Global Transparency:

The More Things Change, The More They Stay The Same

Plus ca change Plus c'est la même chose

PORZIO LifeSciences

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Table of Contents

Introduction

Why are we using a famous saying that originated with a 19th century French writer as the title and theme for our annual global transparency White Paper? Well, the answer is a little complicated. To arrive at the answer, we have to start at the beginning of our White Paper's transparency journey. Our first White Paper was published in 2012, and this is our seventh edition.[1] For the first several years, we wrote about recently enacted Sunshine laws in places like the United States and France, as well as the Disclosure Code adopted by the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). As the reporting deadlines drew near for those laws and the Disclosure Code, our subsequent White Papers addressed the reporting requirements and the guidance and interpretations offered by the relevant governmental authorities and industry groups.

Eventually, when reporting actually began, we analyzed the information that companies disclosed. We scrutinized the data disclosed pursuant to the US Sunshine Act, as well as pursuant to EFPIA's Disclosure Code, including the rate at which healthcare professionals ("HCPs") granted consent to have their financial information reported at the individual level across Europe. In addition, every year we would also discuss new countries or regions where transparency reporting had begun – from laws in Portugal and Belgium to industry codes in Japan and Australia, to name just a few.

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[1] D. JEFFREY CAMPBELL, ESQ. & BRIAN P. SHARKEY, ESQ., LIKE BEAUTY AND ART, TRANSPARENCY IS IN THE EYE OF THE BEHOLDER (2017) [hereinafter 2017 WHITE PAPER]; CAMPBELL & SHARKEY, A MILESTONE MOMENT (OR A DEAD JELLYFISH) FOR THE GLOBAL TRANSPARENCY MOVEMENT (2016) [hereinafter 2016 WHITE PAPER]; CAMPBELL & SHARKEY, READY OR NOT, FULL SPEED AHEAD FOR THE GLOBAL TRANSPARENCY MOVEMENT (2015) [hereinafter 2015 WHITE PAPER]; CAMPBELL & SHARKEY, DO START BELIEVIN': THE LIFE SCIENCES INDUSTRY'S JOURNEY TO GLOBAL TRANSPARENCY (2014) [hereinafter 2014 WHITE PAPER]; CAMPBELL & SHARKEY, THE ONGOING GLOBAL TRANSFORMATION IN LIFE SCIENCES TRANSPARENCY (2013) [hereinafter 2013 WHITE PAPER]; CAMPBELL & SHARKEY, THE TREND TOWARDS GLOBAL TRANSPARENCY: A CHALLENGING NEW WORLD FOR THE LIFE SCIENCES INDUSTRY (2012) [hereinafter 2012 WHITE PAPER].

As we began the process of writing this year's White Paper, we were struck by a feeling of déjà vu. That is, we realized that we would once again be evaluating the data reported in the United States and pursuant to EFPIA's Disclosure Code, and that we would be discussing transparency developments in new areas – this year, in Colombia, Canada, and Saudi Arabia, among others. As that feeling of déjà vu strengthened, we had an epiphany: the more things changed with global transparency – with new reporting obligations arising in more and more places around the world every year – the more they stayed the same, as life sciences companies sought to comply with an ever-growing maze of conflicting, complex, and inconsistent reporting obligations.

Some brief research into the origins of the phrase "the more things change, the more they stay the same," led to the discovery that it was coined by the 19th century French writer Jean-Baptiste Alphonse Karr, who wrote "Plus ca change Plus c'est la même chose." Obviously, the French Sunshine Act has played an instrumental role in the global transparency movement, serving as an inspiration for other governments interested in enacting their own transparency laws and motivating industry groups to adopt self-regulatory codes in an effort to dissuade governments from enacting such laws. Thus, it seemed appropriate to borrow Mr. Karr's famous phrase for this year's White Paper. In the below pages, we will discuss some of the laws, codes, and data that have remained largely the same, as well as new industry codes and laws, including the General Data Protection Regulation ("GDPR") and its impact on consent rates for EFPIA-based reporting.

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 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"). There are three different types of reports that a company may have to submit: 1) a General Payments Report, which includes payments and transfers of value to a covered recipient; 2) a Research Payments Report, which encompasses all payments and transfers of value 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 the data reported by companies publicly available on its Open Payments website.

In 2018, the overall amount reported by applicable manufacturers, as well as the amounts reported for all three discrete categories, decreased from 2017. This is the first time that there has been a decrease from the prior year in the overall amount reported since CMS began publishing Sunshine Act data in 2014. 2018 is also the first time there has been a decrease from the previous year for the General Payments and Research Payments categories. Whether these decreases signal a new trend or a momentary dip can only be answered in time. Before addressing possible reasons for the decreases, as well as legislative developments that could

reshape the Sunshine Act in the years to come, it is helpful to first consider how the data reported in 2018 compares to prior years.

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 increased every year until the release of the 2017 data. For 2014 data, companies reported a total amount of $8.02 billion, which increased to $8.42 billion for 2015 data, and then to $8.81 billion for 2016 data. For the first time since reporting began, there was a decrease in reported payments for 2017 data, as the amount dropped to $8.40 billion.[2]

With respect to the categories of payments, for General Payments, companies reported:

- $2.68 billion for 2014 data;
- $2.70 billion for 2015 data;
- $2.86 billion for 2016 data; and
- $2.82 billion for 2017 data.[3]

As to Research Payments, companies reported:

- $4.23 billion for 2014 data;
- $4.63 billion for 2015 data;
- $4.78 billion for 2016 data; and
- $4.66 billion for 2017 data.[4]

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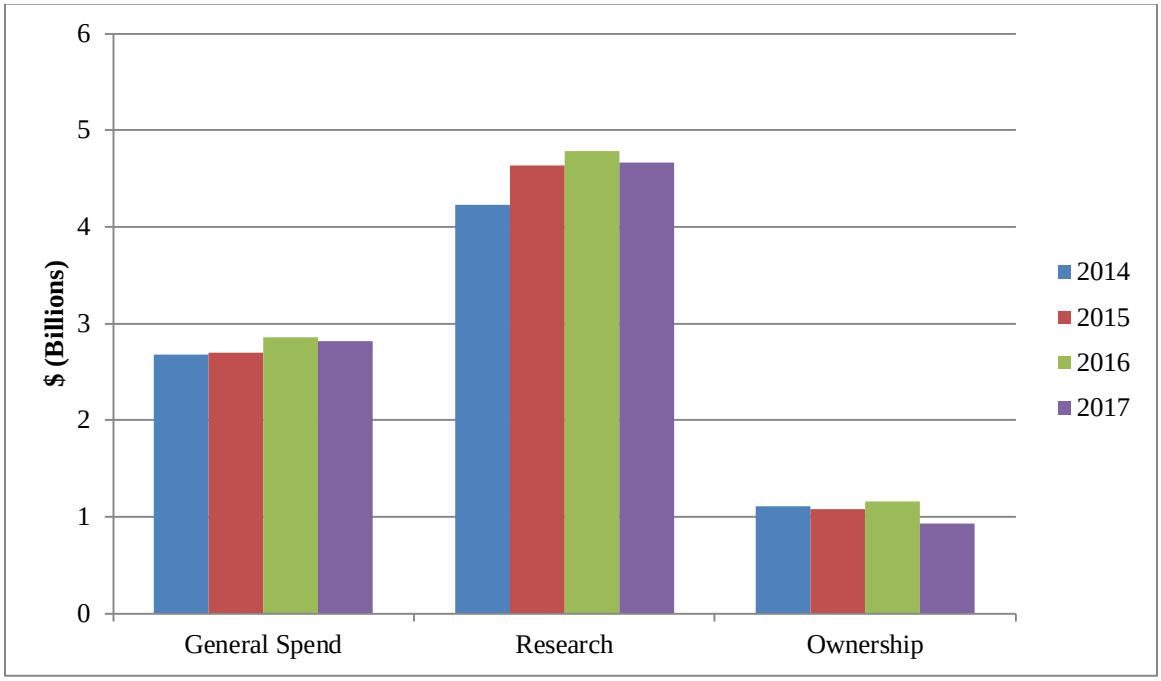
[2] *The Facts About Open Payments Data*, OPENPAYMENTSDATA.CMS.GOV, https://openpaymentsdata.cms.gov/summary (last visited August 15, 2018).
[3] *Id*.
[4] *Id*.

Lastly, for Physicians Ownership and Investment Interest Reports, companies reported:

- $1.11 billion for 2014 data;
- $1.08 billion for 2015 data;
- $1.16 billion for 2016 data; and
- $927.16 million for 2017 data.[5]

Below is a graphical representation of the aforementioned data:



[5] *Id*.

In contrast to prior years, the media reaction to the release of the 2017 Sunshine Act data appears more muted. Perhaps this is just a reflection of how embedded transparency has become in the United States, or perhaps the news cycle is so crowded with other stories that the annual release of Sunshine Act data does not grab the headlines like it did in the past. However, Senator Grassley, one of the co-authors of the Sunshine Act, did offer comments about the latest release of the data:

> This is the fourth full calendar year of reporting by information from Open Payments. The 2017 data found 11.54 million financial transactions attributed to 628,000 physicians and 1,158 teaching hospitals, totaling $8.4 billion. Over the course of four years, $33.42 billion in payments have been reported. Many of these payments are for legitimate research and patient care, but this disclosure provides great benefit to consumers and the public.
>
> The 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[.] … After all, you can't have accountability without transparency.[6]

While the release of 2017 Sunshine Act data may not have been the lead media story in the summer of 2018, the opioid epidemic has gained much national attention in recent years and federal, state, and local governments have begun to exercise their statutory and regulatory authority to address the crisis. For example, at the federal level, efforts include the President's Commission on Combating Drug Addiction and Opioid Abuse, the FDA's Opioid Action Plan, and the DOJ's Opioid Fraud and Abuse Detection Unit. At the state level, at least 45 governors signed on to the Compact to Fight Opioid Addiction and a number of states have passed laws imposing opioid prescription limits and other measures intended to curb opioid abuse. Given the

[6] Press Release, The Office of US Senator Charles Grassley, *CMS Releases its Annual Open Payments Report as Part of Grassley's Sunshine Act* (July 2, 2018), https://www.grassley.senate.gov/news/news-releases/cms-releases-its-annual-open-payments-report-part-grassley-s-sunshine-act.

public attention and rare bipartisan agreement on this issue, some legislators have used the opioid crisis as a justification for further expansion of the Sunshine Act.

