. Thompson are particularly instructive, as they illuminate why the consent rate should not be used as the dispositive arbiter for the success of the pharmaceutical industry's voluntary transparency initiative. Different companies can, and have legitimately, interpreted, recorded, and calculated consent rates in various ways, which necessarily means that any purported calculation of a true consent rate for a particular country is inherently flawed.

Moreover, companies have taken varying approaches with respect to obtaining consent. Some are quite committed to gaining consent, as they thoroughly explain the benefits and purposes of disclosure and strongly encourage the HCPs with whom they work to consent. Others are less concerned about obtaining consent and less willing to aggressively encourage HCPs to consent. Further, as discussed previously, an HCP could choose to consent to a company that is strongly committed to transparency, while declining to consent to a company that is less aggressive in seeking consent, even though the HCP received transfers of value from both companies in the same year. Consequently, labelling high consent rates as a *sine qua non* for a voluntary transparency initiative is an exercise in futility. The data necessary to calculate reliable consent rates is simply not available.

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64 *Id.*

That being said, we do believe that consent rates can be used as one part of the evaluation of the ABPI's, and EFPIA's, transparency initiative. General trends in rates of consent could be meaningful. Unfortunately, the second round of data for EFPIA reporting has not revealed any clear trends with respect to the consent rates, as those reported for Norway (66% to 71%), Poland (22% to 23%), Bulgaria (60% to 66%), Spain (20% to 35%), and Lithuania (65%-75%) all improved from 2015 data to 2016 data. Meanwhile, the consent rate declined in Germany (approximately 33% to 25%) and remained low in countries like Croatia (11%) and Austria (19%). Thus, it would be difficult for anyone to argue that the EFPIA disclosure initiative has not been successful in view of the improvements in consent rates for several countries, though there were also decreases and continued low consent rates in other countries.

Another important consideration for the success of the EFPIA disclosure initiative is what steps can be taken to increase transparency. One suggestion that has been referenced in the United Kingdom is that companies should not work with HCPs who do not consent, a position that has been adopted by NHS England. GSK is an example of a company that has taken this approach, as it applies

> a "no disclosure consent, no contract" principle to enable and drive disclosure at the individual level. In practice this means:
> - Where individual named disclosure is required under the EFPIA Disclosure Code, we will actively seek the necessary consent from each HCP with whom we work.
> - We will not work with HCPs where consent is not given. Where consent is given but subsequently withdrawn we will not work then work with that HCP on activities covered by individual disclosure for a period of one year.[65]

It is difficult to argue against the notion that if all companies took this approach, the overall consent rate would improve. However, the ABPI has resisted suggestions that it should pressure or compel its member companies to follow suit. In that regard, there is the concern that

[65] Overview of GlaxoSmithKline's Approach to EFPIA Disclosure, GLAXOSMITHKLINE, http://www.gsk.com/en-gb/responsibility/our-behaviour/engaging-with-healthcare-professionals/europe/ (last visited August 1, 2017).

including such a "no consent, no contract" provision in an industry code could raise other legal complications, including anti-trust and collusion. Consequently, it seems that the determination about whether to work with an individual HCP based on whether or not he or she consents to individual level disclosure is a decision best left to the discretion of the individual companies. Although such a policy certainly advances the principles of transparency, there could be compelling reasons why a company would want to, or need to, work with an HCP who does not consent to individual level disclosure, particularly companies specializing in rare diseases where the HCP population with whom they could work to develop life-improving or life-saving medicines is very small.

Spain

Spain has taken a different approach to improving the amount of transparency offered by an industry code. The local EFPIA member, Farmaindustria, announced in May 2016 that it had approved changes to its Code of Practice that seemingly require individual level reporting for all TOV, except for research and development, beginning with 2018 reports covering 2017 data.[66] The evolution of the Spanish approach to consent was based on a decision released by the Spanish Data Protection Agency ("SDPA") that found that the legitimacy of disclosure on an individual basis is supported by the current EU and Spanish data protection framework, such that it will only be necessary for companies to inform HCPs that the payments they receive will be disclosed at the individual level rather than asking HCPs to consent, so long as reporting companies take certain steps concerning protection of the privacy of HCPs. As to the SDPA's opinion, Farmaindustria observed that "[t]he report from the Spanish Data Protection Agency has

[66] Press Release, Farmaindustria, *Farmaindustria refuerza su compromiso con la transparencia aprobando la publicación individualizada de las transferencias de valor a profesionales sanitarios* (May 26, 2016), http://www.farmaindustria.es/web/prensa/notas-de-prensa/2016/05/26/farmaindustria-refuerza-su-compromiso-con-la-transparencia-aprobando-la-publicacion-individualizada-de-las-transferencias-de-valor-a-profesionales-sanitarios/.

therefore changed the paradigm, and makes it easier for the sector to undertake the necessary changes to fulfill the maximum aspiration of this initiative: the individualization of all data."[67] Accordingly, Farmaindustria declared that its new approach is "a pioneering step without precedents," and that the amendment to the Code further demonstrated that industry was committed to increasing transparency and improving its disclosure initiative.[68]

Thereafter, Farmaindustria amended its Code to reflect this change. Specifically, the language in the "Form of Disclosure" section of Farmaindustria's Code now states:

> In the case of Healthcare Professionals, in accordance with Directive 95/46/EC article 7f), on the protection of individuals with regard to the processing of personal data and on the free movement of such data, there is a legitimate interest for the companies subject to the Code, recognized by the report issued by the SDPA, of 22 April 2016 (Code Annex I), so that the Healthcare Professionals´ consent is not necessary for the disclosure, on an individual basis, the Transfers of Value made to Healthcare Professionals. In any case, pharmaceutical companies will inform Healthcare Professionals, under Organic Law 15/1999, of 13 December, for Personal Data Protection, that their data will be disclosed in accordance with the Code.[69]

Similarly, in announcing the data that its member companies reported for 2016, Farmaindustria emphasized that

> in the following publication, which will take place in June 2018 whilst … using 2017 data, the entirety of these collaborations will be made public in an individualized way in order to achieve maximum transparency. In any case, the percentage of value transfers published on an individual basis has already grown significantly, from 20% to 35%, between 2015 and 2016, an increase that responds to the growing knowledge and endorsement of health professionals of the Transparency initiative adopted by the pharmaceutical industry with activity in Spain.[70]

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67 *Id.*

68 *Id.*

69 FARMAINDUSTRIA, CODE OF PRACTICE (2016).

70 Press Release, Farmaindustria, *R&D and training continue to be the basis for collaboration between the pharmaceutical industry and healthcare professionals* (June 30, 2017) http://www.farmaindustria.es/web_en/documents/press-releases/2017/06/30/rd-training-continue-basis-collaboration-pharmaceutical-industry-healthcare-professionals/.

