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If the "Physician Payments Sunshine Act" Is a Solution, What Is the Problem?

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The article by Chimonas and colleagues (Chimonas, DeVito, and Rothman 2017) uses focus groups to explore the attitudes of 42 physicians from three cities on the Physician Payments Sunshine Act (PPSA). The PPSA is a federal program mandated by the Affordable Care Act that collects information from pharmaceutical and medical device companies on their payments to physicians and teaching hospitals for travel, speaking fees, research gifts, meals, and equity holdings that they or their families have in these companies. The data collected are maintained on public websites. PPSA became active on August 1, 2013. Between 2013 and 2015 a total of 1,455 companies reported making payments to 618,000 physicians and 1,111 teaching hospitals. The total U.S. dollar value of the payments was $7.33 billion.

The very small number of physicians in the study (0.007%) is not designed to provide a sampling of the entire physician population impacted by PPSA. Other studies and anecdotal reports are consistent with the results found by the authors. For the year 2014 the study data from the Center for Medicare & Medicaid Services indicated that 32% of the payments were from royalties and licenses and 25% for promotional speaking.

The article is largely focused on educating physicians about the law and promoting their awareness of the value of the law to patients.

The PPSA was passed in response to the growing public and media attention to financial conflicts of interest in the medical field. The *New England Journal of Medicine* and the *Journal of the American Medical Association* began requesting authors of papers in their journals to disclose their financial interests relevant to the subject matter of their publication. Subsequently, the Public Health Service and the National Science Foundation issued requirements to all institutions receiving federal research dollars from those agencies to report on their sources of external funding to their institution. If their institution found that in such disclosures there were financial conflicts of interest (COIs), they were required to manage them. The purpose of these regulations was to promote objectivity in science and reduce bias in federally funded research or at least make such biases transparent.

There is a series of assumptions about the PPSA that, if true, could justify the requirement, at least somewhat. Weighing what the PPSA does achieve with the burden it places on the regulated parties would also be relevant to its success.

In the case of financial COIs in journals, there were empirical studies that justified transparency. It was found that studies funded by for-profit institutions, compared to nonprofit institutions or government, were more likely to reach conclusions about risk or efficacy that were concordant with the financial interests of those institutions. Editors of leading medical and science journals felt that their readers and journalists reporting on their publications should be aware of the financial interests of the papers'

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authors. One of the problems with the PPSA is that there have not been clearly measurable endpoints on which to ground the policy. The following questions are relevant to the responses of the physicians interviewed for the Chimonas and colleagues focus-group study.

1. Do the disclosures mandated by the PPSA alter the behavior of patients or physicians?
2. If there is any correlation between payments to physicians and their prescribing behavior, does transparency modify that behavior?
3. Are there any data that inform us about whether patients who acquire physician payment information engage with physicians about their payments? I consider myself well informed about conflicts of interest, but I doubt whether I would engage my internist on a discussion of his or her PPSA disclosures.
4. Is there any evidence that the PPSA has changed institutional behavior regarding the acceptance of gifts to medical students and/or corporate-funded lunches?
5. Since research physicians are required to disclose any financial remuneration they receive from private sources to their institution, the PPSA law uniquely captures those physicians who are unaffiliated with research institutions or who have clinical appointments not covered by the institutional financial COI guidelines. The public could access the institutional information on faculty and researchers COIs, at least on request. That means PPSA provides coverage of physician patient relationships as its unique contribution. Is there sufficient benefit from this coverage?
6. Is it the patient's' right to be able to access information about corporate payments to physicians whether or not they actually access it or use it? Will the mere knowledge that such information exists elevate the patients' trust in their physicians or in the medical community?

Scientific integrity in terms of objectivity and unbiased research is one desirable outcome for any policies on financial COIs. Providing the best unbiased and objective care to patients is another outcome. The first objective is covered by transparency in medical and science journals and within institutions. The second outcome has not been studied with respect to physician payments. There is no evidence that the PPSA will or could change biased patient care to unbiased patient care. Such data are useful in determining whether the policy meets the burdens on the regulated parties.

Does the PPSA transparency reduce the frequency of financial payment giving and taking to physicians? In one study, panel members of the *Diagnostic and Statistical Manual for Mental Disorders* (DSM) were studied prior to and after the American Psychiatric Association adopted disclosure rules (Cosgrove, Bursztajn and Krimsky 2009). The study revealed that there was an increase in financial conflicts of interest after the disclosure policy was instituted in the DSM. There are good reasons to believe that mandatory disclosures simply institutionalize conflicts of interest. Primary prevention of financial COIs should be the primary goal, since disclosure is not necessarily going to eliminate bias (Krimsky 2009). ■

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Conflict of Interest in Medicine: Plausible Deniability?

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The contribution of Chimonas and colleagues (2017) to this issue delineates the views of a modestly sized sample of practicing physicians on the very existence of conflict of interest (COI) in medicine (Chimonas, De Vito, and Rothman 2017). Uncovering as it does adamant dismissal of the very possibility of COI in medicine and of the prospect of personal susceptibility to financial rewards, the study exposes unforeseen sentiments that have rarely been previously reported. As such, the study raises significant questions as to the very rationale of the Physician Payments Sunshine Act, not to mention the enormous annual efforts involved in its implementation by all involved, including

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