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Australia Takes Center Stage in the Global Debate Over Life Sciences Transparency: Legislation vs. Self Regulation

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"There's nothing like Australia." So states the country's official tourism website. But, ironically, that motto also applies to the debate over transparency in the relationships between life sciences companies and healthcare professionals. This debate is rapidly becoming a global contest fought out in North America, Europe, Asia, and the Pacific. While some countries have adopted legislatively-imposed reporting requirements, others rely on requirements created by industry associations. The debate between advocates of transparency legislation, who claim their approach will lead to cost savings and a reduction in corruption, and supporters of industry self-regulation, who assert their model is more efficient and has the potential for global uniformity, continues to rage.

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On February 28, 2013, an Australian senator raised the stakes in this global discourse by introducing legislation that would, among other things, require pharmaceutical companies to report detailed information about the fees paid to individual healthcare practitioners. This latest volley in the debate between legislation and self-regulation is noteworthy. Australia has one of the world's most comprehensive industry association codes, a code that requires reporting of the aggregate amounts spent on healthcare practitioners by each association member in each of a number of promotional areas. What's more, the association recently established a working group devoted to studying even greater transparency in the relationship between industry and healthcare professionals. If the newly introduced legislation becomes law, there truly will be "nothing like Australia," in that no other government has ever replaced industry-imposed aggregate reporting requirements with legislatively-mandated individual reporting requirements.

Countries that have adopted transparency laws similar to Australia's proposed legislation include the United States, France, and Slovakia.[1] Conversely, pharmaceutical industry associations in countries like the United Kingdom, the Netherlands, and Japan have enacted codes that impose reporting requirements on

[1] As a general proposition, under government-adopted laws, pharmaceutical companies and medical device companies are treated the same with respect to reporting obligations. In contrast, for industry codes, which apply only to members of the industry association, pharmaceutical associations have been far more willing to adopt reporting requirements than the medical device industry. For example, on the European level, the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), which is the representative body of the pharmaceutical industry in Europe, has adopted reporting requirements, and EFPIA is expected to amend its code in 2013 and adopt even more rigorous reporting requirements. In contrast, Eucomed, which represents the medical technology industry in Europe, has not adopted reporting requirements and, in a September 2012 White Paper devoted to the topic of transparency and disclosure, expressed its concerns about the need for expansive reporting requirements.

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their members.[2] There is significant tension between these two approaches. Industry favors a self-regulatory approach rather than a governmentally-imposed scheme because it views the former as a less costly and more effective solution that can achieve meaningful buy-in from all stakeholders and uniformity across borders. Some governments and legislators reject self-regulation as the optimal regulatory model. They point to health care scandals and what they perceive to be exorbitant and outrageous payments to physicians as evidence that voluntary industry codes simply do not work. Advocates of legislation also stress the importance of cost savings; they believe that government reporting requirements will drive down the costs of promotion and thereby lower the price of pharmaceuticals and medical devices. This will lead to cost savings for government, the primary health care payor in many countries.

It is against this global backdrop that Senator Richard Di Natale introduced legislation in the Australian Parliament that would radically reshape the relationship between pharmaceutical companies and Australian healthcare practitioners by effectively replacing the governing industry code. In Australia, the pharmaceutical industry is represented by Medicines Australia, which, among other things, promulgates and implements the Medicines Australia Code of Conduct (''Code''). Established in 1960, the Code, currently in its 17th Edition, sets the standard for ethical marketing and promotion of prescription pharmaceutical products in the country. The Code complements the legislative requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act 1989.

The current Code, which became effective only two months ago, imposes a number of reporting requirements on members of Medicines Australia. Companies must supply to Medicines Australia information about the aggregate fees they pay to healthcare professionals who provide various services, e.g., preparing promotional materials, chairing and speaking at educational meetings, assisting with training, and participating in advisory boards. Significantly, companies need not report payments for research and development work, including clinical trials.