Thus far, no other EFPIA industry groups have followed Farmaindustria's pioneering step and shifted to individual level reporting for all HCPs, based on a positive opinion from the local national data privacy authority. It certainly seems that doing so would be an excellent way for national industry groups to demonstrate to their governments that they are strongly committed to the disclosure initiative and are seeking ways to be even more transparent, and may be a step that local industry groups would be more willing to embrace or pursue if there was the possibility that their government was considering the adoption of a Sunshine law.

Germany

Another interesting consent-related development occurred in Germany. Following the first round of disclosures in 2016, CORRECTIV and *Spiegel Online* used the data reported by the member companies of the German industry group to create a searchable database.[71] The database enables users to search for HCPs by name and see the amounts that have been reported by pharmaceutical companies for individual HCPs. Similar databases were also developed for Austria and Switzerland.[72]

Not content with listing the HCPs who had consented to individual level disclosure, in May 2017 CORRECTIV launched its "Zero Euros Doctors" project.[73] With this project, CORRECTIV created a new database for HCPs in Germany who do *not* accept TOVs from the pharmaceutical industry. According to CORRECTIV, after it launched its database last year featuring HCPs who had received TOVs from industry, many HCPs responded by asking to

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[71] Markus Grill et al., *Doctors eagerly welcome big pharma's money*, CORRECTIV (December 15, 2016), https://correctiv.org/en/investigations/euros-doctors/articles/2016/12/15/embracing-millionsbe-embraced/.

[72] *Find your doctor (Germany)*, CORRECTIV, https://correctiv.org/en/investigations/euros-doctors/database/; https://correctiv.org/en/investigations/euros-doctors/database/at/ (last visited August 1, 2017); *Find your doctor (Austria)*, CORRECTIV, https://correctiv.org/en/investigations/euros-doctors/database/ch/ (last visited August 1, 2017); *Find your doctor (Switzerland)*, CORRECTIV, https://correctiv.org/en/investigations/euros-doctors/database/ch/ (last visited August 1, 2017).

[73] Markus Grill et al., *Neue CORRECTIV-Datenbank zeigt erstmals Ärzte in Deutschland, die kein Geld von der Pharmaindustrie annehmen*, CORRECTIV (May 29, 2017), https://correctiv.org/recherchen/euros-fuer-aerzte/artikel/2017/05/29/interesse-am-konflikt/.

appear in the database – but with an entry that they did not receive any funds from industry. Those HCPs wanted that zero euro notation to dispel the notion that they had received funds from industry but had not granted consent to individual level disclosure.

Accordingly, CORRECTIV decided to launch its "Zero Euro Doctors" project, whereby HCPs who did not receive any money from industry can be listed as having received zero euros. CORRECTIV has noted that it does not perform any type of review as to the veracity of an HCP's representation that he or she did not receive any industry funding; rather, CORRECTIV simply accepts the HCP's representation. In addition to Germany, CORRECTIV developed the same databases for Austria and Switzerland so that HCPs in those countries can be listed as having not received any TOVs from industry.[74]

Even though this is not an initiative developed by industry, it is possible that the existence of CORRECTIV's two databases could motivate HCPs who receive monies from industry to consent to individual level disclosure. That is, the existence of the Zero Euros database could encourage an HCP who receives monies from industry to consent to individual level disclosure because the HCP knows that patients could search and find if his or her name was listed in one of the two databases. It could be argued that there would be no reason for an HCP to not consent if patients knew that the HCP had the option to be listed as having not received any monies, whereby the absence of an HCP's name in Zero Euros database would lead the patient to believe the physician had received monies but simply refused to consent.

Of course, a German HCP's decision about whether to consent or even work with industry, in view of the CORRECTIV databases, depends on a multitude of factors. For example, if German patients show the same level of indifference to these databases as the US patient population has to the US Sunshine Act data, the existence of the databases would not

[74] *Id.*

provide much more motivation to an HCP to consent. Further, even if an HCP knows that he or she would not appear in either database by refusing to consent, that HCP might still be unwilling to consent because of concern over either the amount that would be identified, or an unfounded perception of favoritism toward a particular company. Thus, it will be interesting to see if these databases will help to improve consent rates, and the overall transparency experience in Germany, Austria, and Switzerland. Moreover, if there is a positive causal relationship between the databases and improved consent rates, it will also be interesting to see if they are replicated in additional countries.

NHS England

Another way to address the consent rate issue is, as some critics in the United Kingdom have suggested, to adopt a Sunshine law. Although the government has not pursued that approach, it is important to point out a related transparency measure that has been advanced by NHS England. In September 2016, NHS England announced a major consultation on proposals to strengthen the management of conflicts of interests and ensure ethical behavior by its staff.[75] The consultation afforded stakeholders an opportunity to comment on proposals put forward by NHS England with respect to gifts, hospitality, employment, sponsorship, and other issues. Discussing the consultation, Sir Malcolm Grant, the Chair of NHS England, stated:

> The public expects the highest standards of behaviour in the NHS, but we know there are times when the NHS has failed to meet this expectation. We have a responsibility to use the £110bn healthcare budget provided by the taxpayer to the best effect possible for patients, with integrity, and free from undue influence. Spending decisions in healthcare should never be influenced by thoughts of private gain. We want to hear from as wide a range of people and organisations as possible so they can help us bring greater transparency, and clearer guidelines for staff in a way that will benefit taxpayers, patients and the health service.[76]

[75] Press Release, NHS England, *NHS England takes next step on tackling conflicts of interest* (September 20, 2016), https://www.england.nhs.uk/2016/09/conflicts-of-interest/.

