

Statement of

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Submitted for the Record

to the

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United States Senate

“Let the Sunshine in:
Implementing the Physician Payments Sunshine Act”

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Chairman Kohl, Ranking Member Corker, and Senator Grassley, thank you for the opportunity to appear before you today to participate in this Roundtable, "Let the Sunshine in: Implementing the Physician Payments Sunshine Act." As the Chief Responsibility Officer for Edwards Lifesciences and on behalf of our company, I commend you for your continued efforts to ensure that the Physician Payments Sunshine Act, included as Section 6002 of the Patient Protection and Affordable Care Act (PPACA), is promptly and effectively implemented.

Edwards Lifesciences is a California-based medical technology company that has maintained global leadership in the science of heart valves and hemodynamic monitoring for several decades. As a medical device manufacturer with sales in the U.S., Edwards is one of the thousands of companies that will be required to comply with the Sunshine provisions. We have been and remain strong supporters of this legislation, which requires manufacturers to annually disclose qualified transfers of value to U.S. physicians and teaching hospitals exceeding \$100 cumulatively. As you know, the Department of Health and Human Services (HHS) was required under the law to establish reporting procedures for applicable manufacturers to submit information, as well as procedures for making that information available to the public. We appreciate your leadership on this legislation, and your continued efforts to ensure the law is implemented in a timely manner.

We understand the challenges that the Centers for Medicaid and Medicare Services (CMS) face in working through the complicated implementation details surrounding data reporting of certain transfers of value for U.S. physicians and teaching hospitals. Like Members of this Committee, as well as CMS, we are somewhat frustrated with the time it can take to develop clear guidelines for this process. CMS should be commended for their efforts over the last two years to reach out to interested stakeholders and engage in a consultative approach to developing their draft regulations. Despite the guidance you, your staff and Committee staff put into crafting the Sunshine provisions, we know from our company's experience that transitioning from concept to implementation can be very challenging. Based on the quantity and quality of public comments submitted in response to the draft regulations, we believe that CMS should have clear guidance on how a final rule will maximize clarity for those of us who must comply with the law. We know that CMS appreciates how important clarity will be to an effective regulation.

With that said, we are now almost a year beyond the statutory requirement for a final regulation, and more than eight months behind the deadline for implementation of the law. We would like to see CMS release a well-thought out regulation as soon as possible, as delay may be contributing to additional confusion and possible wasted expense. In the absence of a rule, manufacturers have had to guess as to what will be required of them in preparation for an implementation date sometime in the near future. Further delay will thwart the purpose of the law, causing more confusion about the appropriate role of physicians in the collaboration process.

Edwards Lifesciences has some relevant experience with this subject. For the past four years, we have been tracking and reporting financial relationships with U.S. physicians on a voluntary basis. Despite Edwards Lifesciences' own extensive experience with implementing a disclosure program, we spent over 6 months revamping and automating our systems, processes and procedures to meet the requirements under the law and may need several months to adjust our current reporting systems – and

launch an effective employee training program – if we have not guessed properly on what CMS will require of us. Other manufacturers, who may not have their own voluntary program or the resources to implement fully in anticipation of the final regulations, may not be in as enviable position as our company in terms of preparation. It is worthwhile to note that a majority of medical device companies in the U.S. are small to mid-sized businesses that are less likely to have the resources to do this quickly.

We undertook our voluntary program because we strongly believe the public must have full confidence in the important and necessary relationship between the medical device industry and the physician community. Many of the best ideas for new therapies and iterative improvements to existing technologies result from collaboration between physicians, engineers, and entrepreneurs. Edwards has always been proud of its relationships with clinicians, which led to the development of the first commercially available artificial heart valve and the establishment of our company more than 50 years ago. Medical innovation is dependent on these financial partnerships, and we believe that bringing transparency to these relationships will help the public better understand the critical role they play in the advancement of medical technology and patient care.

In late 2008, Edwards announced its plans to publicly disclose its financial transactions with physicians who receive \$5,000 or more a year in consulting fees, royalties, honoraria and other transfers of value from Edwards. We began tracking this data on January 1, 2009, and have published it annually beginning in the second half of 2009. In addition to the primary purpose of providing transparency, launching this voluntary program in advance of a federal mandate helped inform us and our ability to engage in the debate as we learned from our experience. As the first medical device company to implement such a program on a voluntary basis, we were challenged to develop the policies that would apply to our own reporting program, to develop the systems and processes to manage the data, and to work out discrepancies in the unexpected situations that can sometimes arise through the normal course of business. During the legislative process, we were able to share with your staff and other stakeholders some of the insights we gained in the early stages of the development of our program.

Because of our early start, our road to compliance with the federal mandate is fairly unique. We have built and tested the systems necessary to comply with most of the requirements of the Sunshine provisions, but we are not a large and complex company compared to some others. We can appreciate how difficult a process it will be for some companies to prepare to comply with the law. Indeed, if a company has not already invested in the systems, changed its policies and procedures, communicated those changes, trained appropriate personnel, as well as begun testing the data, it is likely that they will have difficulty timely reporting and assuring data integrity for their reports to CMS when those become required under regulation.