Earlier this year, Senator Grassley, along with Senators Sherrod Brown and Richard Blumenthal, introduced legislation to broaden the Sunshine Act, framing it as a measure to help address the opioid crisis. The bill, titled, "Fighting the Opioid Epidemic with Sunshine Act," would expand the definition of "Covered Recipient" to include nurse practitioners and physician assistants.[7] Discussing this legislation, Senator Grassley commented that the "Fighting the Opioid Epidemic with Sunshine Act is one more critical step lawmakers can take to stop the spreading of opioid abuse and hold accountable those who promote opioids for financial gain only."[8]

Another potential expansion of the Sunshine Act, motivated in large part by the opioid epidemic, is the Patient Advocacy Transparency Act of 2018, a bill introduced by Senator Claire McCaskill.[9] Over the last several years, there have been a number of studies examining the relationship between the life sciences industry and health advocacy organizations, including a Georgetown University Medical Center project that found "only a handful of 7,865 health advocacy groups in the U.S. are completely independent of pharmaceutical industry money."[10] In another report by the *New England Journal of Medicine* in March 2017, researchers found that out of 104 organizations, "at least 83% received financial support from drug, device, and biotechnologies companies, and at least 39% have a current or former industry executive on the

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[7] Fighting the Opioid Epidemic with Sunshine Act, S. 2891, 115th Cong. (2018).

[8] Press Release, The Office of US Senator Charles Grassley, *Grassley, Brown, Blumenthal Introduce Bipartisan Sunshine Bill to Help End the Cycle of Opioid Addiction* (May 22, 2018), https://www.grassley.senate.gov/news/news-releases/grassley-brown-blumenthal-introduce-bipartisan-sunshine-bill-help-end-cycle.

[9] Patient Advocacy Transparency Act, S. 3000, 115th Cong. (2018).

[10] Dana Elfin, *Very Few Patient Groups Don't Take Pharma Money*, BLOOMBERG BNA (October 20, 2017), https://www.bna.com/few-patient-groups-b73014471175/.

governing board."[11] According to a January 2017 article in *JAMA Internal Medicine*, more than 67% of 245 examined organizations received industry funding within the last fiscal year, with almost 12% receiving more than half of their funding from industry sources.[12]

Moreover, on April 6, 2018, Kaiser Health News ("KHN") launched a database called "Pre$cription for Power" that tallied donations to patient advocacy groups for 2015[13] – the most recent full year in which documents required by the Internal Revenue Service were available. Using the methodology of the March 2017 report in the *New England Journal of Medicine* referenced above, KHN found that in 2015, pharmaceutical companies gave at least $116 million to patient advocacy groups in a single year. After analyzing the data, KHN asserted that rather than spending their money on lobbying activities, pharmaceutical companies have shifted funding to patient advocacy organizations to lobby on their behalf.[14]

Senator McCaskill has been heavily involved in the largest Congressional investigation into the financial ties between opioid manufacturers and patient advocacy groups. In September 2017, she released, as the top-ranking Democrat on the Senate Homeland Security and Governmental Affairs Commitee, a report titled, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization."[15] Then in February 2018, she issued a

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[11] Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*, NEW ENGLAND JOURNAL OF MEDICINE (Mar. 2, 2017).

[12] Susannah L. Rose et al., *Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest*, JAMA INTERNAL MEDICINE (Mar. 2017).

[13] Emily Kopp et al., *KHN launches "Pre$cription for Power," a groundbreaking database to expose Big Pharma's ties to patient groups*, KHN (April 6, 2018), https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/.

[14] *Id*.

[15] Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs, *McCaskill Opioid Investigation Releases First Report Detailing Systematic Manipulation of Prior Authorization Process by Insys Therapeutics* (September 6, 2017), https://www.hsgac.senate.gov/media/minority-media/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics-.

second report, titled, "Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups,"[16] which she supplemented in July 2018.[17]

Senator McCaskill's focus on this issue led her to introduce the Patient Advocacy Transparency Act of 2018 on June 6, 2018. The proposed legislation would significantly expand the definition of "Covered Recipient" under the Sunshine Act to include many patient facing organizations[18] and would broaden the definition of "grants" to include various types of educational grants and "capacity building grants." The bill would also expand reporting for fundraising event sponsorship, meeting or conference expenses not already covered, funding of marketing and public relations activities, and placement on television programs or internet websites, or social media support. Introducing this legislation, Senator McCaskill reasoned that

> [o]pioid manufacturers have a legal right to donate to third party organizations who can then advocate for policies friendly to the industry—but I believe the public also has a right to know that those financial relationships exist, and right now that's not what's happening[.] … We required increased transparency when it came to payments to individual doctors, and we should extend that visibility to these groups as well.[19]

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[16] Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs, *Millions in Payments Among Findings of McCaskill Opioid Investigation into Ties Between Manufacturers and Third Party Advocacy Groups* (February 12, 2018), https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

[17] Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs, *McCaskill Amends Report After Finding Insys Therapeutics Failed to Report $100,000 in Contributions to Third Party Advocacy Group* (July 24, 2018), https://www.hsgac.senate.gov/media/minority-media/mccaskill-amends-report-after-finding-insys-therapeutics-failed-to-report-100000-in-contributions-to-third-party-advocacy-group.

[18] Professional societies of health care provider or pharmacists; patient advocacy organizations, consumer advocacy organizations, voluntary health agencies, or a coalition of such organizations, including disease-specific advocacy organizations; patient education organizations; providers of continuing education, including medical education or communications companies; clinical trial organizations; education accreditation organizations or other organizations providing financial assistance to patients; and certain other foundations. Patient Advocacy Transparency Act, S. 3000, 115th Cong. (2018).

[19] Press Release, United States Senator Claire McCaskill, *After Groundbreaking Report Showing Millions in Payments Between Opioid Manufacturers & Third Party Advocacy Groups, McCaskill Introduces Bill Requiring Additional Transparency* (June 6, 2018), https://www.mccaskill.senate.gov/media-center/news-releases/after-groundbreaking-report-showing-millions-in-payments-between-opioid-manufacturers-and-third-party-advocacy-groups-mccaskill-introduces-bill-requiring-additional-transparency_.

With the opioid epidemic as a backdrop, it is not necessarily surprising that data from 2017 was the first year in which total payments in the categories of General Payments and Research Payments, as well as the overall amount reported, declined. The increased scrutiny could be a factor leading manufacturers of opioids to cut back on marketing payments to doctors. In that regard, a ProPublica analysis published just before the release of the 2017 Open Payments data shows that pharmaceutical company payments to physicians related to opioid drugs decreased significantly in 2016 from the year before.[20] The analysis found that in 2016, manufacturers spent $15.8 million on physicians for speaking, consulting, meals, and travel related to opioid drugs, which was a 33% decline from the $23.7 million that was reported in 2015, and 21% less than the $19.9 million reported in 2014.[21]

Reduced spending by opioid manufacturers does not completely explain the decline in the amounts reported by applicable manufacturers for 2017 data, but it is fair to identify it as a contributing factor. Thus, it will be necessary to monitor whether the amounts reported by applicable manufacturers decline again next year to assess whether this is the beginning of a trend. It will also be important for industry to monitor the aforementioned Congressional bills because their reporting obligations would dramatically increase if either or both are enacted into law.

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[20] Charles Ornstein et al., *Opioid Makers, Blamed for Overdose Epidemic, Cut Back on Marketing Payments to Doctors*, PROPUBLICA (June 28, 2018), https://www.propublica.org/article/opioid-makers-blamed-for-overdose-epidemic-cut-back-on-marketing-payments-to-doctors.

[21] *Id*.

Europe

EFPIA

Europe has been on a different transparency journey, one that varies by industry and that has been advanced more by self-regulatory industry codes rather than laws. As we have chronicled in our prior White Papers, there are a handful of countries in Europe that have adopted transparency laws, including, among others, France, Portugal, and, most recently, Belgium.[22] These laws differ from each other on a host of topics, including threshold issues like which types of companies are required to report, the scope of covered recipients, and the information to be reported, along with the timing of reporting. While trying to comply with those divergent legislative-based requirements, the industry groups for 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.

The pharmaceutical industry association, EFPIA, has the longest history with transparency reporting, as it adopted its Disclosure Code in 2013. EFPIA adopted that Code to create a consistent, uniform approach to transparency reporting across Europe. In doing so, EFPIA sought to demonstrate to European governments that transparency laws were not needed because self-regulation would shed sufficient light on the financial interactions between industry and HCPs and healthcare organisations ("HCOs").

[22] We extensively chronicled those transparency laws in our prior White Papers and will not focus on them here. We extensively chronicled those transparency laws in our prior White Papers and will not focus on them here. CAMPBELL & SHARKEY, 2017 WHITE PAPER, *supra* note 1; CAMPBELL & SHARKEY, 2016 WHITE PAPER, *supra* note 1; CAMPBELL & SHARKEY, 2015 WHITE PAPER, *supra* note 1; CAMPBELL & SHARKEY, 2014 WHITE PAPER, *supra* note 1; CAMPBELL & SHARKEY, 2013 WHITE PAPER, *supra* note 1; CAMPBELL & SHARKEY, 2012 WHITE PAPER, *supra* note 1.

Because the Disclosure Code is well-established at this point, we will provide only a brief summary of its reporting requirements. The Disclosure Code requires EFPIA's member companies to report specific 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. Significantly, meals and drinks and samples are excluded from the scope of reporting.

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. Member companies have just completed their third year of reporting with the release of reports earlier this year for 2017 data. In advance of the publication of the latest reports from its member companies, EFPIA issued a press release on June 20, 2018, titled, "Pharmaceutical companies continue to drive transparency and underline industry investment in Europe's healthcare."[23] In that press release, EFPIA explained that

> over the next ten days, pharmaceutical companies will disclose details of collaborations with health professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs) across Europe. The figures, which will be available online, underline industry's continued investment in European healthcare, enabling the development of new medicines through sharing best clinical practice, exchanging information on how new medicines fit into the patient pathway and shaping the future of clinical research.
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> …
>
> Covering activities such as research and educational grants to healthcare organisations as well as transfers of value to individuals for activities such as

[23] Press Release, EFPIA, *Pharmaceutical companies continue to drive transparency and underline investment in Europe's healthcare* (June 20, 2018), https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/20062018-pharmaceutical-companies-continue-to-drive-transparency-and-underline-industry-investment-in-europe-s-healthcare/.