[76] *Id.*

On February 9, 2017, NHS England announced that it had adopted new guidance about conflicts of interest that eventually came into force on June 1, 2017.[77] Significantly, this guidance does not require life sciences companies to do any kind of Sunshine reporting, but the guidance and attendant disclosures will shed additional light on the relationship between industry and NHS England staff. The guidance applies to the following NHS bodies: Clinical Commissioning Groups; NHS Trusts and NHS Foundation Trusts; and NHS England. In addition to the organisations, certain aspects of the guidance apply to the individuals who work for and on behalf of those organisations. The guidance does not apply to other organisations, nor does it apply to HCPs who do not work for such organisations.

In a press release outlining the new guidance, Sir Malcolm Grant stated that

> [t]he public rightly expects NHS staff to behave appropriately and use the healthcare budget to achieve the best outcomes for patients. While behaviour is exemplary in virtually all instances, there are times when more could have been done to prevent standards slipping. We have invited comment from the public, patients, NHS staff and other stakeholders on our proposals and have on what they have told us. This new guidance will bring a consistent approach to conflicts of interest and ensure that the public can have faith in the integrity of the NHS.[78]

The press release also noted that the new guidance "[u]nerlin[es] NHS's England's support for the Disclosure UK scheme, which publishes details of payments made to staff by the pharmaceutical industry[.]"[79]

Among other things, the guidance prohibits NHS staff from accepting gifts that may affect, or be seen to affect, their professional judgment, and prohibits their acceptance of gifts from suppliers or contactors doing business with a NHS organization.[80] As to hospitality, the

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[77] *Managing conflicts of interest in the NHS*, NHS ENGLAND, https://www.england.nhs.uk/ourwork/coi/ (last visited August 2, 2017).

[78] Press Release, NHS England, *NHS England publish new guidelines on tackling conflicts of interest* (February 9, 2017), https://www.england.nhs.uk/2017/02/coi-guidelines/.

[79] *Id*.

[80] NHS ENGLAND, MANAGING CONFLICTS OF INTEREST IN THE NHS – GUIDANCE FOR STAFF AND ORGANISATIONS 11 (2017).

guidance acknowledges that the delivery of services by NHS sometimes requires NHS staff to work with a range of partners, including industry, in various settings, often outside of traditional work hours. Therefore, the guidance further acknowledges NHS staff will sometimes appropriately receive hospitality, including the offer of meals, refreshments, travel, accommodation, and other expenses in relation to attendances at meetings, conferences, education, and training events. The guidance provides that meals and refreshments under £25 do not need to be declared; meals and refreshments between £25 and £75 can be accepted but must be declared; and that meals and refreshments over £75 should be refused, unless senior approval is given in exceptional circumstances. The guidance also provides restrictions and declaration requirements for travel and accommodation, including a requirement to declare the value of such costs.[81]

Third, as to outside employment, which covers activities like consultancy work, the guidance requires that the following information should be declared by NHS staff: a description of the nature of the outside employment (who it is with, a description of duties, times commitment); relevant dates; and any other relevant information. Significantly, the amount of earnings from outside employment do not have to be declared. The guidance provides template declaration of interest forms and register of interest forms for NHS staff and organisations, respectively. The guidance also states that "organisations should seek to ensure that staff who are subject to wider transparency initiatives such as the ABPI Disclosure UK scheme are aware of and comply with them[.]"[82] Although not a Sunshine law that is in place in countries like the United States, France, and Portugal, the guidance from NHS England does impose financial transparency reporting requirements on recipients, and it will add to the overall amount of light

[81] *Id*. at 13.
[82] *Id*. at 27.

that is shone on the interactions between industry and HCPs in the United Kingdom. That leads to the next question, one that has been raised in the United Kingdom in the wake of the ABPI's announcement of the data from its member companies' 2017 reports: will the United Kingdom give up on the ABPI's transparency initiative and adopt a Sunshine law?[83]

European Legislation

This past year has seen several developments on the legislative front, as medical device companies are now subject to reporting under Portuguese law[84] and the French reporting system has been significantly revamped, whereby the reporting of amounts listed in agreements and the amounts paid out pursuant to such agreements now must be reported.[85] In addition, Sunshine legislation has been introduced in Ireland, though it is the HCPs who would have the reporting obligation in that proposed transparency program.[86] But arguably the most significant legislative development in European transparency reporting occurred in Belgium.[87] In December 2016, the Belgian government adopted a Sunshine Act that effectively codifies the disclosure requirements that had been adopted by the local pharmaceutical, medical device, and generic industry groups.[88]

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[83] It is important to note, as we have extensively chronicled in our prior White Papers, that some European countries have adopted their own Sunshine law that essentially preempt EFPIA reporting in those jurisdictions. *See* CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2015 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2014 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2013 WHITE PAPER, *supra* note 33; CAMPBELL & SHARKEY, 2012 WHITE PAPER, *supra* note 33.

[84] Decreto-Lei n.° 5/2017 de 6 de Janeiro, https://dre.pt/application/conteudo/105711790 (Port.).

[85] CODE DE LA SANTE PUBLIQUE art. 1453 [C.S.P.] (Fr.), https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000034273056&categorieLien=id; Note D'Information N DGS/PP2/2017/180 du mai 2017, MINISTERE DES SOLIDARITES ET DE LA SANTE, http://circulaires.legifrance.gouv.fr/pdf/2017/06/cir_42320.pdf.

[86] Medical Practitioners (Amendment) Act 2017 (Ir.), available at http://www.irishstatutebook.ie/eli/2017/act/10/enacted/en/html.

[87] The adoption of Sunshine laws has not been confined to Europe over the past year, as such requirements have been adopted by governments in South Korea, Indonesia, and the State of Minas Gerais in Brazil.

[88] Wet houdende diverse bepalingen inzake gezonheid [Law Concerning Various Provisions on Health] of Dec. 18, 2016, BELGISCH STAATSBLAD [B.S.] [Official Gazette of Belgium], December 27, 2016, https://www.betransparent.be/wp-content/uploads/2017/01/Moniteur-Belge-2016-12-27-Belgisch-Staatsblad.pdf.

On June 23, 2017, a Royal Decree implementing the Belgian Sunshine Act was published in the Belgium Official Journal and took effect.[89] The Royal Decree provides that the Sunshine Act will apply to transfers of value made in 2017. The first reports, of 2017 data, due under the Sunshine Act must be submitted to the betransparent.be platform by May 31, 2018, which is the on-line platform that already hosts the data for companies reporting in Belgium pursuant to industry codes via their self-regulatory reporting system. Data from those reports will then be made public by June 30, 2018, at the latest.