Companies must report by April 30, 2014, all payments made during 2013 for any of the above-referenced services, except service on advisory boards. Companies must populate tables developed by Medicines Australia with the following payment details: the total number of consultancies per annum, the total cost of consultancy fees, the total number of consultants, and the total costs of any hospitality, accommodation, and travel. The names of the consultants do not have to be disclosed.

The first report of payments for advisory board services is due on April 30, 2013, to cover activities from January 1, 2013, through March 31, 2013. The report must include the number of consultants, honoraria/sitting fees, costs of any hospitality, accommodation and travel, venue details, and third party costs. The names of individual consultants serving on advisory boards do not have to be revealed. Medicines Australia will publish on its website the information it receives from its members concerning their use of consultants.

The Code also requires member companies to provide reports to Medicines Australia concerning educational meetings and symposia they sponsor. For events held after January 1, 2013, companies must provide details of sponsorships of healthcare professionals to attend any educational event. Sponsorship includes registration fees, costs of accommodation, and travel-related expenses. The information to be disclosed includes the total amount paid for each educational event or meeting for all recipients, along with the total number of recipients, but not the names of the individual recipients.

Furthermore, member companies must disclose the details of any payments to speakers to attend and give presentations at education meetings. Honoraria, registration fees, costs of accommodation, and travel-related expenses must all be disclosed. Specifically, companies must report the total amount of speaking fees for each educational event or meeting as to all speakers, as well as the total number of speakers receiving payment, but, again, the names of the speakers do not have to be listed.

Lastly, companies must submit a report for publication on Medicines Australia's website that lists the health consumer organisations the company supports, either financially or through significant non-financial support, along with other information about such support. The first annual report is due on April 30, 2014, covering support commenced on or after January 1, 2013.

In addition to all of these reporting requirements, the Code further regulates the relationship between companies and healthcare professionals on a broad array of topics, ranging from when meals and beverages may be provided at education events to the type of company-branded items a company can provide.

Medicines Australia emphasized its commitment to disclosure and openness by forming a Transparency Working Group to promulgate recommendations that will further enhance the transparency of payments and transfers of value between pharmaceutical companies and healthcare professionals. The Transparency Working Group, which held its first two meetings in October and November 2012, is expected to issue its final report by December 2013. In developing its recommendations, the Transparency Working Group will consult with all relevant stakeholders and will evaluate various models of increased transparency, including the systems utilized in the United States, the United Kingdom, and continental European countries.

Medicines Australia's proactive approach was not enough for some critics, including Senator Di Natale.[3]

[2] Even in those countries, however, the disclosure schemes are still evolving. In the United States, on February 1, 2013, the Centers for Medicare and Medicaid Services released the final regulations implementing the U.S. ''Sunshine Act,'' which will become effective on April 9, 2013. Meanwhile, in France, the French government is preparing a final decree that will implement a significant health care reform law that was enacted in December 2011. That law, which contains transparency provisions, applies to both pharmaceutical companies and medical device companies. In Japan, it is widely anticipated that in 2013 the Japanese Pharmaceutical Manufacturers Association will revise its disclosure scheme, even though it was adopted only two years ago.

[3] In the Explanatory Memorandum accompanying his legislation, Senator Di Natale explains that ''[t]here is some acknowledgment by the industry that perceptions of undue influence on prescribing patterns do exist, and there is some momentum to limit this behaviour and improve the image of their

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On February 28, Di Natale, a member of the Australian Greens party from the State of Victoria, introduced a bill to amend the Therapeutic Goods Act 1989 to essentially replace the Code and completely redefine how pharmaceutical companies interact with healthcare professionals in Australia. In short, the legislation bars payment to doctors to attend certain educational seminars and scientific conferences, limits gifts and hospitality, and imposes reporting requirements for fees companies pay to healthcare practitioners. Unlike the Code's requirements that companies report expenditures in the aggregate, the legislation requires companies to report the amounts spent on individual recipients.

