Answers That Matter.

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Submitted electronically via Patricia_hameister@aging.senate.gov

Patricia Hameister, Chief Clerk
United States Senate Special Committee on Aging

Dear Ms. Hameister,

Eli Lilly and Company ("Lilly") is pleased to submit this statement for a public round table discussion to be held by the United States Senate Special Committee on Aging regarding the implementation of the final regulations of section 6002 (the "Sunshine Act") of the Patient Protection and Affordable Care Act.

Lilly has been an industry leader with respect to disclosing payments to health care providers and other recipients and has long supported increased transparency. In 2004, Lilly became the first company to voluntarily make public its U.S. clinical trial data in the Lilly Clinical Trial Registry. In 2007, Lilly became the first biopharmaceutical company to publicly report the funding it provides in the U.S. to institutions in the form of educational grants and charitable contributions to support medical education, patient education and other activities that it believes increase health care knowledge and improve patient care.

Currently, Lilly is tracking and reporting a wide range of financial interactions with U.S.-based physicians pursuant to its Corporate Integrity Agreement (CIA) as well as State reporting obligations. Over the past several years, Lilly has gained extensive experience in defining new internal and external processes, creating training and modifying IT systems to enable data tracking and reporting. We have used this knowledge to provide comments that underscore practical implementation insights and suggestions regarding the proposed rule and the statutory interpretations that CMS has shared. In addition, we have proposed clarifications we know will be necessary to ensure consistency, reduce confusion, minimize unintended readings of the law, and substantially improve implementation of the final regulations.

In the spirit of facilitating quality implementation of the Sunshine Act, Lilly would like to highlight the following six points which should be addressed in the final regulations. The first two points focus on implementation timing and a step-wise approach that will help facilitate the most complete and accurate data collection and data reporting to CMS and consequently to the public. The last four points focus on clarification of key issues that have been highlighted in comments submitted by Lilly, PhRMA and the Transparency and Disclosure Coalition[1].

[1] The Coalition is a small working group of five pharmaceutical companies (AstraZeneca, Eli Lilly, Johnson & Johnson, Merck, and Pfizer), each of which has been on the leading edge of efforts to disclose accurate financial information about interactions with physicians and has been reporting detailed information about expenditures and

1. The final rule should allow at least 180 days from publication until the commencement of data collection.

The final rule should provide applicable manufacturers with at least 180 days to implement the final rule. For the majority of applicable manufacturers, the process of implementing a comprehensive system for tracking and reporting will be new, complicated and necessarily imprecise and iterative. When implementing the requirements of its CIA, Lilly learned first-hand, over the span of 23 months leading up to its first full quarterly registry publication, that no reporting scheme can contemplate or anticipate every possible implementation question.

Based on review of the proposed rule, notwithstanding the substantial efforts already undertaken to enable current reporting, Lilly itself would need to revise many of its existing processes and systems to address several areas where the proposed rule differs from the manner in which Lilly is capturing and reporting data today (e.g. meal methodology, patient education materials, knowledge trigger for third party payments). There are simply a series of necessary steps required to implement any change to business processes: first the requirements must be clearly defined (which cannot occur until the final regulation is issued), then the requirements must be translated into required changes on various impacted processes, then those required changes need to be built into documented procedures and configured into IT systems, then those modified IT systems must be tested and validated to ensure they do what they are supposed to do, then the people who use those procedures and systems must be trained. Each and all of these steps must occur and must occur in linear order to effect the required changes. Consequently, the more the final rule requires changes to the business and IT system rules already in place, the more complex the implementation implications for manufacturers and the more lead time that necessarily will be required.

2. The final rule could be implemented more effectively using a phased approach.

Lilly urges CMS to look at the phased implementation of Lilly's CIA requirements and consider a phased approach to enable manufacturers and CMS to manage the complexity of data collection and reporting in a more measured and controlled manner and to reduce the risk of error or incomplete reporting. Phasing will yield better results for all interested parties, especially patients and physicians who expect and deserve these reports to be clear, meaningful and accurate.