As to next steps in Belgium, there is a process that the betransparent.be platform must go through before it is officially approved to host the Sunshine Act reports.[90] Once that approval takes place, which will be in the form of another Royal Decree, betransparent.be will issue a new reporting template. Further, betransparent.be is organizing a major information session in September 2017 to explain the new legal framework, including how it differs from the current self-regulatory framework.[91]

Two of the most significant consequences of the adoption of the Belgian law, even though the reporting provisions will presumably be similar to what is currently in place under the self-regulatory reporting systems, is that consent will no longer be required and the reporting obligations will no longer be restricted to only members of the industry groups. Those two consequences could lead to *more* companies reporting about *more* HCP interactions, which would necessarily mean that there will be *more* transparency. While this is a result that critics of the EFPIA disclosure initiative have advocated, it does not mean that the EFPIA approach has

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[89] Arrete royal portant execution du Sunshine Act [Royal Decree Implementing the Sunshine Act] of June 14, 2017, BELGISCH STAATSBLAD [B.S.] [Official Gazette of Belgium], June 23, 2017, https://www.betransparent.be/wp-content/uploads/2017/06/KB-Sunshine-Act-14.6.17-BS-23.6.17.pdf.

[90] Press Release, betransparent.be, *The Sunshine Act is in Effect!* (June 23, 2017), https://www.betransparent.be/en/the-sunshine-act-is-in-effect/.

[91] *Id.*

not been or cannot be successful. Nor is it the only plausible result, as it is possible that HCPs, facing the prospect of having their personal information and payment details publicly revealed, could choose to not work with life sciences companies, which could lead to *less* reporting of *less* HCP interactions and a possible decline in the quality of patient care.

Ultimately, the arbiters of the success, or lack thereof, of the EFPIA disclosure initiative will not be industry critics, defenders, or other stakeholders. Instead, that decision will be made by government regulators and legislators in each of the countries where the EFPIA disclosure program applies. If legislators in a particular country decide, based on the applicable consent rate or some other combination of factors, that the industry's voluntary transparency initiative has not been successful, then they may pass a Sunshine law. Legislators in other countries may look at their national data and make the opposite determination. While industry hopes that governments will afford its voluntary initiative, which has already revealed tens of thousands of HCP interactions and billions of euros' (and other currencies') worth of financial relationships, sufficient time to develop and further increase transparency, it remains to be seen how long governments will wait before they intervene with their own Sunshine laws.

Australia

The Australian transparency experience provides yet another perspective on the perception of success of such initiatives, as well a debate over what are the most important aspects of transparency and whether the provision of meals can influence HCPs. Though we will discuss the latter subject in more detail, it can be succinctly summarized by the following two statements, the first from an industry critic and the second from Milton Catelin, the Chief Executive of Medicines Australia:

> "Don't let anyone tell you that drug companies wining and dining doctors is a thing of the past. Sadly, these hidden flows of influence are at epidemic

> proportions, with almost 30,000 events every year where pharma picks up the tab. … Drug companies and medical groups argue these events are valuable places for a busy doctor to learn. But the evidence suggests otherwise. This massive dose of marketing maybe [sic] causing harm to patients – and to the public purse – given increasing concerns about sustainability."
>
> "It's ludicrous to suggest that a sandwich and a soda water would sway the opinions of medical practitioners. Suggestions like the one published [in the Australian media] do nothing but undermine a patient's confidence in a robust and accountable system, and call healthcare professionals into disrepute. Moreover, when a doctor is working a 12 hour day, and uses their lunchbreak to inform themselves of the latest developments in medicines, it seems appropriate that they be provided with lunch."

Australia's journey to transparency has involved nearly every subject that we have discussed thus far. In Australia, the pharmaceutical industry is represented by Medicines Australia, which for several years required its member companies to report on various interactions they had with HCPs and HCOs. As with the initial experience of the ABPI, this reporting was done at the aggregate, not individual, level. One of the reports concerned educational meetings and symposia held or sponsored by the company. Member companies were required to disclose, for each event held, a description of the function, including the duration of the educational content; the venue; the professional status of attendees; the hospitality provided (food, drinks, travel, entertainment); the number of attendees; and the total cost of the function.

In 2013, while these aggregate reporting requirements were in place, Sunshine Act legislation was introduced in the Parliament of Australia. That legislation failed, however as Medicines Australia, and other stakeholders, successfully conveyed to the government that the self-regulatory system was effective in delivering transparency into the relationship between industry and HCPs.[92]

[92] *See* CAMPBELL & SHARKEY, 2013 WHITE PAPER, *supra* note 33, at 19-23.

This was due in part to the fact that, beginning in 2012, Medicines Australia began the process of moving away from aggregate level reporting and to individual level reporting.[93] Before those individual level requirements could take effect, however, they had to be approved by Australian Competition and Consumer Commission ("ACCC"). One point of contention during the approval process was how industry would comply with the Australian data privacy laws while still achieving individual level reporting. Ultimately, the ACCC decided and Medicines Australia codified that, for one year, companies would obtain consent from HCPs to report their information at the individual level. If the HCP did not consent, his or her information would be reported in the aggregate. In essence, this is the same approach as embodied in the EFPIA Disclosure Code. Thereafter, however, companies would no longer seek consent; rather, they would inform the HCP with whom they were contracting that they would be reporting the relevant transfers of value. In essence, the same approach as adopted in Spain.

Some details of what must be reported under the current Medicines Australia Code are similar to EFPIA, though some requirements are analogous to what is required in the United States and France, while others are unique to Australia.[94] Reports are due twice a year: August 31, to cover data from November 1-April 30; and February 28, to cover the May 1-October 31 time period. The first year of reporting, whereby companies were required to obtain consent, began in 2015 and ended on October 31, 2016. Two rounds of reports were disclosed by companies, by August 31, 2016, and February 28, 2017, under the consent-based approach.

The next phase of reporting, whereby consent is no longer required, began with the data collection period that ran from November 1, 2016, through April 30, 2017. The first reports under that new paradigm have not yet been revealed – those will be posted on company websites

[93] *See* CAMPBELL & SHARKEY, 2014 WHITE PAPER, *supra* note 33, at 55-63.