> speaking at educational meetings, consultancy and attending advisory boards as well as sponsorship to attend educational meetings, the disclosures will address transfers of value made during 2017.
>
> Bringing greater transparency to these already well-regulated and essential relationships is about strengthening the basis for collaboration in the future.[24] Interactions between industry, HCPs, HCOs and POs are vital to ensure we can continue to develop medicines that advance healthcare and continue to improve the lives of patients across Europe.

In addition, Nathalie Moll, the Director General of EFPIA, commented that

> [d]iscovering, 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, healthcare organisations and patient organisations.[25]

In our White Papers from the last two years, we discussed the data from the 2016 and 2017 reports, with a particular focus on how much data was reported at the individual level. We focused on that because EFPIA's Disclosure Code is a voluntary form of self-regulation and, due to the data protection rights afforded EU citizens by the then-governing EU Data Protection Directive[26] and national laws, as a general proposition companies needed to obtain a HCP's consent to publicly disclose the individual level information called for in the Disclosure Code. If a HCP refuses to consent, then the company must report that HCP's information in the aggregate, along with the information of any other HCPs who did not consent.

As a result of the intersection between EFPIA's self-regulatory code and the governing EU data protection laws, the "consent rate," that is, the percentage of HCPs who consented to

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[24] *Id*.

[25] *Id*.

[26] 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).

having their information disclosed at the individual level, quickly became a barometer to measure the success of the EFPIA Disclosure Code for some stakeholders and observers. In short, some have taken the position that the higher the HCP consent rate is, the more effective EFPIA's initiative is, while the lower the consent rate is, the less successful the initiative is because less individual level information is disclosed. In last year's White Paper, we devoted significant attention to whether "consent rates" were a fair way to evaluate the EFPIA Disclosure Code and offered a number of reasons why they should not be the ultimate arbiter of success of EFPIA's transparency initiative. We will not engage in that same analysis this year, but instead will shift our attention to a significant development in this area: the GDPR and the effect it may have had on this year's disclosure reports.

The GDPR

A belief in the fundamental right to privacy has been an integral part of European culture for decades. The EU Data Protection Directive was adopted in 1995 with the objective of regulating the processing of individuals' personal data, including its collection, use, storage, disclosure, and destruction. In the European Union, a "Directive" is a type of legislative act that sets out a goal(s) that all EU countries must achieve, but each country has the discretion to adopt and implement their own laws to achieve the goal of the Directive. Thus, under the Data Protection Directive, EU countries were responsible for transposing the Directive's principles into their own national laws. As a result, although one of the Data Protection Directive's major goals was the harmonization of data protection laws across the EU, its non-binding nature gave Member States the ability to interpret and apply its principles differently, which ultimately led to inconsistencies among the various Member State national data protection laws on a host of issues.

The variability of the data privacy laws across the EU, as well as technological advances since 1995, spurred the need for a new regulatory regime in the EU. The Data Protection Directive was superseded by the GDPR, which was adopted by the European Parliament and European Council in April 2016 and became effective on May 25, 2018. Significantly, unlike a "Directive," a "Regulation," like the GDPR, is a binding legislative act that must be applied in its entirety across the EU.

Perhaps the most well-known, or most-feared, aspect of the GDPR is its sanctions provisions. The GDPR established the possibility of significant fines for violations, as the most serious infractions can result in fines of up to 4% of global annual revenue or €20,000,000 (whichever is higher). To avoid such sanctions, companies must be aware of and comply with all of the GDPR's provisions, several of which are different from the prior data protection regime. Although the part of the GDPR most relevant to the transparency discussion in this White Paper is its treatment of consent, it is nonetheless important to briefly highlight a few other key aspects of the GDPR.

The GDPR's underlying principles are similar to the principles set forth in the Data Protection Directive. Article 5(1) sets forth seven principles that embody the spirit of the Regulation and relate to the processing of personal data:

(1) personal data should be processed lawfully, fairly, and in a transparent manner in relation to individuals ("lawfulness, fairness and transparency");

(2) personal data should be collected for specified, explicit, and legitimate purposes and not further processed in a manner that is incompatible with those purposes ("purpose limitation");

(3) the processing of personal data should be adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed ("data minimization");

(4) personal data must be accurate and up to date, and inaccurate data must be erased or rectified without delay ("accuracy");

(5) personal data should be maintained for no longer than necessary for the purpose of the processing ("storage limitation");

(6) personal data should be processed securely and should be protected against unauthorized or unlawful processing and accidental loss, destruction, or damage ("integrity and confidentiality"); and

(7) data controllers[27] are responsible for, and should be able to demonstrate compliance with, the aforementioned principles ("accountability").

Because it is a Regulation, the GDPR established one set of data protection rules across the EU and was immediately applicable and enforceable in all Member States. Even before its effective date, however, the GDPR caused seismic changes to the data privacy regulatory landscape due to its extraterritorial reach. The GDPR applies not only to EU-based organizations, but also to organizations outside of the EU if they process the "personal data" (broadly defined as "any information relating to an identified or identifiable natural person")[28] of EU-based data subjects by offering goods or services to individuals in the EU, or if they monitor the behavior of data subjects who are located within the EU. The long reach of the GDPR has

[27] A "Data Controller" is defined in Art. 4(7) of the GDPR as "the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data."

[28] Art. 4 GDPR.

led companies all over the world to assess the personal data that they collect, use, share, and store, and to re-examine their data privacy practices for compliance purposes.

The GDPR ushered in other significant changes. In keeping with the GDPR's principle of transparency in data processing, data subjects have the "right to be informed" regarding the processing of their personal data, and can ask data controllers whether their personal data is being processed and what the rationale is for such processing. Further, their "right to access" gives them the ability to obtain access to their personal data as well as to request copies. The GDPR also provides EU data subjects with the right to request the deletion of their data (the "right to erasure") in certain circumstances, the "right to object" to the processing of their personal data in certain circumstances, the "right to withdraw consent" for a data processing operation when consent was previously provided, and the "right to portability," which allows data subjects to easily and securely transfer personal data from one IT environment to another.

The GDPR also introduced several new requirements, including the requirement for Data Protection Officers to be appointed for all public authorities or bodies and certain private companies; a data breach notification requirement; and heightened standards for consent when data subjects agree to the processing of their personal data. The GDPR defines "consent" in Article 4(11) as "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her," thereby indicating that consent requires an active opt-in on the part of the data subject in order to be valid. However, that definition is merely the start of the deeper dive that entities subject to the GDPR must take in order to fully understand the consent requirements.

The Article 29 Working Party's[29] "Guidelines on consent under Regulation 2016/679" (referred to here as "the Guidelines") further interpret each of the elements of valid consent. According to the Working Party, consent must be freely given and involve "real choice and control for data subjects;" without this free choice, consent will not be valid. Consent bundled in non-negotiable terms and conditions will be presumed not to have been freely given, and the data subject must be able to refuse to provide, or withdraw, his or her consent without detriment. The Guidelines also clarify that it must be as easy for data subjects to withdraw consent as it is for them to provide it.

The Guidelines also state that an imbalance of power between the data subject and data controller is another key component of whether consent is freely given, noting that an imbalance of power occurs in the employment context as a result of the dependency that results from the employer/employee relationship because "it is unlikely that the data subject is able to deny his/her employer consent to a data processing without experiencing the fear or real risk of detrimental effects as a result of a refusal."[30] The Article 29 Working Party stresses that consent will not be freely given in cases where there is any element of compulsion, pressure, or inability to exercise free will.

Moreover, the Guidelines emphasize that the "bundling" of consent with acceptance of other terms or conditions, or "tying" the provision of a contract or service to a request to process personal data that is not necessary for the performance of that contract or service, is presumed to be not freely given. Further, when a service involves multiple processing operations for more

[29] The Article 29 Working Party was an advisory body made up of a representative from the data protection authority of each EU Member State, the European Data Protection Supervisor and the European Commission. Once the GDPR became effective, it was replaced by the European Data Protection Board ("EDPB").

[30] Art. 29 Working Party "Guidelines on consent under Regulation 2016/679," p. 7.

than one purpose, the data subjects should be free to choose which purpose(s) they accept as opposed to having to provide "blanket consent" for a bundle of processing services.

The Guidelines also provide that consent must be specific to ensure a degree of user control and transparency for the data subject. Article 6(1)(1) of the GDPR states that consent must be given in relation to one or more specific purposes and the data subject should have a choice regarding each of them. The data controller must specify the purpose of the data collection to make sure that these purposes do not blur into others, gradually widen, or expand. In addition, the data controller must obtain separate consent for different purposes and types of processing, and clearly separate information related to obtaining consent for data processing activities from information about other matters.

Finally, the Guidelines reinforce the GDPR's requirement that consent must be informed, and specify minimum content requirements to satisfy this criteria. Overall, data controllers must use clear and plain language that is easily understandable for the average person and not just lawyers, and consent must be provided in an intelligible and easily accessible form instead of buried in general terms and conditions.

Because of the EFPIA Disclosure Code's self-regulatory nature, and the need for companies to obtain consent from HCPs to report at the individual level due to European data protection law, companies must now comply with the GDPR's requirements. Did the GDPR affect consent rates in the latest round of EFPIA reporting? It is difficult to provide a definitive answer, but at least one national member association of EFPIA has attributed a decrease in consent rates for 2017 data to the GDPR.

United Kingdom

In 2017, the Association of the British Pharmaceutical Industry ("ABPI"), the local EFPIA member for the United Kingdom, reported that an estimated 65% of HCPs consented to disclose payments and benefits in kind at the individual level. That 65% consent rate was significant because it was an increase from the prior year's 55% consent rate. However, in 2018, the ABPI reported that the consent rate for 2017 data decreased to 49.1%.[31]

Before examining that decrease in further detail, it is important to highlight that the overall spend reported by the ABPI's member companies increased from a total of £454.5m for 2016 data to a total of £499.3m for 2017 data. Spend for research and development increased from last year's £338.1m to £370.9m, and accounted for approximately 75% of the overall amount reported. The remaining £128.4m of 2017 spend was broken down as follows:

- Registration fees – £3.9m;
- Sponsorship agreement with HCOs/3rd parties – £23.9m;
- Travel and accommodation – £10.1m;
- Donations and grants – £31.0m;
- Fees for service and consultancy – £48.9m;
- Expenses related to consultancy fees – £6.0m; and
- Joint Working – £4.6m.[32]

Each of these categories demonstrated an increase from 2016 spend, except for expenses related to consultancy fees, which dropped to £6.0m from last year's £9.6m.

