The sun never sets on transparency

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Abstract
The financial relationships between the pharmaceutical and device industries and healthcare practitioners appear frequently in the spotlight because of their potential to create bias and influence prescribing choices. Public disclosure of these transactions may help patients make informed choices about their healthcare practitioners and may help reduce healthcare costs. The US Sunshine Act, a Federal law that requires disclosure of transactions between industry and healthcare practitioners, was passed in 2010. Similar disclosure laws and codes now exist globally. Unfortunately, none of the current requirements are clear about the reportability of industry support for medical writing and editorial services. Regardless, medical writers should be aware of these requirements, which can help them as they forge relationships with authors.

Introduction
The public continues to be made aware of the financial relationships between industry and healthcare practitioners (HCPs) and the role that these transactions may play in creating bias and influencing prescribing choices. Current best practice guidelines, such as Good Publication Practice 3 (GPP3) and the International Committee for Medical Journal Editors (ICMJE) criteria for authorship support integrity and transparency in the publication of industry-sponsored clinical trials' data.[1,2] A HCP-industry specific transparency law, known as the US Federal Sunshine Act, was passed in 2010.[3] Its main goal is to help reduce potential conflicts of interest that could harm clinical integrity and patient care and increase healthcare costs.[4] Other countries have followed suit (Figure 1).

Unfortunately, the global transparency reporting requirements have little detail about non-monetary support for medical writing and editing, and whether or not it constitutes a transfer of value (TOV) to HCPs. Despite this lack of clarity, medical writers should be aware of the current landscape and should be able to discuss the various aspects of the global transparency requirements.

The US Sunshine Act
Overview
In brief, the Sunshine Act requires that applicable manufacturers and group purchasing organisations make public certain financial relationships between themselves and certain HCPs, known as covered recipients, and teaching hospitals (see Table 1 for a list of terms and definitions). The granular details of the requirements of the Sunshine Act were published in February 2013 in a document called the Rules for Implementation.[4] According to the Rules for Implementation, the financial relationships that must be reported can be in the form of direct payment or TOV, and include payment or TOV of 10 USD or more. Employees of sponsoring companies who meet the definition of covered

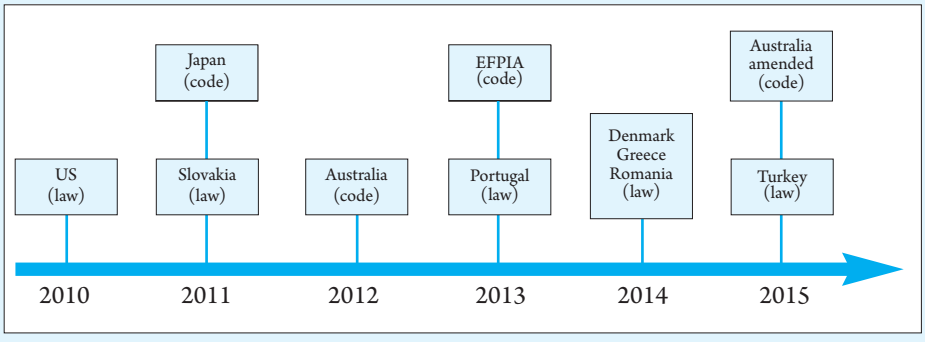

Figure 1. Timeline for passage of transparency laws and codes[3,11] The US Sunshine Act, passed in 2010, is a transparency law requiring public disclosure of financial transactions between the pharmaceutical and device industries and healthcare practitioners. Many other countries have followed suit, with either laws or codes. It is anticipated that this trend will continue in 2016 and beyond.

Term	Definition
Applicable manufacturers	Manufacturers of covered drugs, devices, biologicals, and medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program
Group purchasing organisations	An entity that helps healthcare providers, such as hospitals, nursing homes and home health agencies, save money by purchasing large volumes and use that as leverage to negotiate discounts with manufacturers, distributors and other vendors.
Covered recipients	Licensed medical doctors, doctors of osteopathy, dentists, optometrists, podiatrists, and chiropractors
Teaching hospitals	All hospitals that receive direct or indirect graduate medical education payments from Medicare
Transfer of value (TOV)	Anything of value given by an applicable manufacturer or group purchasing organisation to a covered recipient or physician owner/investor that does not fall within one of the excluded categories under the Sunshine Act Rules for Implementation
Healthcare organisations (HCO)	A legal person whose business address, place of incorporation, or primary place of operation is in Europe that is involved in the provision of healthcare services (e.g., hospital, learned society, association of HCPs).
Healthcare provider (HCP)	Any licensed healthcare practitioner who provides patient care

Table 1. Specific terms and definitions related to the Sunshine Act

recipient are excluded.