[94] *See* CAMPBELL & SHARKEY, 2015 WHITE PAPER, *supra* note 33, at 35-43; CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 33, at 71-73.

by August 31, 2017. It will be interesting to evaluate how the data reported by companies compares to that reported during the first year when HCPs had to consent to individual level disclosure. This is particularly true with respect to the number of HCPs who work with industry and the amounts that companies report, as it will become evident whether some, or a significant number, of HCPs stop working with industry out of concern over their information being reported at the individual level.

As we outlined at the outset of our discussion of Australia, whether meals should be reported, and whether they influence HCPs, has become a controversial topic recently. Under the aggregate report approach initially adopted by Medicines Australia, member companies would report on the amount of hospitality provided at educational events and symposia, but would not identify any HCPs. However, under the current, individual level reporting regime, meals and drinks do not have to be reported, but other types of payments to HCPs are reported at the individual level.

As to meals, Medicines Australia imposed a maximum cost of a meal (including beverages) of $120 (excluding GST and gratuities), but determined that such expenditures should not be reported.[95] This is the same approach that EFPIA has taken with respect to meal limits, and not requiring that meals be reported. Initially, this aspect of Australian reporting did not appear to be particularly controversial, and, as noted previously, member companies disclosed two rounds of reports under the individual level approach that did not include meal expenditures.

However, in February 2017, the Australian press began to focus on industry's financial relationships with HCPs. On February 12, ABC News (Australian Broadcasting Corporation) posted two articles on its website. The first was titled, "Blood-thinners Xarelto, Eliquis and

[95] *See* CAMPBELL & SHARKEY, 2015 WHITE PAPER, *supra* note 33, at 42.

Pradaxa marketed to doctors as drug companies splash cash."[96] This article described an ABC investigation that found that pharmaceutical companies spent more than $2.6 million on educational events about blood thinners for doctors in "just six months in 2015."[97] The article highlighted some discrete (and expensive) expenditures by pharmaceutical companies and included statements from HCPs who were critical of such spending, while other critics claimed that doctors are more likely to prescribe drugs if they attended events or received meals from a manufacturer. Other statements criticized educational events as "marketing masquerading as education."[98]

After examining prescription rates and suggesting that higher rates are causally tied to industry support, the article identified amounts spent by specific companies, which ABC ascertained by reviewing the educational reports that companies submitted to Medicines Australia. The article also included statements from representatives of several pharmaceutical companies defending their interactions with HCPs, as well as the following statement from a spokesman for Medicines Australia: "Without the support of the pharmaceutical companies, access to the latest innovations in medicines, biotechnology and important medical breakthroughs would be unattainable for the majority of medical practitioners in Australia."[99]

The second article from February 12, titled "Rule changes to 'wining and dining' of doctors by drug companies 'a step backwards,'"[100] emphasized that pharmaceutical companies

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[96] Sophie Scott & Alison Branley, *Blood-thinners Xarelto, Eliquis and Pradaxa marketed to doctors as drug companies splash cash*, ABC NEWS (February 12, 2017, 12:57 AM), http://www.abc.net.au/news/2017-02-12/prescriptions-for-new-blood-thinning-drugs-skyrocket/8250856.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] Sophie Scott & Alison Branley, *Rule changes to 'wining and dining' of doctors by drug companies 'a step backwards'*, ABC NEWS (February 12, 2017, 2:02 PM), http://www.abc.net.au/news/2017-02-13/rule-changes-to-wining-and-dining-of-doctors-by-drug-companies/8258520.

no longer had to publish educational event reports under the Medicines Australia Code. The article alleged that

> under a horse trade done with the regulator, the Australian Competition and Consumer Commission (ACCC), the industry will only publish names of individual doctors and the 'transfers of value' they receive for things like speaking events and trips to conferences. It will no longer have to report food and beverage spending, with a $120 meal cap now applying to hospitality.[101]

According to article, these changes angered academics and public health officials, who expressed unhappiness with the alleged lack of transparency and loopholes in the Medicines Australia reporting system.[102]

Further, the article included a statement from the ACCC that if industry's spending on meals rises significantly, it may reconsider its position on Medicines Australia's reporting requirements. Medicines Australia provided the following statement for the article:

> [we continually evaluate the Code and] regularly engage[] with the medical profession, the Government and the community to ensure that it continues to provide the highest standard in ethical conduct and transparency within our industry. No other part of the medicines industry in Australia provides this degree of transparency about its engagements with medical, nursing, pharmacy and other healthcare professionals.[103]

The Australia Medical Association ("AMA") also defended the transparency system, as its president stated that "I believe it affords appropriate protections both for patients and doctors. There are very strict rules about the levels of hospitality. Those rules are appropriate."[104]

In a third article, titled, "What is a journal club and do they change the way doctors prescribe," ABC focused on journal clubs, which are meetings where specialists meet to discuss

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101 *Id.*
102 *Id.*
103 *Id.*
104 *Id.*

recent journal articles.[105] Pharmaceutical companies sometimes sponsor such meetings, and the article took a negative view of that sponsorship, claiming that such activities could influence HCP prescribing habits. As with the aforementioned articles, this article included statements from Medicines Australia and the AMA defending the relationship between industry and HCPs, as Medicines Australia commented that "[o]ur member companies are committed to transparency in their interactions with medical professionals and regularly report on them."[106]

Medicines Australia did not make any changes to its reporting requirements following this flurry of media attention. However, this summer the media once again examined industry's financial relationships with HCPs. This was prompted by the publication of an article in *BMJ Open*, authored by researchers from the University of Sydney, titled, "A cross-sectional analysis of pharmaceutical industry-funded events for health professionals in Australia."[107] The objectives of the study were to analyze patterns and characteristics of pharmaceutical industry sponsorship of events for Australian HCPs and to understand the implications of recent changes in transparency provisions that no longer require reporting of payments for food and beverages. The authors reviewed 301 company transparency reports that were available on and downloaded from the website of Medicines Australia covering the period from 2011-2015. The authors created a searchable database so that anyone can examine the data that is derived from those reports.[108] The authors concluded that

> [o]ver this 4-year period, industry-sponsored events were widespread and pharmaceutical companies maintained a high frequency of contact with health professionals. Most events were held in clinical settings, suggesting a pervasive commercial presence in everyday clinical practice. Food and beverages, known

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105 Alison Branley & Sophie Scott, *What is a journal club and do they change the way doctors prescribe?*, ABC RADIO AUSTRALIA (February 14, 2017, 7:00 AM), http://www.radioaustralia.net.au/international/2017-02-14/what-is-a-journal-club-and-do-they-change-the-way-doctors-prescribe/1651388.