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[31] Press Release, ABPI, *Pharmaceutical Industry Continues to Invest Significantly in UK Research and Development* (June 29, 2018), http://www.abpi.org.uk/media-centre/news/2018/june/pharmaceutical-industry-continues-to-invest-significantly-in-uk-research-and-development/.

[32] *Id*.

In the ABPI's press release discussing this data, Mike Thompson, the group's Chief Executive, stated:

> It is an encouraging testament to the pharmaceutical industry's commitment to the UK as a hub of science and innovation that, in the wake of Brexit uncertainty, it continues to invest significantly in research and development as shown in this latest disclosure data.
>
> £370 million spent on partnerships with leading healthcare experts and organisations on scientific discovery of life-enhancing medicines cements our place as a scientific hub which must be retained alongside continued cooperation on the regulation, trade and supply of medicines, after Brexit.[33]

With respect to the consent rate, the ABPI stressed that HCPs remained committed to transparency because, of the 102 companies that reported both in 2017 and 2018, 53 companies saw their consent rates remain the same or increase, while 49 companies had their consent rates decrease. However, the ABPI acknowledged that the overall consent rate decreased 16% from last year's reports. As to why the consent rate decreased, the ABPI reasoned:

> **The reduction for 2017 data can be attributed to the introduction of the Europe-wide General Data Protection Regulation (GDPR)**, which replaces the UK's 20-year-old Data Protection Act 1998 and aims to harmonise data privacy rules across Europe and gives greater protection and rights to individuals regarding their personal data.
>
> In considering how to best address the requirements of GDPR, some of which may not have been clear when companies first worked with HCPs in 2017, companies are likely to have taken one of the following courses of action, the first two of which have the potential to impact consent rates, both at company and industry level:
>
> [] Disclosed all 2017 data in aggregate to avoid publishing individuals' personal data.
>
> [] Re-sought consent from the individuals that they have worked with, in a new way compliant with GDPR, which may have resulted in a different consent rate.

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33 *Id*.

[] Not made any changes to their processes.[34]

(emphasis added)

Commenting on the consent rate and the GDPR, Mr. Thompson observed:

> GDPR applies to all industries and organsiations across Europe and inevitably brings challenges for all as processes and procedures are checked. **I am confident that this drop in consent rate for 2017 data reflects the balance that companies have had to strike between meeting transparency requirements and respecting the rights of individuals as they implement this new legislation.**
>
> **We expect this figure to rise for 2018 data and, alongside NHS England, remain committed to achieving 100%.** Doctors, nurses and pharmacists have demonstrated their commitment to greater transparency over the past two years and I would urge them to continue to do so as we strive for 100% disclosure.[35]

(emphasis added)

One's view of the data reported by the ABPI is a matter of perspective. On the one hand, the mere fact that the consent rate decreased is not a positive development and could be used by critics of self-regulation as evidence that legislation is needed. On the other hand, it is encouraging that more than half of the companies that reported in both 2017 and 2018 had their consent rates remain the same or increase. Moreover, it is certainly reasonable for supporters of self-regulation to contend that a decrease in the consent rate is not surprising, and in fact should have been expected, because the GDPR caused some companies to take a cautious approach to data protection issues and report all HCP information in the aggregate or to obtain "GDPR consent," which could lead to some HCPs not granting consent. The logical extension of this position is that the consent rates will improve next year, and in future years, as companies further

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34 *Id*.

35 *Id*.

implement GDPR processes and HCPs become more familiar and comfortable with those processes and more willing to grant consent.

Other counties also saw decreases in their consent rates. For example, in Germany, the consent rate declined from approximately 33% in 2017 to 20% in 2018.[36] In terms of the financial data reported, companies reported approximately €605 million in total for Germany. Of that amount, and consistent with reporting from prior years, the largest share – €398 million – was for research and development. €105 million was reported against HCPs for lectures/consulting/etc., and €102 million was reported against HCOs for events, donations, etc.[37]

Despite the German industry group's efforts to demonstrate industry's commitment to transparency, some press articles did not paint a positive picture of the disclosures, as they tended to focus on the fact that the amount reported by industry increased from last year while the consent rate, and corresponding individual level disclosures, decreased.[38] Another theme from the coverage has been that, due to the low consent rates, patients are not able to understand whether or not their HCPs have received financial support from industry.[39]

Other counties, including Austria, Poland, and Croatia, had their consent rates remain essentially flat, or increase slightly. Unfortunately for supporters of self-regulation, however,

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[36] Press Release, German Association of Research-Based Pharmaceutical Companies (vfa), *Transparenzkodex setzt Standard* (June 21, 2018), https://www.vfa.de/de/presse/pressemitteilungen/pg-004-2018-transparenzkodex-setzt-standard.html.

[37] *Id*.

[38] Jan Keuchel, *Pharmakonzerne zahlen über 600 Millionen Euro an deutsche Ärzte*, HANDELSBLATT (June 21, 2018), https://www.handelsblatt.com/unternehmen/industrie/pharmabranche-pharmakonzerne-zahlen-ueber-600-millionen-euro-an-deutsche-aerzte/22719240.html?ticket=ST-3337613-yGNfKx5PzKpuBvPo4gF2-ap6; *Pharmaindustrie legt Leistungen an Ärzte offen: 605 Millionen Euro im Jahr 2017*, HEALTHCARE MARKETING (June 22, 2018), http://www.healthcaremarketing.eu/publicaffairs/detail.php?rubric=Politik&nr=56442.

[39] *Id*.

those consent rates are fairly low. In Croatia, the consent rate increased from 11% to 14%,[40] and in Poland it increased from 23% to 25%.[41] Meanwhile, in Austria, the consent rate remained largely unchanged at just below 20%.[42] At the other end of the spectrum, Norway saw an increase in its consent rate from 71% last year to 76% this year.[43]

Again, depending on one's perspective, one can look at these figures and present different arguments. Supporters of the EFPIA approach can argue that, although there may have been decreases in consent rates in some countries, that was to be expected due to the GDPR and heightened awareness of privacy issues across Europe. Moreover, supporters could contend that several countries actually saw increases in their consent rates in places like Norway, Poland, and Croatia. Critics of self-regulation, however, will undoubtedly highlight those countries, like the United Kingdom and Germany, where HCP consent rates significantly decreased. Furthermore, even in many of the countries that saw increases, the consent rates still remain quite low overall. Taken together, the decreases in consent rates and the continued low consent rates for many countries would support a critic's argument that self-regulation is not working effectively and not leading to true transparency.

In that regard, critics could assert that the purpose of the EFPIA Disclosure Code is not being fulfilled and patients and other relevant stakeholders are not able to understand industry's financial ties to HCPs from the information that is being reported in the aggregate. To such

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[40] Press Release, Inovativna Farmaceutska Inicijativa, *Prijenos vrijednosti inovativnih farmaceutskih kompanija prema zdravstvenim radnicima i organizacijama u prošloj godini iznosio 131,5 milijuna kuna* (June 30, 2018), http://ifi.hr/priopcenje-za-medije-javna-objava-za-2017-godinu/.

[41] *Transparency Reports 2015-2017*, KODEKS Przejrzystosci, https://www.kodeksprzejrzystosci.pl/raport-przejrzystosci-2017/ (last visited August 12, 2018).

[42] Press Release, Pharmig, *Mit Investitionen die Gesundheitsversorgung verbessern* (July 2, 2018), http://www.pharmig.at/DE/Presse/Pressemitteilungen/Pressemitteilungen%202018/Pressemitteilungen+2017.aspx.

[43] Øyvind Bosnes Engen, *Industrien ga 181 millioner til helsepersonell og organisasjoner i fjor*, Dagens Medisin (June 29, 2018), https://www.dagensmedisin.no/artikler/2018/062/29/industrien-ga-181-millioner-til-helsepersonell-og-organisasjoner-i-fjor/.

critics, a more effective alternative would be governmental laws that require pharmaceutical companies, and potentially medical device companies and other life sciences companies, to report on their financial interactions with HCPs and others. For example, in response to the data released in Austria, the Austrian chapter of Transparency International issued its own press release in which it welcomed industry's transparency initiative but asserted that a Sunshine law should be enacted if the HCP consent rate did not improve.[44] Before we examine that alternative, it is first helpful to consider how Spain addressed its low consent rate.

Spain

Spain has taken a different – and thus far, unique – approach to increasing the transparency provided by self-regulatory reporting. In May 2016, Farmaindustria, the local EFPIA member, announced that it had revised its Code of Practice to essentially require individual level reporting for all transfers of value, except for research and development, beginning with 2018 reports covering 2017 data.[45] Those changes resulted from a decision that Farmaindustria sought from the Spanish Data Protection Agency ("SDPA") in which the SDPA determined that the legitimacy of disclosure on an individual basis pursuant to Farmaindustria's Code was supported by the EU and Spanish data protection framework, such that it would 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. Responding to the SDPA's opinion,

[44] Press Release, Transparency International – Austrian Chapter, *Transparency International – Austrian Chapter begrüßt Offenlegung von Zahlungen der Pharmaindustrie an Ärzte*, https://www.ots.at/presseaussendung/OTS_20180702_OTS0031/transparency-international-austrian-chapter-begruesst-offenlegung-von-zahlungen-der-pharmaindustrie-an-aerzte.

[45] 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/.

Farmaindustria reasoned it had "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."[46] In addition, Farmaindustria announced that its new approach was "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.[47]

After its member companies reported their 2016 data in 2017, at which time companies still needed to obtain consent to report at the individual level, Farmaindustria declared 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.[48]

On June 28, 2018, Farmaindustria issued a press release about the reports of its member companies for 2017 data.[49] As noted above, these reports, and the associated data, are particularly significant because this is the first year for which members of Farmaindustria did not need to obtain consent from HCPs to publish at the individual level. Thus, all of the relevant transfers of value to HCPs were reported at the individual level (except for research and

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[46] *Id*.

[47] *Id*.

[48] 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/.

[49] Press Release, Farmaindustria, *La industria farmacéutica reafirma su colaboración con el sistema sanitario a través de la I+D y el apoyo a la formación continuada* (June 28, 2018), http://www.farmaindustria.es/web/prensa/notas-de-prensa/2018/06/28/la-industria-farmaceutica-reafirma-su-colaboracion-con-el-sistema-sanitario-a-traves-de-la-id-y-el-apoyo-a-la-formacion-continuada/.

development, which continues to be reported in the aggregate). Stated differently, this year there was 100% individual level reporting in Spain, whereas the consent rate for the first two years of reporting was 20% for 2015 data and 35% for 2016 data.