Senator Di Natale's bill covers a range of topics and imposes various civil monetary penalties for violations. First, the legislation bars a ''regulated corporation''[4] from entering into an arrangement to provide sponsorship for a conference, convention, educational seminar, or other event to be held outside of Australia if the corporation expects that a majority of attendees will be registered medical practitioners. Second, the legislation bars regulated corporations from providing hospitality, including meals and entertainment, to medical practitioners when they are attending an educational seminar or event if the value exceeds $100 per registered practitioner. Third, regulated corporations would be barred from paying a medical practitioner to attend a conference, convention, educational seminar or other event, or paying the travel and/or accommodation costs of a medical practitioner attending an event, if the practitioner is not representing the corporation or a sponsor at the event.[5]

Under the legislation's reporting requirements, regulated corporations would be required to prepare a report that contains the following information about each ''reportable payment''[6] it made during the relevant financial year: 1) the amount or value of the payment; 2) the name of the recipient of the payment; 3) the date on which the payment was made; 4) the nature of the payment; and 5) the reasons for making the payment. ''Reportable payments'' do not, however, include payments to medical practitioners who are: 1) full-time employees of the regulated corporation; 2) employees of the corporation who provide a majority of their employment services to the corporation; and 3) consultants retained by the corporation who provide the majority of their consultancy services to the corporation. A regulated corporation is required to make the report available to the public on its website within one month after the end of its financial year.

Before his legislation was introduced, Senator Di Natale expressed confidence that it would pass, while the chief executive of Medicines Australia claimed that the legislation was ''jumping the gun'' on the efforts of the Transparency Working Group. Both sides recognize that passage of the bill would have not only a swift and far-reaching impact on the pharmaceutical industry in Australia, but also consequences far beyond the continent. Passage would signal the first legislative supplanting of a well-established industry code. Conversely, defeat of the legislation would encourage pro-industry forces who are already seeking to solidify self-regulation as the dominant scheme in Europe. In either case, the debate that is unfolding Down Under is unprecedented. As the motto proudly states, ''there's nothing like Australia.''

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profession. A recent update to the Medicines Australia Code of Conduct strengthened the restrictions on these sorts of promotions. However, the Code does not, for instance, specify that medical practitioners who receive any form of largesse from drug companies should be named. The Code only covers members of Medicines Australia and participation is voluntary. This proposed Act will replace the industry code with legislation that sets more stringent restrictions on the interactions between pharmaceutical companies and physicians that minimises the opportunity to provide inducements and thereby unduly influence prescribing behaviours.''

[4] A ''regulated corporation'' is defined as a corporation that imports regulated pharmaceutical products into Australia, manufactures pharmaceutical products in Australia, or supplies regulated pharmaceutical products in Australia.

[5] In this context, a corporation is considered to have made a payment to a practitioner to attend a conference, convention, educational seminar, or other event if the corporation does any of the following in exchange for a practitioner's attendance at the event:

> ''(a) pays a fee, honorarium or other amount to the practitioner or to the practitioner's employer;
> (b) pays an amount that will be used, whether or not by the practitioner, for the purposes of medical research;
> (c) makes a donation to a charity on behalf or in relation to the registered medical practitioner;
> (d) gives a gift of more than $25 in value to the practitioner or to the practitioner's employer.''

[6] The legislation defines ''reportable payments'' as follows:

> ''(a) the corporation pays a fee, honorarium or other amount to a registered medical practitioner who attends a conference, convention, educational seminar or other event on behalf of the corporation;
> (b) the corporation pays a fee, honorarium or other amount to a registered medical practitioner or to the practitioner's employer; or
> (c) the corporation provides a service to a registered medical practitioner or to the practitioner's employer; or
> (d) the corporation pays the travel or accommodation costs of a registered medical practitioner, or provides travel or accommodation related services to a registered medical practitioner or to the practitioner's employer; or
> (e) the corporation pays an amount that will be used for the purposes of medical research; or
> (f) the corporation makes a donation to a charity on behalf or in relation to the registered medical practitioner; or
> (g) the corporation gives a gift of more than $25 in value to a registered medical practitioner or to the practitioner's employer.''