106 *Id*.

107 Alice Fabbri et al., *A cross-sectional analysis of pharmaceutical industry-funded events for health professionals in Australia*, BMJ OPEN (June 1, 2017), http://bmjopen.bmj.com/content/7/6/e016701.

108 *Id*.

> to be associated with changes to prescribing practice, were almost always provided. New Australian transparency provisions explicitly exclude meals from the reporting requirements; thus, a large proportion of potentially influential payments from pharmaceutical companies to health professionals will disappear from public view.[109]

Press coverage picked out various statistics and data from the study to demonstrate how much industry "wines and dines" HCPs.[110] One article went so far as to declare that "it seems that Australia has dropped the ball, with moves towards individual disclosures overshadowed by abandoning transparency around routine wining and dining, and is slopping backwards into the darkness of secrecy."[111]

Medicines Australia quickly responded by issuing a press release from its Chief Executive titled, "A sandwich won't sway a doctor,"[112] in which he proclaimed:

> Engagement with pharmaceutical companies is an important and legitimate part of a medical practitioner's ongoing education; foremost, because patients want to be sure that their doctors know how to use the medicines they're being prescribed.
>
> The developers of these medicines are the highest authority on how a medicine works, its interactions with other compounds, its efficacy and other information. It stands to reason that a medical practitioner would consider information from the maker of the medicine when making an informed decision about prescribing a medicine. It's not however, the only source. Medical practitioners do their own research, network with their peers, consult with other clinical experts, read independent medical journals and receive information from independent bodies such as *NPS MedicineWise*.
>
> It's ludicrous to suggest that a sandwich and a soda water would sway the opinions of medical practitioners. Suggestions like the one published in the Conversation and in the BMJ article do nothing but undermine a patient's

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109 *Id.*

110 Sue Dunlevy, *Pharmaceutical companies spent $290 million wining and dining doctors*, HERALD SUN (July 4, 2017, 8:00 AM), http://www.heraldsun.com.au/lifestyle/health/pharmaceutical-companies-spent-290-million-wining-and-dining-doctors/news-story/c52aa0abebe28043895788dd208ef962; Alice Fabbri et al., *Who's paying for lunch? Here's exactly how drug companies wine and dine our doctors*, THE CONVERSATION (July 3, 2017, 12:26 AM), http://theconversation.com/whos-paying-for-lunch-heres-exactly-how-drug-companies-wine-and-dine-our-doctors-78395; Ester Han, *Drug companies spent $287 million in four years on 'educational' events for doctors*, THE SYDNEY MORNING HERALD (July 7, 2017), http://www.smh.com.au/national/health/drug-companies-spent-287-million-in-four-years-on-educational-events-for-doctors-20170706-gx688a.html.

111 Fabbri et al., *supra* note 110.

112 *A sandwich won't sway a doctor.*, MEDICINES AUSTRALIA (July 4, 2017), https://medicinesaustralia.com.au/from-the-chief-executive/a-sandwich-wont-sway-a-doctor/.

> confidence in a robust and accountable system, and call healthcare professionals into disrepute.
>
> Moreover, when a doctor is working a 12 hour day, and uses their lunchbreak to inform themselves of the latest developments in medicines, it seems appropriate that they be provided with lunch.
>
> ….
>
> The Code of Conduct is the Australian benchmark for accountability and transparency reporting in the therapeutic goods sector. This is the same standard that pharmaceutical companies are held to in Europe, and significantly more detailed than industry self-regulation in the USA.
>
> Medicines Australia members are proud of their Code of Conduct. They have voluntarily submitted themselves to this significant transparency despite the fact that non-Medicines Australia members do not, that includes generic medicines manufacturers and the makers of medical devices. Our positive experience with increasing transparency of our members should stand as a beacon to others to join us on the journey.
>
> A better informed patient has more confidence in the relationships between doctor and company. They are more likely to understand the value of these relationships in the development of better medicines and devices, including a doctor's or patient's participation in Australian-based clinical trials.
>
> Australian patients should be assured that their medical practitioners are keeping up to date with the latest innovation in medicines and the sharing of knowledge so that medical practitioners can determine the best outcomes for their patients.

Shortly thereafter, one of the authors of the aforementioned study responded by writing an article for the *Sydney Morning Herald* titled, "Australian doctors get a massive dose of marketing."[113] The following statements from that article are representative of its tone and tenor:

> Don't let anyone tell you that drug companies wining and dining doctors is a thing of the past. Sadly, these hidden flows of influence are at epidemic proportions, with almost 30,000 events every year where pharma picks up the tab.
>
> …
>
> Drug companies and medical groups argue these events are valuable places for a busy doctor to learn. But the evidence suggests otherwise. This massive dose of

[113] Ray Moynihan, *Australian doctors get a massive dose of marketing*, THE SYDNEY MORNING HERALD (July 11, 2017), http://www.smh.com.au/comment/australian-doctors-get-a-massive-dose-of-marketing-20170710-gx8b30.html.

> marketing maybe [sic] causing harm to patients – at risk of being prescribed a drug they don't need – and to the public purse – given increasing concerns about sustainability.
>
> …
>
> In 2017, Australia has sadly fallen behind with the latest changes in the self-regulatory code covering pharma marketing. As of this year, companies have to disclose the names of doctors paid for speaking or consultancies. But at the same time, from now on companies will no longer be required to disclose details of the almost 30,000 'educational' events they sponsor annually.[114]

The point, counterpoint between Medicines Australia and its critics is representative of the ongoing debate taking place throughout the world. Whether industry critics in Australia are able to foment public outrage and galvanize governmental support for Sunshine legislation remains to be seen. Can Medicines Australia continue to explain and justify not only how and why industry works with HCPs, but also the effectiveness of its transparency initiative? Perhaps the expansion of reporting requirements to include meals will tip the balance. The only clear conclusion is that with more data available than ever before, the success of Australia's transparency movement remains clouded.