The public database that contains the financial transaction data is known as Open Payments, and is administered by the US Centers for Medicare and Medicaid Services. The first financial transaction data were released on September 30, 2014, and within 24 hours, there were reportedly 11 million hits.[5] On October 1, 2015, the *BMJ* released a feature article detailing the types of payments made, the top five companies making payments, the top five drugs to which payments were attributed, and the five most highly paid physicians. The article also included the following quote from a 2014 article published in the *Annals of Internal Medicine*: [6]

> "One may presume that the public may have difficulty distinguishing between donated drugs for research and transfers of financial value to physicians. Such confusion frustrates the purpose of [the Act], casting shadows where bright light had been promised."

And in fact, this may be the case. For example, the reporting of funding for a clinical trial, which would likely include administrative costs for conducting the trial as well as the cost of the drug, might be recorded in the database as a large payment made to an individual physician investigator.

"There were ~ 11 million hits within the first 24 hours following release of the first Open Payments data set"

Updates and Changes to the Sunshine Act

Since the initial publication of the Rules for Implementation in February 2013, we have seen some changes intended to help clarify the reporting requirements. For example, the exemption for reporting payment to physician speakers at accredited or certified continuing medical education (CME) events was deleted.[7] According to the Centers for Medicare and Medicaid Services, this was done to create consistency in the reporting of payments to speakers at certain accredited or certified CME events, and to give clarity to consumers who will ultimately have access to the reported data. Thus:

> "Starting in 2016, when an applicable manufacturer provides an indirect payment or other [TOV] to a continuing education organization for a continuing education event to physicians, and knows or finds out the identity of the physician attendees/speakers within the reporting year or by the end of the second quarter of the following reporting year, that payment must be reported to the Centers for Medicare and Medicaid Services in 2017."

Under the Rules for Implementation, reprints and textbooks provided by applicable manufacturers to covered recipients is a reportable TOV.[4] In November 2013, 23 members of the US House of Representatives communicated their disagreement to the Centers for Medicare and Medicaid Services regarding classification of these items as a reportable TOV, as this type of information promotes good medical care and, ultimately, supports patients. The Centers for Medicare and Medicaid Services did not agree, and declined to change the classification of these items.[8] There continues to be widespread disagreement with the decision made by the Centers for Medicare and Medicaid.

"It is unclear as to whether the US Senate will address proposed Sunshine Act exemptations for reprints and textbooks."

In July of 2015, the US House of Representatives overwhelmingly voted in favour of the 21st Century Cures Act.[9] The major purpose of this act is to increase the speed with which new medicines reach patients. It also includes a provision to exempt certified CME events and the acceptance medical texts and journal reprints by covered recipients from Sunshine reporting. The proposed changes to the Rules for Implementation include the following:

> "In the case of a [covered recipient] who is a physician, an indirect payment or TOV to the [covered recipient] for speaking at, or preparing educational materials for, an educational event for physicians or other health care professionals that does not commercially promote a covered drug, device, biological, or medical supply" [would be exempt from reporting under the Act].

The US Senate has declined to vote on the bill as a single entity. Instead, they are addressing the legislation as smaller, individual bills. It is unclear at this time whether they will address the above-mentioned proposed Sunshine Act exemptions for reprints and textbooks.

In October 2015, the US Senate proposed legislation that would broaden the Sunshine Act to include the reporting of financial transactions between applicable manufacturers and physician assistants, nurse practitioners, and other advanced practice nurses, all of whom are licensed to prescribe covered products.[10] If passed, reporting for this expanded group of covered recipients would begin in 2017.

Global Transparency

Focus on France

Other countries and regions of the world have joined the transparency movement. Europe has experienced the most activity on the transparency front, but it has also extended to places like Australia and Japan. Unlike the US, where transparency reporting requirements have been established in Federal and State laws, in Europe the transparency requirements have been created either by governments through laws and regulations or by self-regulatory bodies in the form of voluntary industry codes.

The first, best-known, and most comprehensive law was enacted in France in December 2011, *LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé*, also known as the French Act.[11] The French Act, and its implementing decrees, requires broad disclosure by pharmaceutical and medical device companies of agreements with and benefits provided to HCPs and various entities. Under the French Act, there are two main types of disclosure requirements:

1. All agreements, except for commercial sales agreements of goods and services, that companies have with specified individuals, including HCPs, and entities, must be reported within 15 days of signing;
2. Certain benefits given to those individuals and entities, must be reported biannually. Companies must report the required information about benefits and agreements to the French government via a web portal, and the information is made publicly available on a governmental website (www.transparence.sante.gouv.fr).