One of the major concerns about the new Spanish approach to reporting focused on whether HCPs would no longer work with pharmaceutical companies because their information would be reported at the individual level, a concern based in part on the low consent rates from the prior years of reporting. A related concern about this year's reports was whether the amounts disclosed by member companies of Farmaindustria would decrease as a result of HCPs refusing to work with industry. In short, those concerns appear to be red herrings, as the data reported by Farmaindustria's member companies essentially increased for all categories of reporting.

Specifically, in terms of the amounts reported, companies spent €251 million on research and development; €115 million for HCPs to attend events/conferences; €90.5 million for HCOs for events/conferences; €79.5 million for consulting services; and €28 million for donations and grants. Farmaindustria emphasized that, for the most part, the amount spent per category was basically the same as last year, with the only significant increase being for research and development. An example of that year-over-year consistency is exemplified by the category of consulting services, which rose from €79 million for 2016 data to €79.5 million for 2017 data.

To date, no other EFPIA industry groups have followed Farmaindustria's pioneering step and sought an opinion from their national data privacy authority to shift to individual level reporting for all HCPs. In the abstract, it would appear that following the Spanish approach would be an attractive option for national industry groups seeking to further demonstrate to local governments and other stakeholders that they are strongly committed to enhancing transparency. However, it may be that there are local legal and data protection issues that would convince

industry groups to not seek such an opinion. Nonetheless, in view of the positive experience that Farmaindustria has had, whereby it has achieved 100% individual level HCP reporting without any seemingly negative impact on industry-HCP relations, some national industry groups may be more willing to pursue a similar approach in their countries, particularly if they believe it would be helpful in convincing a government to not enact a local Sunshine law.

Belgium

As to European transparency laws, it is useful to consider what has happened in Belgium, which could serve as a model for other governments interested in adopting a transparency law. In December 2016, the Belgian government adopted a Sunshine Act that largely codified the disclosure requirements that had been previously adopted by the local pharmaceutical, medical device, and generic industry groups.[50] Pursuant to the Act and implementing decrees,[51] data collection for reporting began in January 2017, with first reports required to be submitted by May 31, 2018, to the betransparent.be platform, the on-line platform that hosts the Belgian reporting program and data. Covered companies were required to report transfers of value provided to not only HCPs and HCOs, but also to patient organizations.

[50] 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.

[51] 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; Arrêté royal portant agréation de l'organisation visée à l'article 44, § 1er de la loi du 18 décembre 2016 portant des dispositions diverses en matière de santé [Royal Decree Approving the Organization Referred to in Article 44, Section 1 of the Law of December 18, 2016 Laying Down Various Provisions in the Field of Health] of July 31, 2017, Belgisch Staatsblad [B.S.] [Official Gazette of Belgium], August 22, 2017, https://www.betransparent.be/wp-content/uploads/2017/08/KB-Erkenning-Staatsblad-22.08.2017-1.pdf.

On June 26, 2018, betransparent.be issued a press release about the data that had been reported.[52] According to the press release, 530 companies submitted their 2017 data, which revealed total financial interactions with covered recipients in the amount of €203.271.730. For 2017 data, there were over 11,800 HCPs reported on, as well as 2,600 organizations.

By way of comparison, for 2016 data, which was based on industry codes and required companies to obtain consent from HCPs to report at the individual level, 198 companies reported a total amount of €169,715,284.[53] Approximately 3,500 HCPs granted consent and had their transfer of value information reported at the individual level.

Of the total amount reported for 2017 data, €115.648.996, which was 57% of the overall amount, was reported for research and development. €39.033.549, which was 19% of the overall amount, was reported for scientific meetings, and within that category €23.781.539 was spent on HCOs, while €15.252.010 was on HCPs. €21.268.155, which was 10% of the overall amount, was reported in the category of donations and grants to HCOs. €19.541.705, which was approximately 10% of the overall amount, was reported in the category of consultant fees and expenses, and of that amount €10.092.864 was for HCPs; €8.089.930 was for HCOs; and €1.358.911 was for patient organizations. Lastly, €7.779.325, or 4% of the overall amount, was reported as support for patient organizations.[54]

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[52] Press Release, betransparent.be, *Première publication des collaborations conformément au nouveau cadre légal* (June 26, 2018), https://www.betransparent.be/fr/communique-de-presse-les-entreprises-prestataires-de-soins-institutions-de-soins-et-organisations-de-patients-jouent-pleinement-la-carte-de-la-transparence/.

[53] Press Release, betransparent.be, *Encore plus de transparence pour la seconde publication des collaborations entre l'industrie et les organisations et professionnels du secteur de la santé* (June 29, 2018), https://www.betransparent.be/fr/communique-de-presse-encore-plus-de-transparence-pour-la-seconde-publication-des-collaborations-entre-lindustrie-et-les-organisations-et-professionnels-du-secteur-de-la-sante/.

[54] Press Release, betransparent.be, *Première publication des collaborations conformément au nouveau cadre légal* (June 26, 2018), https://www.betransparent.be/fr/communique-de-presse-les-entreprises-prestataires-de-soins-institutions-de-soins-et-organisations-de-patients-jouent-pleinement-la-carte-de-la-transparence/.

In addition to the betransparent.be press release, pharma.be, which represents the Belgian pharmaceutical industry and is a member of EFPIA, issued its own press release about the reported data.[55] The press release noted that 92 members of pharma.be reported their 2017 transfers of value, which totaled approximately €162 million. Of that amount, 66% of the overall amount reported was for research and development. As to the other reporting categories, 9% was for donations/grants; 15% for scientific events/meetings; 6% for consultant fees; and 4% for patient organizations. The press release, in addition to including supportive statements about the group's commitment to transparency, pointed out that the overall spend, as well as the amounts spent by category, was similar to last year when reporting was based on its industry code rather than the government's Sunshine Act, but that spend on research and development increased by approximately €7 million this year.

In our White Paper last year, we discussed the shift in Belgium from industry code-based reporting to legislative-based reporting. We suggested that as a result of the Belgian law, there would be more individual level reporting because consent would no longer be required, and that more companies would report because that obligation would no longer be restricted to only members of the relevant industry groups. We also predicted that those two effects would lead to *more* companies reporting about *more* HCP interactions with *more* value being reported.

As discussed above, in the first year of legislative-based reporting, there were in fact significant increases in the number of companies that reported, the number of HCPs who were reported on at the individual level, and the overall amount reported. Those increases certainly

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[55] Press Release, pharma.be, *FINANCIERING VAN WETENSCHAPPELIJK ONDERZOEK STAAT VOOROP IN DE RELATIES TUSSEN INNOVATIEVE FARMACEUTISCHE BEDRIJVEN EN DE BELGISCHE MEDISCHE GEMEENSCHAP* (June 26, 2018), https://pharma.be/nl/news/persberichten/232-financiering-van-wetenschappelijk-onderzoek.html.

could be used by critics of self-regulation as evidence that laws lead to increased transparency. Alternatively, one could take the position that the Spanish approach to transparency, whereby there was 100% reporting at the individual level this year, achieved essentially the same objective as the Belgian law, which could make such an approach more appealing to national industry groups if they feel that legislation may be imminent in their countries. Of course, it is important to not overlook the fact that three years of EFPIA's self-regulatory reporting has already revealed tens of thousands of HCP interactions and billions of euros' (and other currencies') worth of financial relationships, which clearly sheds a significant amount of light on the interactions between industry and HCPs.

However, it may be that some governments determine that self-regulation has not led to enough transparency and they decide to pursue a legislative solution. In that regard, Italy and Ireland are two countries where Sunshine legislation is pending, and those bills reflect different approaches to achieving transparency. In Ireland, the Medical Practitioners (Amendment) Bill 2017, No. 42 of 2017, was introduced in March 2017.[56] This legislation would require registered medical practitioners to provide the Medical Council a signed annual declaration that provides the "particulars of all declarable income and gifts received from any medical equipment suppliers, its servants or agents, and or any pharmaceutical companies, its servants or agents, within the previous 12 months not before the 31st day of January of each year."[57] In turn, the Medical Council would be required to maintain a publicly accessible and searchable electronic register of all declared gifts and declarable income.[58] The Irish legislation defines "declarable

[56] Medical Practitioners (Amendment) Act (Bill No. 42/2017) (Ir.), *available at* https://www.oireachtas.ie/en/bills/bill/2017/42/.
[57] *Id*.
[58] *Id*.

income" as "any money or other form of payment that a medical practitioner receives from a medical requirement supplier, its servants or agents, or pharmaceutical company and its servants or agents above the value of €600[.]" Reportable "gifts" are defined as "any voluntary transfer of money, grant for research, bursary, service or property without compensation above the value of €600[.]" Thus, the proposed Irish Sunshine legislation would impose an annual reporting obligation on the HCPs instead of industry.

In contrast, a law proposal introduced in Italy's House of Representatives in April 2018 follows the more traditional transparency approach and would impose reporting obligations on pharmaceutical and medical device companies.[59] In some ways, the Italian legislation is similar to the US Sunshine Act, as it would require companies to report – to an electronic register established by the Italian government – certain details of financial benefits they provide to HCPs (HCP name, professional qualifications, address, etc.; date of payment, nature of payment, amount of payment, etc.). The legislation also provides for a host of potential penalties for companies that fail to report or omit required information.[60]

Over the next year, industry will be tracking whether these legislative proposals proceed in Italy and Ireland, and whether additional countries seek to impose their own legislative solution. Such legislative developments, which could be interpreted as a response to the amount of transparency provided by EFPIA's self-regulatory approach, are significant not just for the pharmaceutical industry but also the medical device and generic industries, as such laws often require companies in those industries to also report their transfers of value. Accordingly, it is important to evaluate how those industries have chosen to address transparency thus far.

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59 Proposta Di Legge 10 aprile 2018, 491 (It.).

60 *Id*.

Medicines for Europe

Medicines for Europe, formerly known as the European Generic Medicines Association, is the official trade association for the European generic, biosimilar, and value-added pharmaceutical industries. In December 2015, it amended its Code of Conduct on Interactions with the Healthcare Community to include disclosure requirements for transfers of value to HCPs, HCOs, and Patient Organisations.[61] Under this Code, data collection began in 2017, and member companies of Medicines for Europe were required to disclose their first reports in 2018.