Canada

Canada is our final focus in this examination of the global transparency movement because it is at the beginning of its journey to transparency. Unlike the United States, France, or Portugal, Canada does not have a national Sunshine Act. And unlike EFPIA or Australia, the Canadian pharmaceutical industry group, Innovative Medicines Canada, does not include reporting requirements in its Code of Ethical Practices. However, in March 2016, ten pharmaceutical companies announced that they would voluntarily publish statistics on their overall payments to HCPs in Canada. Significantly, the companies decided that the information they would publish would be at the aggregate level and would not identify individual physicians,

[114] *Id.*

much as the transparency movement began in the United Kingdom and Australia. The ten companies that agreed to this voluntary, aggregate disclosure were: Abbvie, Amgen, Bristol-Myers Squibb, Gilead, GSK, Eli Lilly, Merck, Novartis, Purdue, and Roche.

Those companies ultimately disclosed that information in June 2017, following coverage in the Canadian press in the lead-up to those June disclosures.[115] Those articles contrasted the anticipated disclosures with the type of data reported in the United States. The coverage tended to criticize the lack of information that would be revealed by the Canadian reports, as evidenced by titles like "Ain't no sunshine on Canadian doctors' conflicts of interest" and "Doctors should have to publicly disclose ties to drug industry: experts."[116] The latter article highlighted the fact that a number of HCPs who had participated in developing new national standards for prescribing opioids had financial ties to the pharmaceutical industry, ties that were not known during the development of the guidelines.[117] The article concluded with a statement from a spokesperson from Health Canada, the Canadian federal health agency, that "provinces and territories have primary responsibility for health care, so it would be up to them to develop an equivalent of a sunshine act in Canada."[118]

Prior to the voluntary disclosures by the ten Canadian companies, a campaign called "Open Pharma" was launched in June 2017 by a 12-member Advisory Board comprised of HCPs and researchers. According to the Open Pharma group, pharmaceutical companies should be forced to reveal their payments to HCPs at the individual level because Canada is "lagging behind" other countries on this issue. The members of Open Pharma deemed the to-be-published

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115 Kelly Crowe, *Ain't no sunshine on Canadian doctors' conflicts of interest*, CBCNEWS (May 6, 2017, 5:00 AM), http://www.cbc.ca/news/health/second-opinion-conflicts-1.4102733; Karen Howlett, *Doctors should have to publicly disclose ties to drug industry: experts*, THE GLOBE AND MAIL (last updated May 30, 2017, 5:34 AM), https://www.theglobeandmail.com/news/national/doctors-should-have-to-publicly-disclose-ties-to-drug-industry-experts/article35145979/.

116 *Id.*

117 Howlett, *supra* note 115.

118 *Id.*

aggregate reports of the ten companies as "meaningless" and called upon the Canadian government to adopt a Sunshine Act.[119]

In response, Innovative Medicines Canada acknowledged that the aggregate disclosures were a first step in the transparency journey and that the companies had decided to publish aggregate information in part because HCPs that had been consulted did not want their payment information released. Innovative Medicines Canada also criticized legislative transparency efforts, pointing out that self-regulation has proved effective in Canada. Meanwhile, a spokesman for the Canadian Health Minister conceded that while financial transparency is best left to local governments, "[w]e always remain open to new approaches to increase transparency for Canadians."[120]

Following the launch of Open Pharma, the *Toronto Star* ran an editorial titled, "Shine a spotlight on doctor-drug company relationships."[121] The editorial asserted that "[f]or too long cozy arrangements between doctors and pharmaceutical companies in Canada have been the health industry's dirty little secret. It's a kind of relationship critics say enriches doctors and drug companies at a potential cost to patient health. … The Open Pharma campaign … is most welcome and long overdue." Moreover, the editorial called for the adoption of a federal Sunshine law that would require disclosure of a variety of items, including "meals at boozy 'educational' dinners[.]"[122] Similarly, *The Globe and Mail* ran an article titled, "The pressure of

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[119] Theresa Boyle, *Open Pharma wants public to know ties between MDs and pharmaceutical industry*, THESTAR.COM (June 9, 2017), https://www.thestar.com/news/canada/2017/06/09/open-pharma-wants-public-to-know-ties-between-mds-and-pharmaceutical-industry.html; Kelly Grant, *Open Pharma campaign puts pressure on drug industry to reveal payments to doctors*, THE GLOBE AND MAIL (June 9, 2017, 7:29 PM), https://www.theglobeandmail.com/news/national/open-pharma-campaign-puts-pressure-on-drug-industry-to-reveal-payments-to-doctors/article35277557/.

[120]. Grant, *supra* note 119.

[121] Editorial, *Shine a spotlight on doctor-drug company relationships: Editorial*, THESTAR.COM (June 12, 2017), https://www.thestar.com/opinion/editorials/2017/06/12/shine-a-spotlight-on-doctor-drug-company-relationships-editorial.html.

[122]. *Id.*

Big Pharma."[123] The article discussed an analysis the newspaper had conducted that found that HCP-industry conflicts of interest were common in clinical practice guidelines. After highlighting some of those conflicts, the article concluded that the analysis "illuminates the pervasiveness of [the pharmaceutical] industry ties to Canada's medical community, especially among the top-flight researchers and 'key opinion leaders' who often sit on important guideline panels."[124]

As to the aggregate voluntary disclosures by the ten companies, they disclosed a total of 48.3 million in financial interactions with HCPs and HCOs. The companies disclosed the following information:

- One sum total of the company's payments to HCPs for services, including speaking or consulting;
- One sum total of the company's payments to HCOs that provide support for various charitable, educational, or scientific activities; and
- One sum total of the company's funds given to HCPs to support their travel to attend international conferences or global standalone meetings.[125]

The media coverage included various criticisms of the disclosures, including: the lack of identification of individual HCPs; the total number of doctors is not provided; the reported spend does not include research and development; some of the companies did not report a full year's worth of data and it was difficult to find the reports on the company websites. In defense of the disclosures, a representative of Innovative Medicines Canada stressed that self-regulation was

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[123] Kelly Grant, *The pressure of Big Pharma: Financial conflicts of interest common on medical guideline panels*, THE GLOBE AND MAIL (last updated June 20, 2017, 11:08 AM), https://www.theglobeandmail.com/news/national/the-pressure-of-big-pharma-financial-conflicts-of-interest-common-on-medical-guidelinepanels/article35389639/.

[124] *Id*.