During the past three years, Edwards has built the systems to track and manage accounts payable, purchasing and expense reporting activities to ensure that we capture all payments to U.S. physicians that may add up to the minimum reporting threshold. As a global company with sales in more than 100 countries, we needed to develop systems to merge data from different financial reporting systems around the world to ensure that if any of our global operations incur an expense related to a U.S. physician, we are able to accurately capture and report that information. This presented many challenges. For instance, in an absence of unique identification numbers for each

physician, we had to manage the challenge of verifying that transactions are appropriately matched (or not) to individuals that have similar names or where their names may have been misspelled. We have found that we needed to convert financial reporting systems that were originally built to help our company track and report financial information solely for accounting and tax compliance purposes, so this was no easy task.

Our experience has illuminated a number of issues that may present ongoing challenges to covered entities as we strive to develop a national policy that fair and accurately characterizes the financial relationships between medical technology companies and clinicians. We have provided CMS with comments on the proposed regulation through our trade association, AdvaMed, and remain concerned about a number of key issues that we hope will be adequately addressed through the final regulation. Among those concerns are:

1. **Identifying Covered Recipients:** Accurately capturing transfers of value to third parties “*At the request of or designated on behalf of. . .*” covered recipients can be difficult. For example, we learned through our own program that individual clinicians may set up or work for small businesses that manage the financial transactions related to their consulting arrangements. Sometimes these businesses have names that provide data managers with little indication of any association with a physician (e.g., “Pinetree, LLC”). Even with aggressive employee training and education, it can be very challenging to identify every construct that could be used to manage a physician practice. Moreover, it is generally unknown by a medical device company how much, if any, of the compensation paid to the entity is received by the physician.

This is a complex issue that we’ve worked with other stakeholders to try to solve. Unfortunately, we believe there lacks consensus in this area, although there is promise that a reasonable approach could be found in time. While it is important the regulation captures relevant transactions, we believe that only a very small population of transactions will fail to be captured as a result of these types of situations, yet the burden on companies to try to ensure this data is captured will be significant. At this point, it is more important to get a final regulation out as quickly as possible so that manufacturers can have time to prepare for implementation in a timely manner. In the interest of time, we recommend that CMS and this Committee take the approach proposed by AdvaMed in this case: where a transfer of value is reportable to the Internal Revenue Service as gross income attributed to a covered recipient by the medical device company, it should qualify for reporting by that company under the Sunshine provisions. It is possible that this approach could still result in difficulty identifying covered recipients if physicians wish to intentionally avoid the intent of this law. Therefore, unless CMS has already developed a better solution, we would urge CMS and Congress to view this aspect of the regulation as an ongoing process and to remain open to developing further clarification through additional guidance or regulation. We urge you and the Committee to continue your oversight of this important issue.

2. **Context:** It is important that manufacturers are provided ample opportunity to voluntarily provide meaningful context surrounding a transfer of value. For example, information regarding the contribution an expert physician provided to a research project related to a disease she is uniquely familiar with could be very valuable to a patient's understanding of that physician's clinical capabilities. Without sufficient details justifying the reported expenditure, patients and the public may unfairly conclude that the mere existence of a financial relationship is suggestive of an inappropriate relationship that would compromise the integrity of the physician and his/her judgment. CMS should ensure that it develops an information system capable of handling data submissions in their appropriate context. Correspondingly, CMS should seek adequate resources to ensure that this information is easily accessible to the public and is displayed in a user-friendly manner when it is published for the first time. We are extremely concerned that appropriate planning and funding for adequate systems to accomplish these goals has not occurred by the federal government, and we urge you and the Committee to continue your efforts to remedy this situation.
3. **Covered Recipient Notification/Preview:** Under Edwards Lifesciences' voluntary disclosure program, we provide physicians with reasonable notice and a preview of the information we plan to publish on our website. This gives them a better understanding of the process, sets their expectations so that they can respond to patient inquiries, and provides them an opportunity to verify our data. CMS's draft regulation appropriately contemplates the need for a dispute resolution process prior to publication by CMS, and we believe that providing a minimum amount of time for a reasonable "back-and-forth" between the manufacturer and physician is necessary once CMS makes the data available to physicians.
4. **Unique Individual or Entity Identification:** It is important that companies appropriately attribute expenses to the correct covered recipient. To assist companies in accurately identifying individual physicians or teaching hospitals, CMS should publish a list of unique identification numbers for teaching hospitals and physicians.

We understand that the behavior of some individuals and a few companies in the past has caused some to question the nature of relationships between industry and physicians. However, we know that high ethical standards and close collaboration between the two can and must exist. Our experience with the voluntary program at Edwards demonstrates that we can provide information required to assess these relationships. The overall goal of this program must be to increase public understanding of industry-physician relationships so that patients can feel confident in their physician's medical advice.

Edwards looks forward to working with the Committee, Congress, and CMS to ensure that stakeholders have prompt and consistent access to the information required by this law. Thank you for the opportunity to participate in this Roundtable discussion, and we welcome any questions you or your staff may have.