Under the Code, a transfer of value includes anything of value that is transferred or provided by a member company (directly or indirectly via a third party acting at the member company's direction) to a recipient, including monetary payments or in-kind benefits, such as meals, travel, hospitality, gifts, etc. The Code requires member companies to disclose, on an individual basis, the following types of transfers of value:

1) Transfers of Value to Patient Organisations:

- Support – financial and in-kind support;
- Fee for services – contracted services per Patient Organisation, including a description of the nature of the transfer of value (e.g., educational summer camp; disease awareness world day; development of information brochures for an awareness campaign) and the amount provided.

2) Transfers of Value to HCPs:

- Fees for service and consultancy – aggregated honoraria (excluding expenses for meals and drinks, travel and accommodation) paid to a HCP for the provision of services, such

[61] MEDICINES FOR EUROPE, CODE OF CONDUCT (2015).

as serving on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc. Fees paid in connection with R&D activities or market research are excluded from disclosure.

- Meetings, educational support, and site visits – Companies have two options for how to report such transfers of value:
  - **Option 1** - Total number (but not actual monetary value) of events for which a HCP has received support (which may include registration fees, travel, and/or hotel costs). Support is to be disclosed per HCP in the following categories:
    - Sponsorship for attending a third party organised congress where the company pays for registration fees, travel, or accommodation. (Companies are required to indicate whether each event is local/domestic, within Europe, or outside Europe).
    - Site visits.
    - Company-organised meetings for which a HCP received company funded hotel accommodation and/or airplane travel.
  - **Option 2** – Aggregate total amount of support provided to HCPs per individual conference or meeting as follows:
    - Sponsorship for attending a third party organised congress: name of congress; aggregated amount spent for the congress, including the number of HCPs financially supported to attend.
    - Site visits: aggregated amount spent, including the number of HCPs financially supported to attend.

- Company organised meeting: aggregated amount spent, including the number of HCPs financially supported to attend.

3) Transfers of Value to HCOs:

- Fees for service and consultancy – aggregated honoraria (excluding expenses such as meals drinks, travel and accommodation) paid to a HCO in exchange for the provision of services, such as serving on an advisory board, speaking at a company-organised educational event, participating in a focus group, etc. Fees paid in connection with R&D activities or market research are excluded from disclosure.
- Grants and donations – aggregated monetary amounts and a brief description of the nature of the grant or donation (e.g., research grant, equipment donation, product donation, etc.).[62]

As with the EFPIA Disclosure Code, the Medicines for Europe Code requires companies to publish a methodology note summarizing the methodology they used in preparing their disclosures that addresses, among other things, multi-year contracts, VAT, currency, and other issues relating to the timing and amount of their transfers of value.

Because this is an industry code-based reporting system, Medicines for Europe addressed consent and data privacy issues by requiring companies to "respect the applicable data privacy laws and regulations." According to the Code, to the extent required by applicable data privacy laws and regulations, companies should seek consent from HCPs to publish their individual level information. If a HCP refuses to consent, the Code requires companies to publish the HCP's information on an anonymous basis, and if there are multiple HCPs that refuse to consent, then

62 *Id*.

the relevant transfers of value data can be aggregated and the company should note the total number of HCPs included in the aggregation.[63]

As to the platform of disclosure, the Code requires companies to disclose their transfers of value "in a way in which the public can easily access such information. This means via the relevant company's website, and/or on a central platform (such as one provided by the relevant government, regulatory or professional authority board, or a Medicines for Europe national association)." Companies are required to ensure that their transfers of value are "accessible online for a reasonable period of time." The Code also provides that companies do not have to report if they are already subject to the EFPIA Disclosure Code or local laws so long as they are "as robust as the Medicines for Europe's [reporting requirements], including public availability of reports."[64]

As noted previously, data collection began in 2017 and companies disclosed their first reports in 2018, as they were required to do so by June 30, 2018, at the latest. In that regard, on June 22, 2018, Medicines for Europe issued a press release titled, "Medicines for Europe members publish disclosure of Transfers of Value to the healthcare community."[65] In that press release, Medicines for Europe stressed that it

> is committed to bringing accessible, high quality medicines to patients across Europe. Already today our industry supplies 63% of dispensed medicines in Europe.
>
> As part of our commitment to improve public health, Medicines for Europe and its members regularly engage and collaborate with the stakeholder community, including healthcare professionals and patient representatives. This enables us to

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63 *Id*.

64 *Id*.

65 Press Release, Medicines for Europe, *Members Publish Disclosure of Transfers of Value to the Healthcare Community* (June 22, 2018) https://www.medicinesforeurope.com/news/medicines-for-europe-members-publish-disclosure-of-transfers-of-value-to-the-healthcare-community/.

> deliver accessible healthcare solutions that work best for our stakeholders, and ultimately contribute to the sustainability of healthcare systems across Europe. Disclosure of transfers of value related to these interactions enables the industry, healthcare professionals and patient organisations to jointly promote shared values of transparency, integrity, accountability and collaboration.[66]

Due to its commitment to improving patient health and advancing the principles of transparency, integrity, accountability, and collaboration, Medicines for Europe further explained that

> All Medicines for Europe corporate members, including the corporate members of our national associations, are required to disclose according to the trade association Code of Conduct. Where national legislation or rules already require this, companies must follow the law of the specific Member State and of the Medicines for Europe code (in cases where our rules are stricter).
>
> In accordance with the Medicines for Europe Code of Conduct, disclosure is to be made on an annual basis and each reporting period covers the previous calendar year. The first reporting period is calendar year 2017, with disclosures published by June 30, 2018. The information will be published on the website of each member and will be accessible to the public. Where disclosure is made through a national authority database, the information will be available on that authority's website.[67]

Medicines for Europe also emphasized that the disclosures of its member companies "mark[] a milestone in Medicines for Europe's commitment to transparency in its interactions with the healthcare community."[68]

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66 *Id*.
67 *Id*.
68 *Id*.

MedTech Europe

MedTech Europe represents the medical device industry in Europe and is an alliance of associations: European Diagnostic Manufacturer Association ("EDMA"), which represents the European in vitro diagnostic industry, and Eucomed, which represents the medical device industry in Europe. On December 2, 2015, MedTech Europe approved a new Code of Ethical Business Practices, and in July 2018 issued updated Q&As for the Code.[69] Part 2 of the Code, The Dispute Resolution Principles, entered into force on January 1, 2016, and the remainder of the Code entered into force on January 1, 2017.

Most significantly, the Code does not include EFPIA-like transparency reporting requirements. Instead, the Code prohibits, as of January 1, 2018, member companies from providing financial or in-kind support directly to individual HCPs to cover costs, such as registration fees, travel, or hospitality, of their attendance at third party organized educational events (except for third party organized procedure training meetings or pursuant to a consulting agreement with a HCP speaker engaged by the company to speak at a satellite symposium).[70]

Although the Code does not include broad-based reporting requirements like EFPIA, it does include specific transparency sections. For example, in the Chapter focused on Consultant Arrangements, the "Disclosure and Transparency" section provides:

> Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants. All required consents and approval shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national

[69] MEDTECH EUROPE, GUIDANCE DOCUMENT: QUESTIONS AND ANSWERS (Q&AS) ON THE MEDTECH EUROPE CODE OF ETHICAL BUSINESS PRACTICE (2018).

[70] MEDTECH EUROPE, CODE OF ETHICAL BUSINESS PRACTICE (2015).

> requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.[71]

But most significantly, Part 2 of the Code, titled, "Disclosure Guidelines," requires member companies to publicly disclose Educational Grants that they provide. The general obligation that the Code imposes on member companies is to "document and disclose all payments related to Educational Grants[72] … that it makes to a Healthcare Organization based on or registered in Europe, without limitation of value." Member companies are obligated to disclose, for each clearly identifiable and separate recipient, the amounts paid as Educational Grants in each reporting period, with the disclosure being on an aggregate basis. The amounts must be aggregated on a category-by-category basis, though the member company must be able to provide itemized disclosure upon request of the recipient or relevant authorities. The categories for disclosure are:

- Educational Grants to support Third Party Organised Events (including Support for HCP Participation at Third Party Organised Educational Events); and
- Other Educational Grants to Healthcare Organisations (including Scholarships, Fellowships, and/or Grants for Public Awareness Campaigns).

Similar to the disclosure requirements adopted by EFPIA and Medicines for Europe, MedTech Europe requires its member companies to "create a note summarising the

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[71] *Id*.

[72] Educational Grants are defined in the Code as follows: "provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved."

methodologies used by it in preparation the disclosures and identifying Educational Grants for each category described [above]." Moreover, the Code provides that

> [t]he note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This methodology note shall be made available upon request by an interested party.[73]

With respect to timing, disclosures are made on an annual basis, with each reporting period covering a full calendar year, and first reports were due in 2018 for 2017 data. Companies are required to submit their disclosure report within six months of the end of the calendar year to the EthicalMedTech website. In turn, the website, https://www.ethicalmedtech.eu/, makes the reports publicly available by August 31 on its Transparent MedTech platform. (Accordingly, at the time of publication of this White Paper, the first reports under the MedTech Europe's transparency rules have not yet been made publicly available.) Annex II of the Code provides a template for member companies to use for their disclosure reports, and the EthicalMedTech website offers a vast array of resources and guidance materials.[74]

Although MedTech Europe has taken a specific and unique approach to transparency reporting, medical device companies must remain aware that they can also be subject to legislative reporting requirements in Europe. Moreover, there are some countries in which the local industry groups have chosen to adopt transparency reporting requirements. For example, in the Netherlands, member companies of certain local medical device industry groups have an

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73 *Id*.

74 Resources, Ethical MedTech, https://www.ethicalmedtech.eu/resources/ (last visited August 12, 2018).

obligation to report the same type of information as their pharmaceutical counterparts to the Dutch Healthcare Transparency Register.[75]

Furthermore, Assobiomedica, which is the Italian medical device association member of MedTech Europe, includes in its latest Code of Ethics transparency provisions that are very similar to EFPIA's Disclosure Code.[76] Like the EFPIA Disclosure Code, the Assobiomedica Code requires member companies to annually report certain transfers of value they make to HCPs and HCOs on their websites, using a template that is very similar to EFPIA's template. And although not identical to EFPIA's Disclosure Code, the categories of reporting in the Assobiomedica Code, as well as the need to obtain the consent of HCPs in order to report at the individual level, are also comparable to EFPIA's requirements. As to timing, member companies of Assobiomedica will be required to begin collecting data in 2020, with first reports being due by June 30, 2021.[77] In the coming years, medical device companies should monitor whether Assobiomedica serves as a model for other national industry groups as they adopt their own disclosure requirements or whether Assobiomedica will be an outlier in terms of imposing EFPIA-like reporting requirements on its member companies.