[125] Voluntary Framework on Disclosure of Payments, INNOVATIVE MEDICINES CANADA, http://innovativemedicines.ca/ethics/voluntary-disclosure-of-payments/ (last visited August 3, 2017).

effective, that more companies were expected to disclose data next year, and that the companies reported in the aggregate because of the data privacy protections afforded to HCPs.[126]

In the wake of the aggregate disclosures, the federal health minister told reporters that she was sympathetic to the calls for more transparency, but that any Sunshine legislation should be left to the provinces. Specifically, she stated that "in principle, I think this is an important concept[.] I know that some provinces are moving in this area and it's a conversation that I'm open to having, but obviously I can't wade into the [provincial] territory of regulating health professionals."[127] While the federal government in Canada may not be moving to adopt a federal Sunshine Act, the health minister for Ontario, while terming the voluntary disclosures a positive step, announced that he will begin consultations this summer about whether a law should be passed requiring companies to disclose their transfers of value to HCPs.[128] While transparency advocates lauded Ontario's initiative, they also expressed concern about "piecemeal transparency" and reiterated their preference for a federal Sunshine law.[129]

Following the aggregate disclosures, *The Star* published an editorial in which it endorsed the decision of the Health Minister of Ontario to begin consultations on whether pharmaceutical companies should be required to disclose their transfers of value to HCPs. The editorial

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[126] *Canadian industry pursues voluntary disclosure route*, TPL (June 21, 2017), https://www.thepharmaletter.com/article/canadian-industry-pursues-voluntary-disclosure-route; Kelly Grant, *Canadian drug makers assailed for lack of transparency over payments*, THE GLOBE AND MAIL (last updated June 20, 2017, 10:06 PM), https://www.theglobeandmail.com/news/national/canadian-drug-makers-assailed-for-lack-of-transparency-over-payments/article35392284/; Genia Kuypers, *Open Pharma campaign seeks pharmaceutical transparency*, HUMBER NEWS, http://humbernews.ca/new-campaign-seeks-pharmaceutical-transparency/ (last visited August 3, 2017); Jesse McLean & David Bruser, *Health minister considering forcing drug companies to reveal payments to doctors*, THESTAR.COM (June 20, 2017), https://www.thestar.com/news/canada/2017/06/20/health-minister-considering-forcing-drug-companies-to-reveal-payments-to-doctors.html; Angela Mulholland, *Drug companies reveal info on gifts to doctors*, CTV NEWS (last updated June 20, 2017, 2:07 PM), http://www.ctvnews.ca/canada/drug-companies-reveal-info-on-gifts-to-doctors-1.3467928.

[127] Grant, *supra* note 126.

[128] *Id*.

[129] Kelly Grant, *Advocates urge Ottawa to expand physician transparency beyond Ontario*, THE GLOBE AND MAIL (July 21, 2017), https://beta.theglobeandmail.com/news/national/advocates-urge-ottawa-to-expand-physician-transparency-beyond-ontario/article35757782/.

criticized the limited information that came from the voluntary aggregate disclosures and outlined what it perceived to be the dangers resulting from industry's relationship with HCPs. The editorial concluded by arguing that "[w]ith this week's pathetic disclosures, pharmaceutical companies have made it clear to the government they will not voluntarily report how much they pay individual doctors. Now the government must step in as quickly as possible and force the issue. Our confidence in Ontario's health system depends on it."[130] Similar articles also appeared in Canadian media, with titles like, "Drug companies should be required to reveal payments to doctors: author,"[131] and "Time for full transparency on pharmaceutical money."[132]

The progress of the transparency movement in Canada will be important, not only for Canadian stakeholders, but also for other parts of the world where transparency has not yet taken root. Clearly, the aggregate reports of the ten companies failed to satisfy those interested in more transparency. The relevant question now is not whether there will be more transparency in Canada, but rather in what manner will transparency be imposed.

It is possible that Innovative Medicines Canada could intervene and demonstrate industry's commitment to transparency by adopting a more robust, individual level reporting system like EFPIA or Australia. Of course, it is also possible that that might not satisfy critics and government regulators. It may ultimately be an issue that is left to the provinces, with Ontario leading the way. It is clear that there will be more transparency in Canada; the real

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[130] Editorial, *Release full data on drug company payments to doctors: Editorial*, THESTAR.COM (June 24, 2017), https://www.thestar.com/opinion/editorials/2017/06/24/release-full-data-on-drug-company-payments-to-doctors-editorial.html.

[131] Elizabeth Payne, *Drug companies should be required to reveal payments to doctors: author*, OTTAWA CITIZEN (last updated June 28, 2017, 7:15 PM), http://ottawacitizen.com/news/local-news/drug-companies-should-be-required-to-reveal-payments-to-doctors-says-author-of-book-on-the-issue.

[132] Trudo Lemmens & Paul D. Thacker, *Time for full transparency on pharmaceutical money*, THESTAR.COM (July 7, 2017), https://www.thestar.com/opinion/commentary/2017/07/07/time-for-full-transparency-on-pharmaceutical-money.html.

question is whether industry or the government (and which government(s)) will be shining the light on industry's interactions with HCPs.

Conclusion

As we promised at the outset, we "brought data" from the US Sunshine Act, from the ABPI, and from various scholarly articles and press reports. We also tried to offer explanations for the data, context for how and why the global transparency movement is expanding, and analysis of whether it has been successful. In doing so, we raised a number of questions and issues that do not have easy, or even ascertainable, answers – answers that depend as much on guess work as on forensics.

The ultimate determination of whether the global transparency movement, or any of the particular countries we focused on, is successful depends primarily on how one chooses to define success, as opposed to an independent, objective measure. For some, the fact that the transparency movement has brought a truly enormous amount of data about the financial interactions between the life sciences industry and HCPs into the public domain means that it has succeeded, while others look at that same enormous amount of data and contend that the movement is a failure because the data has spawned as many questions as it has answered.

Like the transparency movement itself, we tried to shine a light on part of the life sciences compliance landscape – Sunshine reporting – that can often be misunderstood. And like the question of whether the global transparency movement has been successful in places like the United States, the United Kingdom, or Australia, and whether it will be successful in Canada, a determination of whether we fulfilled our purposes is ultimately in the eye of the beholder because, to quote Henry David Thoreau, "[i]t's not what you look at that matters, it's what you see."

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