Forecasting Unanticipated Consequences of “The Sunshine Act”: Mostly Cloudy

Mark J. Ratain, *The University of Chicago, Chicago, IL*

On September 6, 2007, Senator Chuck Grassley (R-Iowa) and five bipartisan cosponsors introduced the Physician Payment Sunshine Act (S. 2029)¹ in the wake of public concerns regarding conflict of interest of practicing physicians. Although the Grassley bill was never passed, its fundamental concept was incorporated into Section 6002 of the Patient Protection and Affordable Care Act (ACA), which was signed into law by President Barack Obama on March 22, 2010.² This section of the ACA is commonly referred to as “The Sunshine Act,” which was subsequently implemented by the Centers for Medicare & Medicaid Services (CMS) through its Final Rule, as published on February 8, 2013, in the Federal Register.³

There is little dispute that significant financial interests in pharmaceutical, biotechnology, and medical device companies can have an impact on physician behavior.⁴ This is of particular concern in regard to expensive drugs, such as most proprietary oncology products.⁵ However, physician-industry relationships (both financial and nonfinancial) are complex and multidimensional. They must be considered in the context of the physician’s research and clinical activities, the activities (if any) performed on behalf of the industry, and the magnitude of tangible benefit to the physician (both direct and indirect). In particular, it is important to distinguish financial relationships between physicians and companies that are intended to promote sales of one or more products (eg, speakers bureaus, some phase IV trials) from those relationships that are focused on research and development (eg, early clinical trials, consulting regarding preclinical or early clinical products). Although the Final Rule does attempt to distinguish financial relationships between physicians and companies by distinguishing payments associated with a marketed product from other payments, this categorization is necessarily imperfect. For example, payments for consulting with a marketing team before approval by the US Food and Drug Administration would not be considered product-specific consulting. Furthermore, payments for consulting with a company before approval by the US Food and Drug Administration of its first product would presumably not be reported at all (even if the consulting were focused on marketing), because only companies with marketed products are “applicable manufacturers” subject to reporting under the ACA.

The Final Rule requires reporting of not only direct cash payments but of all “payments or transfers of value” (POTV) to physicians, including payments by companies to third parties that are deemed to benefit physicians. The CMS Open Payments User Guide⁶ indicates that such POTV should be categorized as General Payments or Research Payments, with payments identified as to recipient (phy-

sicians or teaching hospitals). All POTV are also identified as being either a financial asset (eg, cash, stock) or in-kind items and services. This latter category encompasses nonmonetary transfers of value to physicians that have been of concern to Congress, such as lavish dinners, tickets to sporting events, and exotic foreign travel.⁷ Implementation of the Final Rule will further reduce the use of gifts to physicians as a marketing tool, but it is likely to have unanticipated consequences, the focus of the remainder of this article.

There has been extensive debate regarding the required reporting of indirect transfers, because this language was not included in the ACA, as argued by Dr James Madara, Chief Executive Officer of the American Medical Association, in an October 2012 letter to CMS.⁸ Furthermore, this has been broadly interpreted (at least by some companies) to encompass some of the usual costs of business, specifically grants to charitable organizations and publication expenses, which have been construed as indirect transfers of value to physicians.

The Final Rule specifically requires companies to report any indirect transfers, if they can identify the recipient, even if they did not have any role in selecting the recipient. Thus, corporate gifts to foundations to support research grants, even if reviewed and directly funded by charitable organizations, are required to be reported to CMS as indirect transfers of value from companies to individual physicians and/or their employers. This will potentially create the illusion of a relationship between specific physicians and companies with whom they may not wish to be associated. Corporate philanthropy is common in the United States, with approximately \$5 billion in total gifts to foundations in 2010. Pharmaceutical companies are no exception to the norm; as examples, in 2010 Merck donated \$72.6 million and Pfizer donated \$69.1 million.⁹ Thus, it should be no surprise that pharmaceutical companies are generous supporters of the Conquer Cancer Foundation (CCF) and its predecessor, the American Society of Clinical Oncology (ASCO) Foundation.

As a CCF Translational Research Professorship Awardee, I recently became aware that Genentech, which happens to fund this award, now considers this to be a corporate transfer of value. This was communicated in an e-mail on December 16, 2013, from CCF: “Indirect payments through a professional organization like the American Society of Clinical Oncology (ASCO) or a charitable organization like the Conquer Cancer Foundation (CCF) are reportable as an indirect transfer of value from the company, and the company is responsible for reporting the payment to the CMS.” The following text appeared in another paragraph: “Pursuant to the Physician Payment Sunshine Act, payments for research grants must be reported. As a recipient of a

Conquer Cancer Foundation of ASCO Translational Research Professorship, your grant may be reported by the healthcare company supporters of the Conquer Cancer Foundation of ASCO Translational Research Professorship.”

