

Written Statement for the Record

Roundtable on Implementation of the Physician Payments Sunshine Act U.S. Senate Special Committee on Aging September 12, 2012

**Dr. Daniel J. Carlat
Director, Pew Prescription Project
Pew Health Group, The Pew Charitable Trusts**

Chairman Kohl, Ranking Member Corker and members of the Special Committee on Aging, thank you for the opportunity to testify about the importance of implementing the Physician Payments Sunshine Act (the “Sunshine Act”) as quickly as possible.

The Sunshine Act will bring critical and much needed transparency to the financial relationships between physicians and pharmaceutical manufacturers and medical device companies, and it has the broad support of diverse stakeholders, including consumer groups, industry groups and leaders within the medical profession. Industry trade organizations have publicly weighed in on the need to move forward with transparency measures contained within the Sunshine Act. Congress recognized the importance of making these relationships transparent when it included the Physician Payments Sunshine Act in the Patient Protection and Affordable Care Act (2010). Yet, despite an October 1, 2011 statutory deadline, the final regulation implementing the Sunshine Act has not been released.

The Pew Charitable Trusts is driven by the power of knowledge to solve today’s most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Based on research and critical analysis, the Pew Health Group seeks to improve the health and well-being of all Americans.

The Sunshine Act requires pharmaceutical and medical device companies to publicly report their gifts and payments to physicians and teaching hospitals. Medical products are central to modern health care, and academic-industry collaboration is vital for their development. At the same time, it is essential that the use of these products be guided by sound evidence and good science. Every patient deserves the safest, most effective treatment.

The drug and medical device industries spend heavily to influence a physician’s choice of

products. Estimates of the exact amount vary, but pharmaceutical companies alone spend tens of billions of dollars per year on marketing.¹ According to a study published in 2010 in the Archives of Internal Medicine, 84 percent of U.S. physicians have some kind of financial relationship with industry, including receiving payments, drug samples or, most often, free meals or gifts.² About 14 percent of physicians reported being paid by one or more companies for services such as serving on speaker bureaus, consulting or enrolling patients in clinical trials.

The influence of pharmaceutical marketing is well established.^{3,4} Leaders within the medical profession have recognized these impacts and called for transparency. A major Institute of Medicine (IOM) report in 2009, entitled “Conflict of Interest in Medical Research, Education and Practice,”⁵ emphasized that some financial relationships between physicians and industry raise concerns about the risk of bias in clinical decisions. For example, companies have paid some physicians large but generally undisclosed amounts to give talks to other physicians, whose prescribing practices were then tracked by company sales representatives. Drug samples and other gifts to physicians by company sales representatives are major marketing tools that evidence suggests influence prescribing choices. The IOM concluded that conflicts of interest “present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public’s trust in medicine.”

An optimal reporting system will ensure that all payments are reported clearly enough for consumers to understand what the numbers mean. For example, companies fund research in a variety of ways, sometimes by paying doctors directly, and other times by paying hospitals which then pass the funds on to doctors in charge of the research. It is important that in both cases, whether the payment to doctors is direct or indirect, that consumers be informed when doctors are receiving research payments from industry. This is not to suggest that research payments are undesirable. Indeed, these collaborations are vital, but the financial relationships should be

¹ Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the united states. PLoS Med. 2008;5:e1

² Campbell EG, Rao SR, DesRoches CM, et al. Physician Professionalism and Changes in Physician-Industry Relationships from 2004 to 2009. Archives of Internal Medicine. 2010; 170 (20)

³ Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? JAMA. 2000; 283(3)

⁴ Dana J, Loewenstein G. JAMA. 2003; 290

⁵ Institute of Medicine. Conflict of Interest in Medical Research, Education and Practice. IOM Report Brief. April 2009

transparent.

A related issue is that some stakeholders have suggested that only IRS-reportable payments should be reported. However, this allows for a possible scenario in which physicians could deliberately create LLCs or other entities so that the payments would be reported under a corporate name, as a way of avoiding disclosure under their own names. The intent of the law is to ensure that the financial relationship between companies and physicians is reported, and there should be no third party structures that might serve to obscure the reporting of such payments. Without language clarifying that all payments to physicians should be captured, whether IRS-reportable or not, there is the potential for undermining comprehensive reporting of payments.

Pew is committed to working with industry, CMS, Congress, and other stakeholders to ensure the system is as strong as it can be. The issues we discuss above should not be a reason to delay the final regulations. Failure to fully implement this law as quickly as possible runs counter to the clear intent of Congress in passing the law, which was to start tracking payments as of January 1, 2012. The Sunshine Act was passed 2 ½ years ago after years of discussion, which provided ample time for companies to set up tracking and compliance systems. Similar state transparency laws have been in place since the early 1990s. Many companies are already disclosing payments, either voluntarily or as a condition of legal settlements with the Department of Justice. In fact, most companies are already substantially prepared for the disclosure requirements. A recent Deloitte survey of pharmaceutical executives found that 88 percent of companies reported being at least 50% prepared for Sunshine Act compliance requirements, with 33% of companies being 100% prepared.⁶ Companies will be able to begin reporting payment data by January of 2013 if the final regulations are released soon. Stakeholders agree that it is important to begin the data collection process soon so that CMS can test the new system and can address any technical issues that will arise as quickly as possible.

The intent of the Sunshine Act is to protect patients and restore trust in the medical profession. The Pew Health Group urges the Administration to avoid further delay and act quickly to implement this important consumer protection legislation.

⁶ Deloitte. Physician Payment Sunshine Act: Physicians and life sciences companies coming to terms with transparency? 2012