Lilly suggests Sunshine data collection and reporting be divided into three phases.

Phase I, for which data collection could commence in early 2013, could include all direct payments from manufacturers to physicians and teaching hospitals. These direct payment data are the most readily identifiable and accessible in most company systems. It is recommended that Phase 1 direct payments not include payments for research made to Clinical Research Organizations (CROs) or payments to reimburse expenses as the processes needed enable detailed reporting of these payments do not usually exist. For Lilly, a Phase I report of payments would disclose over 70% of the total dollars currently being reported by Lilly in our CIA registry. If we were to assume a similar distribution for most manufacturers, focusing a Phase I implementation

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other items of economic value they provide to physicians substantially in advance of the requirements of Section 6002. Each company has devoted significant resources to such efforts and has developed considerable experience and expertise in addressing the complex issues involving such disclosures.

on direct payments only (versus other transfers of value) would enable the public to have visibility to over 70% of what is targeted for disclosure under the Sunshine Act while providing applicable manufacturers additional time to investigate and implement data collection processes and systems that would be necessary to enable the next phases.

Phase II could reasonably commence 6-12 months later and could include all reimbursed expenses as well as any indirect research payments made by CROs. Reimbursed expenses are suggested to be separated from Phase I because reporting of such expenses will likely require modifications to billing and invoicing practices, expense re-categorization to align to Sunshine Act definitions and requirements, and modifying IT systems to ensure that elements of such reimbursements get reported under the proper categories with the proper associated level of detail, all as dictated by the yet-to-be-issued final rule. Payments made to CROs for research should be included in this category for such reporting requires alignment of systems, training and new processes for data collection by the CROs that are currently not in place. For Lilly, in 2011, of all the value reported on Lilly's payment registry, 21% represented payments to CROs for research done by CROs. By the end of Phase II, there could be over 90% visibility into disclosure required under the Sunshine Act.

Finally, Phase III could commence 12-18 months after Phase I and would complete the Sunshine Act reporting requirements by adding disclosure of any non-cash transfers of value. Non-cash transfers of value would include transfers such as business meals, travel and educational materials for physician benefit. Importantly, these non-cash value transfers represent a very small percentage of total value transfers to be reported under the Sunshine Act. Specifically, for Lilly, in 2011, of all the value reported on Lilly's payment registry, only 8% represented non-cash value. On the other hand, to capture this data for such reporting requires significant business process modifications. For instance, for some non-cash items, new processes will be required to first assign a market value, then to record the distribution at the individual recipient level, and to train personnel to identify situations where such capture is required. These types of processes do not typically pre-exist in companies because such information and data is not needed for any other business purpose. These processes are distinct from the processes that companies would normally have in place to know about and record payments (the proposed focus of Phases I and II).

A phased approach would balance the goal of timely, quality and reliable public reporting with the very real challenges faced by manufacturers in implementing comprehensive and complex process and systems changes within the practical limitations of existing and unique organizational structures, systems, and practices of individual companies. It would also provide wide visibility into over 90% of manufacturers' spend in the first phase, thereby substantially and meaningfully delivering on the goal of the Sunshine Act in providing greater transparency regarding financial relationships with health care providers.

3. The standard of knowledge for reporting third party payments should be based on influence or control.

The proposed rule would require manufacturers to report payments and transfers of value made to a covered recipient by a third party (i.e. indirect payments) even when the applicable manufacturer has no influence or control over the selection or engagement of the covered recipient.

For example, Lilly may contract with a vendor to develop medical information software and not be aware that the vendor will contract with a licensed physician to provide advice related to the software. In this case, Lilly would have no transparency in the down-stream compensation to any sub-contractors because such contracting was neither required nor influenced by Lilly.