Rest of World

While there have been significant transparency developments over the past several years in Europe, such developments are not limited to just that continent. For example, pharmaceutical companies continue to participate in industry code-based reporting in Australia; pharmaceutical and medical device companies continue to report in Japan based upon their governing industry

[75] Transparantieregister zorg, Stichting Transparantieregister Zorg, https://www.transparantieregister.nl/en-gb/voor-bedrijven (last visited August 12, 2018).
[76] ASSOBIOMEDICA, CODE OF ETHICS (2018).
[77] *Id*.

codes; companies subject to the transparency laws in Indonesia and the Philippines continue to submit their sponsorship reports; and companies began data collection this year for their new Sunshine reporting obligations in South Korea.

Moreover, in 2018, the Saudi Food and Drug Authority issued three updated versions of its "Transparency and Payments Disclosure Guidelines for Medical Companies" ("Saudi Guidelines").[78] The most recent update, version 2.2, was issued in July 2018. Significantly, the Saudi FDA announced that the effective date for the Guidelines is October 1, 2018, but it is not yet known when data collection or reporting will actually begin. Pursuant to version 2.2 of the Saudi Guidelines, pharmaceutical and medical device companies will be required to submit transparency reports via an electronic portal, https://td.shdt.sa/, that disclose the names of HCPs and healthcare institutions to whom they have provided payments and other relevant transfers of value. Version 2.2 of the Saudi Guidelines identifies eight different types of reportable activities:

1. Consulting fees;
2. Speaking fees;
3. Training fees;
4. Sponsorship of HCPs to attend an educational event;
5. Research or educational grants;
6. Symposium or conferences sponsorships;
7. Hospitality; and
8. Supplying scientific materials (e.g., books or instruments).

[78] SAUDI FOOD & DRUG ADMINISTRATION, TRANSPARENCY AND PAYMENTS DISCLOSURE GUIDANCE FOR MEDICAL COMPANIES (v. 2.2) (July 11, 2018).

Another significant transparency development occurred in July 2018 when Colombia enacted a transparency law.[79] While the passage of the law is itself significant, the fact that companies must obtain "prior, express and informed consent" in order to fulfill their reporting obligations makes the Colombian legislative approach to transparency distinct – and also particularly challenging for companies to satisfy.

As stated at the outset of the law, its purpose is

> to frame the Register of Transfers of Valuables in the Health Sector, with a view to transparency in the relationships between the parties to the health sector and for easier public policy making upon the analysis of the supplied information. The provisions herein shall be binding upon both the parties with a duty to supply data related to transfers of valuables in the health sector and their recipients designated herein.

Pharmaceutical and medical device companies, as well as other types of entities, are required to report in Colombia twice a year. One report covers transfers of value provided from January through June, while the other report covers transfers of value made from July through December. Companies are required to submit their reports to the government's Register of Transfer of Valuables in the Health Sector, RTVSS, via a reporting platform within three months of the end of the applicable reporting period. The first mandatory report will cover transfers of value made from July-December 2019, and must be submitted by the end of March 2020. The data reported by companies will be made publicly available via the reporting platform in an open format.[80]

There are thirteen different categories of covered recipients, including five different types of individuals and eight different types of organizations. Covered individuals include, among others, those who prescribe services and products and those who are responsible for the

[79] L. 2881, julio 5, 2018, DIARIO OFICIAL [D.O.] (Colom.).

[80] *Id*.

procurement of health products. Covered organizations include, for example, educational institutions and patient organizations. There are eleven different types of reportable transfers of value, including food and drinks, service payments, and samples. Exemptions from reporting include transfers of value that are below the reporting threshold, payments to an employee, market research, and certain types of software licenses.[81]

One aspect of the Colombian law that distinguishes it from many other transparency laws is the notion of consent. Specifically, Paragraph 17 of the governing Resolution provides:

> As part of their obligation, the parties required to report shall obtain the prior, express and informed consent of recipients for the Ministry of Health and Social Protection to release the information related to the value of the payments or transfers of valuables reported in the name of recipients, respecting in any event data deemed as proprietary within the legal framework.
>
> For such purpose, the sought informed consent shall clearly state personal data to be released and explicitly warn that the value of the transfer and the specific aim of the disclosure linked to the consent shall be disclosed. Exhibit 2, enclosed herewith, furnishes a model of the information that should be contained in the informed consent. Notwithstanding, the parties required to report may use any format deemed as appropriate.

In addition to providing a model template for the consent that companies must obtain with the aforementioned Exhibit 2, the Colombian law includes, as Exhibit 1, details about how companies are required to report their data, including specifications for data files; requirements for file characteristics; and various other data transfer requirements. Moreover, the Colombian law addresses a host of other reporting issues, including the threshold for reporting; indirect reporting; reporting of transfers of value by parents, affiliates, and subsidiaries; cross-border spend; and various record-keeping requirements.[82]

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81 *Id*.

82 *Id*.

While companies analyze the Colombian law and establish, or revise, their policies and procedures for collecting relevant data in order to be able to report in 2020, they also need to be aware of other legislative developments in South America. For example, in Brazil, the State of Minas Gerais enacted two transparency laws, the first in 2016 and the second in 2018.

First, in 2016, the State of Minas Gerais enacted LEI 22440, which requires that companies in the medicine, orthoses, prosthetics, equipment, and implants industries declare their financial relationships with HCPs that could constitute potential conflicts of interest. This includes any type of donation or benefit, whether direct or indirect. The law identifies the following examples of what must be reported: gifts; travel tickets; event registration; lodging; financing of research; consulting; and lectures. Under this law, companies must submit a report on an annual basis by the last day in January for the previous year's data. Company reports must include the HCP's name and local registration number; the amount of the benefit; and the nature of the benefit.

In December 2017, the State government issued Decree 47334 to implement the Sunshine law. The decree expanded the scope of the reporting obligation to include auxiliary industries and clarified the nature of indirect benefits. The decree also provided that companies must use the digital form provided on the State Department of Health's website for their annual reports, and that the information reported will be published on the Department's website.[83]

As noted previously, the January 31 deadline for the submission of 2017 data was extended through the end of 2018, in part to allow for adaptations to the government's reporting platform to accommodate Law No. 22921 of January 21, 2018, which requires companies to

[83] The platform is established, and data that companies have already reported can be accessed and viewed at http://declarasus.saude.mg.gov.br/.

report about their sponsorship of scientific events, including items like financing of speakers, provision of food, and travel and accommodation. This is an annual obligation, with reports due on January 31, and the first report being due in 2019 on 2018 data.

While Minas Gerais became the first State in Brazil to adopt a Sunshine law, on July 4, 2017, Sunshine legislation, PL 7990-2017, was introduced at the federal level in the Brazilian National Congress. The legislation would apply to pharmaceutical and medical device companies and would require them to report the following transfers of value that they provide to HCPs and HCOs: premiums and bonuses; travel, flights, accommodation, and meals; payments of benefits and costs for participation in congresses and similar meetings; prizes and gifts; free samples; consultancies, scientific papers, lectures, and other similar presentations; studies and scientific research; and payments for copyrights, royalties, and trademarks. Annual reports, which will be made public, would be submitted to the government within 90 days of the end of the reporting year. Similarly, there is federal legislation pending in Chile, Boletin N. 9914-11, that would impose disclosure requirements on pharmaceutical and medical device companies to report their transfers of value to HCPs, HCOs, and other stakeholders. The information reported would be made publicly available on a governmental website, and many of the details of the transparency initiative would be further defined in regulations.

Canada is the last country we will examine, in part because it presents a unique combination of all the different types of transparency developments we have already discussed, from voluntary reporting to local Sunshine laws to potential federal involvement. 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 – Abbvie, Amgen, Bristol-Myers Squibb, Gilead, GSK, Eli Lilly, Merck, Novartis,

Purdue, and Roche – announced that they would voluntarily publish information about their overall payments to HCPs in Canada. The companies decided that the information they would publish would be at the aggregate level and would not identify individual physicians. In June 2017, those companies disclosed their information and faced criticism for reporting at the aggregate, as opposed to individual, level.[84]

Those same ten companies again reported aggregate information in June 2018 for 2017 data, and once again faced criticism for not providing enough transparency about their financial relationships with HCPs. An article from *The Globe and Mail* titled, "Drug makers in Canada disclose doctor payments as transparency debate heats up,"[85] reported that the 10 companies disclosed a total of approximately $75 million. The article also featured critics of the voluntary reporting initiative, who argued that the data was insufficient and only served to reinforce the need for a legislative solution. However, the article also included a statement from Innovative Medicines Canada, as it explained that the release of the aggregate data "provides more transparent disclosure, and it increases understanding of the industry's collaboration and contributions across the health sector."[86]

More criticism of the aggregate disclosures was featured in Canadian editorials. For example, *The Star* published an editorial that argued

> [t]here's no way of knowing who got the money or what they were paid to do. … [M]any other drug companies don't reveal even aggregate numbers. It's impossible to know where Big Pharma's money goes, so it's impossible to figure

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[84] CAMPBELL & SHARKEY, 2017 WHITE PAPER, *supra* note 1, at 53-55.

[85] Kelly Grant, *Drug makers in Canada disclose doctor payments as transparency debate heats up*, THE GLOBE AND MAIL (June 28, 2018), https://www.theglobeandmail.com/canada/article-drug-companies-paid-nearly-75-million-to-doctors-health-care/?utm_medium=Referrer:+Social+Network+/+Media&utm_campaign=Shared+Web+Article+Links.

[86] *Id*.