Although this reporting is technically concordant with the Final Rule, it is illogical because Genentech had committed the funds for this Professorship before any applications had been submitted and had no role whatsoever in CCF’s review of applications and final decision. It is unclear whether the public reporting of this POTV will have an impact on my relationships with patients or colleagues; however, such transparency reports could be particularly detrimental to the reputation of a young unestablished investigator. Notably, the CCF Web site now includes a disclosure to the effect that if one receives a CCF grant, then a company (to be named) may report to CMS that they provided funds to the applicant.

Ironically, indirect honoraria payments (clearly a direct and tangible benefit) from pharmaceutical companies are not automatically reported to CMS. If a company provides funds to an accredited Continuing Medical Education provider but does not pay the speaker directly and has no input into speaker selection, then there is no required report to CMS. In contrast, the same criteria, when applied to philanthropic grants to foundations, do result in a CMS report. Thus, one specific recommendation to CMS is to apply the same criteria for exempting grant payments as for exempting honoraria payments.

Another area of concern is the imputation to physicians of corporate expenses related to dissemination of research results. This became of interest to me when I received an e-mail on July 31, 2013, from Bristol-Myers Squibb (BMS) attaching a “Dear Author” memo, containing the following notification: “BMS will collect and report POTV that are provided in connection with the development of a scientific publication for which you participated as an author. This report may include medical writing and editorial assistance, statistical applications, and payment of congress (eg, submission fees) or journal (eg, page charges) fees made by BMS.”

Although BMS subsequently indicated that they probably would not need to report POTV for this manuscript, my colleagues and I are aware of multiple examples of companies notifying physicians that they will be submitting reports to CMS for similar academic activities. Furthermore, the exact interpretation of the Final Rule varies by company and is deemed subject to changes in CMS’s implementation of the ACA. On the basis of the CMS Open Payments User Guide for Industry, it is presumed that these will be reported as in-kind items and services for medical research writing or publication.⁶ Because any transparency reports may be potentially construed as *prima facie* evidence of unethical or illegal behavior,⁸ investigators may find themselves explaining (eg, to patients and others) that they did not actually receive anything from the companies but simply agreed to be listed as a coauthor on an abstract or manuscript.

Publication of articles demonstrating efficacy of marketed or investigational products is important to many companies, regardless of whether it is directly related to potential sales of a marketed product. Such publications enhance the image of the company and could potentially have an impact on valuation in the context of potential mergers and acquisitions. Thus, publications are often led by the most influential and recognized authors, who may be selected to enhance the corporate value of the publication. Some authors would deem their participation in a publication to be of greater importance to the company than to themselves and thus may not wish to be associated

with a publication if it could be construed that they received a corporate gift. (In fact, the new ASCO Policy for Relationships with Companies—once fully implemented—would preclude this journal from publishing the primary results of an important clinical trial if all authors were employees of the sponsoring company.¹⁰) CMS should clarify that corporate publication expenses should not be imputed to physician authors, because Senator Grassley and his colleagues did not intend for the transparency requirements of the ACA to chill or curb appropriate interactions between physicians and the pharmaceutical industry.^{8,11}

Congress has previously been concerned about unpublished clinical trials, which led to the inclusion of requirements for submission of results to Clinicaltrials.gov in Section 801 of the Food and Drug Administration Amendments Act of 2007.^{12,13} Any perception that authorship could be associated with a transparency report could delay the dissemination of important research findings, because some investigators will choose not to participate in a publication effort that will be associated with a report of an imputed payment to CMS, particularly if the resulting publication is not of high importance to that investigator. In the case of the BMS publication, we have agreed that the assistance provided will not constitute an imputed transfer of value (at least for now), although the timeline for submitting this article has been delayed by more than 6 months.

This is not meant to be a criticism of the fundamental concept behind “The Sunshine Act,” namely transparency in regard to potential physician biases on the subject of marketed products. If the result is a marked reduction in physician participation in activities best described as “marketing,” that will be considered a success. However, as discussed earlier, there needs to be greater attention to unintended consequences. The issue of corporate publication expenses being imputed to physicians requires urgent attention, and one suggestion is to include language in institutional clinical trial agreements addressing this issue. Standard language could be developed by organizations such as the American Association for Medical Colleges or the Council for Medical Subspecialty Societies that articulates the responsibilities of the sponsor and investigators regarding publication of trials, ideally including any potential imputed transfers of value as part of such an agreement (which would be reported as research payments, if appropriate).

Without intervention, some physicians may be reluctant to even engage in company-supported clinical trials because of potential stigmatization by CMS reports in the context of abstracts and publications. However, even if there were widespread concerns, companies would still be able to get their clinical trials completed by using foreign investigators, because only physicians licensed in the United States are subject to CMS transparency reports. We would then have to tell our patients seeking investigational drugs to go to Canada and/or to write their congressmen to amend the ACA.

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