Under the proposed rule, Lilly would have an obligation to proactively identify the relationship between the vendor and the physician at any point during the contract period and report the payment (or some portion thereof) as an indirect payment by the manufacturer. This is an approach that is different than what Lilly and other reporting companies employ today and would require substantial changes in its existing processes to achieve. Further, such an expanded approach would challenge the independence of third parties and their justifiable interest in protecting their own dealings and compensation arrangements as proprietary and confidential.

Lilly urges that indirect payments be reportable only when the applicable manufacturer controls or influences the selection of the covered recipients engaged by the third party.

4. The meal allocation methodology must be factual and workable.

The meal allocation methodology in the proposed rule is unworkable and inappropriate in several ways: (1) It would require applicable manufacturers to undertake the operationally unmanageable task of identifying and attributing value to physicians that do not partake in a meal but are employed by or associated with a group practice or department; (2) It would require allocation of meal expenses to physicians with whom the applicable manufacturer does not actually interact (and may be legally restricted from interacting); and (3) It would force attribution to physicians and/or teaching hospitals of meal value provided to non-physician employees, functionally broadening the statutory definition of "covered recipient."

The final rule should not force manufacturers to attribute value to anyone who does not actually receive a meal because it is factually inaccurate and therefore misleading and will result in disputes and confusion regarding the reliability and accuracy of the reported data. Further, requiring manufacturers to identify affiliations and employment relationships for persons attending business meals adds an inordinate level of complexity in record keeping and related processes, which will substantially increase the burden and cost relative to the added benefits of these incremental disclosures. Finally, flexibility will be necessary to address variables such as opt-outs, excess food, and no-shows.

5. The patient materials exclusion should be more broadly interpreted.

The Sunshine Act expressly excludes educational materials intended for patient use from reporting. In the proposed rule, however, CMS states that this exclusion is limited to written or electronic materials and does not include services or other items. CMS's interpretation of the statutory exclusion for educational materials is unnecessarily restrictive, and as a result, Lilly is concerned that the continued availability of patient-centered programs and services (e.g., patient assistance programs or patient starter kits) would be jeopardized, with a potential negative impact on patient care.

For example, Lilly provides reimbursement support services that help patients understand their insurance coverage prior to initiation of a particular drug therapy. Lilly also makes available pa-

tient items such as starter kits and disease state resources (e.g., blood sugar logs; anatomical models; nutrition books). Lilly strongly believes that provision of these programs, services, and items do not constitute a "transfer of value" because they do not benefit physicians personally or professionally. The physician is not the ultimate intended recipient of these materials; they are provided to the physician as a "pass through," so that the physician can make them available to his or her patients.

Lilly therefore urges the final rule to (1) explicitly interpret the exclusion more broadly to encompass any materials, including programs, services, and items provided to covered recipients for the direct use or benefit of patients or (2) further clarify that such programs, services, and items do not need an express exclusion because they do not constitute transfers of value to covered recipients.

6. The definition of 'applicable manufacturer' should align with the statutory definition.

The proposed rule definition of "applicable manufacturer" would require companies to track and report payments and transfers of value even if they are not operating in the United States. This definition sweeps in many foreign affiliates that do not operate in the United States but that do produce a covered product or a product component. These foreign affiliates are not preparing to report under the statute. Lilly urges that the final rule align with the statutory definition of "applicable manufacturer," which expressly includes a requirement for the manufacturer to be operating in the United States.

Finally, Lilly encourages CMS to recognize the need for ongoing communication with industry throughout implementation of the final rule to help ensure clarity and consistency and to address the implementation challenges or questions that will inevitably arise.

Lilly appreciates the consideration of these comments on CMS-5060-P by the Senate Special Committee on Aging. We encourage CMS to continue to engage stakeholders as it evaluates the proposed rule and its implementation. Lilly welcomes the opportunity to further share its experiences and to provide any additional information that would be helpful. If you have questions, please feel free to contact me at 317.655.1965 or ofarrell_elizabeth_g@lilly.com.

Sincerely,

Elizabeth G. O'Farrell
Senior Vice President, Policy & Finance