> out whether it affects which drugs doctors prescribe or whether some drugs are over-prescribed.[87]

In another editorial titled, "What Big Pharma pays your doctor,"[88] Dr. Joel Lexchin, a Canadian transparency advocate, stressed that the same 10 companies that reported last year reported again this year, and he criticized the fact that the

> disclosures are actually not on the [Innovative Medicines Canada] website, they are on the individual companies' websites and are not easy to find. It takes at least a couple of mouse clicks to locate the material. Nor is there any more detail this year than last year about how the money is used. … [A]ll that the companies have disclosed are gross figures — with no information about what they paid for.[89]

Although voluntary reporting in Canada remained the same in 2018 as it was last year, the province of Ontario radically transformed the Canadian transparency landscape in 2017. In September 2017, the Ontario Minister of Health and Long-Term Care ("Minister") introduced Bill 160, the Health Sector Payment Transparency Act. That legislation advanced quickly through the legislative process and was enacted into law on December 12, 2017.[90]

In the very beginning of the Act, it identifies its purpose as follows:

> to require the reporting of information about financial relationships that exist within Ontario's health care system, including within health care research and education, and to enable the collection, analysis and publication of that information in order to,
> (a) strengthen transparency in order to sustain and enhance the trust that patients have in their health care providers and in the health care system;
> (b) provide patients with access to information that may assist them in making informed decisions about their health care;

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87 Editorial, *Ontario's new government should carry through on making drug company payments public*, THESTAR.COM (June 28, 2018), https://www.thestar.com/opinion/editorials/2018/06/28/ontarios-new-government-should-carry-through-on-making-drug-company-payments-public.html.

88 Joel Lexchin, *What Big Pharma pays your doctor*, THE CONVERSATION (July 4, 2018, 7:04 PM EDT), http://theconversation.com/what-big-pharma-pays-your-doctor-99431.

89 *Id*.

90 Health Sector Payment Transparency Act, 2017, S.O. 2017, c. 25, Sched. 4 (Can. Ont.).

> (c) provide the Minister and others with information for the purposes of health system research and evaluation, planning and policy analysis; and
> (d) provide for the collection, use and disclosure of personal information for these purposes.[91]

In short, the Act requires pharmaceutical and medical device manufacturers to annually report transfers of value, defined as "a transfer of value of any kind and includes a payment, benefit, gift, advantage, perquisite or any other prescribed benefit," that they make to a "recipient," which is defined as "a prescribed person or entity that receives a transfer of value from a [covered company.]"[92] The Act provides that the information reported will be made available "on a website and in any other manner that the Minister considers appropriate at least once in a calendar year and at any other time as the Minister considers appropriate." The Act also provides for a range of monetary sanctions.

The Act requires companies to report, "[s]ubject to the regulations," the following information:

> 1. The name of the parties to the transaction including,
> i. if a party is a business, its legal and operating names,
> ii. if a party is an individual, the individual's name, profession or title and any other prescribed identifying information.
> 2. If requested by the Minister from an intermediary or an affiliate of an intermediary under subsection (3), the source of the transfer of value.
> 3. The parties' respective business addresses.
> 4. The date of the transfer of value.
> 5. The transfer of value's dollar value or, in the case of a non-monetary transfer of value, its approximate dollar value.
> 6. A description of the transfer of value, including the reasons for it.
> 7. Any other prescribed information.[93]

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91 *Id*.
92 *Id*.
93 *Id*.

However, aside from that level of detail, the Act leaves many of the specifics of reporting, including, for example, the further definition of "recipient," the timing of reporting, and the complete information to be reported, to the regulatory process.

On February 6, 2018, the Ministry of Health and Long-Term Care issued proposed regulations and requested that interested parties submit comments by April 6, 2018.[94] As anticipated, the proposed regulations filled in many of the details and specifics that had been left open by the Act. First, as to timing, the regulations proposed that companies would submit their annual report to the government by June 30, to cover data from the previous year via an electronic platform to be developed by the Ministry. The proposed regulations also included a review/dispute process before that, whereby companies would be required to notify recipients in writing of the information they intended to report by March 31. The regulations proposed that they would come into force on **January 1, 2019**, with the first annual reporting due by **June 30, 2020.**

The proposed regulations contained an expansive definition of covered "recipients," as the following individuals and organizations would be prescribed as "recipients" under the Act:

- Member of a health regulatory college
- Hospital or psychiatric facility
- Licensed long-term care home
- Home care provider contracted by LHIN
- Non-profit community health centre, Aboriginal health access centre, family health team, nurse-practitioner-led clinic
- Primary care nursing, interprofessional, or maternal care service provider
- Non-profit community mental health and addiction service provider
- Non-profit palliative care provider, including hospice
- Physiotherapy clinic
- Independent health facility

[94] Ontario's Regulatory Registry, Ontario Government Website, https://www.ontariocanada.com/registry/view.do?postingId=26846&language=en (last visited on August 14, 2018).

- Pharmacy
- Laboratory or specimen collection centre
- Health regulatory college
- Association that advocates for the interest of health care professionals or organizations.
- Advocacy organization
- A foundation or other health charity
- Group purchasing or shared services organization
- University, college or post-secondary institution
- A person fulfilling the requirements to become a member of a regulated health profession
- Researcher or non-profit health research institute/organization
- Anyone who is a board member, director, trustee, officer, appointee, employee or agent of the above
- Subsidiary, as defined in the Business Corporations Act, of the above
- An immediate family member of any individual outlined above.

In addition, the proposed regulations offered additional details and specifications about the following issues: the scope of a reportable "transfer of value"; applicable exemptions; the scope of companies required to report, including intermediaries; the information to be reported; and the process by which recipients and reporting companies would correct reported information. But before these regulations could be approved, something intervened in Ontario: electoral politics.

The party in power at the time that the Act was adopted, and when the regulations were proposed, was the Liberal Party of Ontario. However, in Ontario's General Election on June 7, 2018, the Progressive Conservative Party of Ontario resoundingly defeated the Liberal Party and won a majority government. Significant to this discussion, during the campaign, the Progressive Conservative Party's 2018 election platform, titled, "Plan for the People," included, among other things, more business-friendly policies and a promise to "cut red tape and stifling regulations that are crippling job creating and growth."[95]

[95] Plan for the People, Ontario PC, https://www.ontariopc.ca/plan_for_the_people (last visited on August 14, 2018).

The Progressive Conservative Party government was sworn in and assumed power in Ontario on June 29, 2018. Since that time, there have been no new proposed regulations to implement the Ontario Sunshine Act, and the future of when and how the Act will be implemented remains an unknown at the time of publication of this White Paper. In that regard, an editorial in *The Star* titled, "Ontario's new government should carry through on making drug company payments public," noted that Ontario had passed a Sunshine law but that its Legislature dissolved before implementing regulations were adopted; thus, "it's now in limbo." The editorial called on the new Ontario government to "pick up the ball and make sure the regulations are passed[]" because "Ontario's approach is the right one[.]"[96]

While the situation in Ontario remains "in limbo," another province, British Columbia, is beginning its own transparency journey. According to an article from *The Globe and Mail* titled, "B.C. considers forcing drug companies to disclose payments to doctors,"[97] the province of British Columbia announced at the end of June 2018 that consultations on potential transparency reporting requirements for the life sciences industry would take place over the summer, with a focus on whether, and how, drug and medical device manufacturers should disclose their payments to HCPs, HCOs, patient organizations, and other organizations. The article includes statements from an interview with Adrian Dix, the B.C. Minister of Health, in which he acknowledged that payments from industry are not necessarily a bad thing but that disclosing them would be beneficial for patients who will be able to determine if their doctors have any

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[96] Editorial, *Ontario's new government should carry through on making drug company payments public*, THESTAR.COM (June 28, 2018), https://www.thestar.com/opinion/editorials/2018/06/28/ontarios-new-government-should-carry-through-on-making-drug-company-payments-public.html.

[97] Kelly Grant, *B.C. considers forcing drug companies to disclose payments to doctors*, THE GLOBE AND MAIL (June 26, 2018), https://www.theglobeandmail.com/canada/british-columbia/article-bc-considers-forcing-drug-companies-to-disclose-payments-to-doctors/?utm_medium=Referrer:+Social+Network+/+Media&utm_campaign=Shared+Web+Article+Links.

conflicts of interest. Mr. Dix commented that "[t]here's no question there's a significant … potential for conflict in this relationships [with the pharmaceutical industry]. And if you want to put the patient at the centre of health care, the patient should know what those relationships are."[98]

The article also includes supportive statements from Andrew Boozary, a pro-transparency Canadian doctor and leader of the Open Pharma movement in Canada, and Eric Cadesky, the president of Doctors of BC. In that regard, Dr. Cadesky observed that the [pharmaceutical] industry "is involved in training, education and research and we want to make sure that those things continue to be funded properly and that the relationship is one that is transparent and proper[.] We want to make sure that those important activities are not negatively affected in an unintended way." Lastly, the article pointed out that Innovative Medicines Canada had issued a statement welcoming British Columbia's consultations.[99]

In our White Paper last year we discussed how Canada's federal government had not shown an interest in legislating in this area, instead indicating that this was an issue for provinces. However, *The Globe and Mail* article discussed above also noted that a spokesman for the federal Health Minister stated that "Health Canada is consulting with other jurisdictions to see how their transparency laws are working."[100]

We predicted last year that there would be more transparency in Canada, and the real question was whether industry or the government (or which government(s)) would be leading the way on this issue. Our position is essentially the same once again this year: there have been significant Sunshine developments in Canada but the future remains murky. Although a law was

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98 *Id*.
99 *Id*.
100 *Id*.

passed in Ontario, the status of implementing regulations remains "in limbo," while British Columbia is just starting on its journey to a potential Sunshine law. Meanwhile, other provinces have not gotten involved in this area and the federal government is consulting with other jurisdictions to see how their transparency laws are working. Thus, the only prediction we can safely make for the upcoming year is that we will definitely be writing about Canada in our 2019 White Paper, but we do not if we will be writing about Ontario regulations, more provincial laws, a new federal approach to Sunshine reporting, or more on the current status quo.

Conclusion

Since we used a French saying for the title and theme of this White Paper, we thought we would conclude with one too. Unfortunately, we found that many of the French sayings we examined were about romance and love, concepts that are not normally associated with global transparency.

Although it is difficult to predict with any specificity what will happen in the coming year, it is safe to assume that there will be transparency developments around the world. Some of these will occur in places we have discussed in this edition of our White Paper, like Canada, the United States, and Europe, but we also fully anticipate that in next year's edition we will be writing about new countries or regions that burst onto the transparency scene with the adoption of Sunshine laws or codes for the first time. In short, we expect to engage in a similar exercise next year as we did this year. Not too get too far ahead of ourselves, but it may be that for the title of next year's White Paper we adapt a few famous quotes from the great Yogi Berra: "It's

Déjà Vu All Over Again [Because the Global Transparency Movement] Ain't Over 'Til It's Over."[101]

[101] Yogi-isms, Yogi Berra Museum & Learning Center, https://yogiberramuseum.org/about-yogi/yogisms/ (last visited on August 14, 2018).

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