Initially, only the existence of an agreement – but not the amount – had to be reported. An update is now pending that will require details on the amount of payment to be reported.

> "It is important to understand the distinction between transparency laws and transparency codes."

Beyond France: Laws and Codes

A number of other European countries have introduced laws requiring or codes recommending reporting requirements (Figure 1).[11] It is important to understand the distinction between the two: laws are governmental or legislative requirements whereas codes are only binding on companies that are members of the particular industry group. For example, in Denmark, pharmaceutical and medical device companies are required by law to report certain details about their relationships with HCPs but not the amounts paid.

SCHEDULE 2 - TEMPLATE

Date of publication: .....

	Full Name (Art. 1.01)	**HCPs:** City of Principal Practice **HCOs:** city where registered (Art. 3)	Country of Principal Practice (Schedule 1)	Principal Practice Address (Art. 3)	Unique country identifier *OPTIONAL* (Art. 3)	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a)			Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c)			**TOTAL** *OPTIONAL*
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP*** *(i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*		*Optional*
	Number of Recipients in aggregate disclosure - *Art. 3.02*					N/A	N/A	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - *Art. 3.02*					N/A	N/A	%	%	%	%		N/A
HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO*** *(i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
	Number of Recipients in aggregate disclosure - *Art. 3.02*					*number*	*number*	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - *Art. 3.02*					%	%	%	%	%	%		N/A

	AGGREGATE DISCLOSURE		
R &D	Transfers of Value re Research & Development as defined - *Article 3.04 and Schedule 1*	*TOTAL AMOUNT*	*OPTIONAL*

Figure 2. An example of the EFPIA template for reporting TOV. Source: http://transparency.efpia.eu/

Instead, it is the Danish HCPs that must report such financial support. Portuguese law requires companies to report support and sponsorship provided to HCPs that exceeds € 60. Other European countries with financial transparency reporting laws include Slovakia, Romania, Greece, and Turkey. In the Pacific Rim, industry groups in Japan and Australia have also introduced code-based transparency requirements. Although the specifics of the requirements may differ by individual country, the message is clear: global transparency is here.

EFPIA: Industry driven approach to transparency

The European pharmaceutical industry has been proactive in seeking to develop and implement an industry-driven approach to transparency. This effort has been led by the European Federation of Pharmaceutical Industries and Associations (EFPIA), which includes 33 national member associations and 40 corporate members. The EFPIA adopted a Disclosure Code in June 2013, which was slightly amended in 2014. The EFPIA Disclosure Code requires individual-level reporting of TOVs to HCPs and healthcare organisations (HCOs) by its members.[12]

EFPIA's goal in adopting its Disclosure Code was to create a uniform approach to transparency reporting across Europe for the pharmaceutical industry. In contrast to the pharmaceutical industry's aggressive approach to transparency, Eucomed, which represents the medical device industry in Europe, has chosen to not impose reporting requirements on its members.

> "The goal of EFPIA's Disclosure Code is to create a uniform approach to transparency across Europe."

Under EFPIA's Disclosure Code, the first year of data collection was 2015, and first reports are due in 2016. The Code includes three individual-level categories for companies to report their direct payments and TOV provided to HCPs and HCOs (Table 2).[13]

According to EFPIA's Disclosure Code, disclosures must be made on an annual basis, with each reporting period covering a full calendar year. Companies must make their disclosure within 6 months of the end of the preceding reporting period, and the disclosed information must remain in the public domain for 3 years, unless local laws require a shorter time or a recipient withdraws his or her previously granted consent relating to a specific disclosure. Companies must document all payments and TOV required by the code and maintain records for at least 5 years, unless local law requires a shorter period.

The Disclosure Code provides two options for disclosure: 1. on the reporting company's website; or 2. on a central platform, which can be developed by the national member association. The disclosures must be made in the local language, although companies are encouraged to also make the disclosures in English. The EFPIA provides a reporting template that lists the types of data that companies must disclose. (see Figure 2 for example of the template).

Individual vs aggregate reporting

Although EFPIA wants as much individual-level reporting as possible, there are two instances in which companies will report at the aggregate level.[12]

1. When legal reasons prevent certain information from being disclosed. The Disclosure Code is not a law and is superseded by data privacy laws, so companies must obtain the consent of a recipient to publicly disclose individual information. If consent is not provided, individual-level data cannot be reported.
2. Research and development. This includes TOV to HCPs or HCOs for the planning or conduct of clinical trials or non-interventional studies that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

For instances in which legal reasons prevent individual-level disclosure, for each reported category, the aggregate disclosure must identify the number of recipients covered by the disclosure (on both an absolute basis and as a percentage of all recipients) and the aggregate amount attributable to the TOV. In contrast, when companies report research and development TOV at the aggregate level, they simply disclose a single monetary figure that encompasses all such transfers in a jurisdiction,

Category	Description
1	Donations and grants (HCOs only)
2	Contributions to costs related to events, including registration fees; travel and accommodation, to the extent permissible; and, for HCOs only, sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event
3	Fees for service and consultancy. In contrast to the US, companies do not have to report the details of every single transaction that they have with a HCP or HCO; instead, they are permitted to aggregate all their TOV to a HCP or HCO on a category-by-category basis
Exclusions	1. Transfers that are solely related to over-the-counter medicines
	2. Transfers that are not explicitly identified in the Code, including, for example, items of medical utility, meals/drinks, and medical samples
	3. Transfers that are part of ordinary course purchases and sales of medicinal products by and between a member company and a HCP or HCO

Table 2. EFPIA Disclosure Code Reporting Categories

without having to provide any accompanying details.

Bringing EFPIA home

The Disclosure Code requires EFPIA's national member associations to integrate the disclosure requirements into their own national codes, except when the reporting requirements are inconsistent with national laws or regulations.[12] Such inconsistencies exist in France, Denmark, and Portugal. In these cases, EFPIA permits deviations from the Disclosure Code, so that companies are not required to report under both the governing law and a national industry code.

EFPIA's approach to transparency should produce some consistency across Europe, although it is impossible to achieve absolute consistency for two main reasons. First, the various national disclosure laws, which may have different reporting requirements, take precedence over industry's self-regulatory approach. Second, although EFPIA's member associations have almost uniformly adopted the categories of TOV that must be reported at the individual or aggregate levels, some have taken slightly different approaches to some issues. For example, a handful of jurisdictions, including Spain, the Netherlands, and Belgium, require companies to disclose a unique country identifier for each recipient on their reports. As noted previously, under the Disclosure Code national associations have the option of either creating a central registry for reports or having companies place their reports on their own corporate websites. Most national member associations have chosen to have companies simply place the reports on their websites instead of creating a central registry.

Global Sunshine and medical writing: what do we know?

One area of the Sunshine Act that continues to lack clarity is whether providing non-monetary medical writing and editorial support constitutes a TOV. Interpretation of the Rules for Implementation has varied between industry companies, with some reporting it as a TOV and others not (Table 3).[14]

As noted by Toroser and colleagues, we still lack definitive guidance in this area.[15] The support provided to covered recipient authors is intended to ensure that applicable manufacturers can meet their ethical obligations to publish clinical trial data in as timely a manner as possible. This benefits the applicable manufacturer. Ascribing TOV to this support for an author could undermine the credibility of the authors, the study sponsor, and the results of the research, because the support may be misconstrued as payment for authorship.[16]

> Medical writers need to know the nuances around the reportability of non-monetary medical writing support."

Similar to the US experience with the Sunshine Act, the EFPIA Disclosure Code does not explicitly address the reportability of TOV associated with medical writing and editorial support. A Frequently Asked Questions document issued by EFPIA does address the topic, although the comments are somewhat ambiguous.[13] Accordingly, companies will have to determine whether and how they report TOV associated with medical writing and editorial support, and they will have an opportunity to publicly explain their rationale for their decisions. The Disclosure Code requires companies to publicly disclose a note that summarises the methodologies they used to prepare their disclosures and to identify TOV for each category.[12] Although companies are not obligated to address how they treated medical writing and editorial support in their methodology notes, they can explain their decision and rationale. As with the US, this lack of clarity may likely lead to inconsistencies among companies and could lead to confusion among authors who work with different companies.[17] There could also be a chilling effect on industry-HCP relationships.[15,17] The potential negative impact may be in the form of investigators declining to work with industry on clinical trials and clinicians declining to participate as authors of clinical-trial publications. The latter example may lead to the loss of critical real-world clinical-practice interpretation of clinical trial results, which could, ultimately, harm patient care.

Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect the opinions of their employers. The authors have no financial conflicts of interest to declare.

No, the support does not need to be reported	**Yes, the support must be reported**	**Maybe**
The support is of value to applicable manufacturers because it helps them meet their ethical obligations to publish their data in as timely a manner as possible. In this case, the support is of no value to the covered recipient authors.	The support is of value to the covered recipient authors because they would have had to either do the work or pay for the support had the applicable manufacturer not provided the support.	Whether the support needs to be reported depends on the circumstances. For example, there is no TOV for clinical study manuscripts, but there is a TOV for authors who request support from the applicable manufacturer for publication of data from an investigator-initiated study.

Source: International Society for Medical Publication Professionals[14]

Table 3. Reporting Scenarios for Publication Support Under the Sunshine Act

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