Op-Ed

The Importance of Physicians' Financial Disclosure for the Public's Health

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YOU MIGHT ASK WHY IT IS IMPORTANT FOR THE PUBLIC'S health that physicians and other authors disclose their financial relationships with pharmaceutical and medical device companies when they publish in biomedical, health science, and policy journals. And why is it important that the public have access to payments made to physicians by pharmaceutical and medical device companies? The short answer is that while there is no ironclad guarantee, these critical disclosures help ensure that the authors whose articles are published in peer-reviewed journals are open and honest about the funders, connections, institutions or companies, and associations related to their studies. Equally important, these disclosures give some assurance that the prescribed medications, therapies, or devices recommended in these articles provide the best options for patients and, hence, the public's health.

Now for the long answer.

Financial Disclosures in Medical Journals

Many, if not most, of the high-impact biomedical, health science, and policy journals (including *The Milbank Quarterly*) require authors to disclose their financial relationships with pharmaceutical or medical device companies, either by completing the International Committee of Medical Journal Editors (ICMJE) author form or in another manner prescribed by that journal. This helps the journal's editor determine whether or not that financial arrangement might have had too much influence on the outcome of the study or article and therefore can choose not to publish it. When these disclosures are published along with the article, they allow its readers to decide what, if any, influence the payment might have had on the published article.

This is not to say that the financial sponsor of a study related to that sponsor's product makes that article suspect for manipulated outcomes, but it does heighten the review and scrutiny of the study. A 2012 *Cochrane Review* of 48 published papers found that the likelihood of a study's positive outcome was higher when the study had been sponsored by the pharmaceutical company manufacturing the drug than if the study had been sponsored by some other entity.¹

To be fair, the vast majority of clinical trials are sponsored by pharmaceutical companies that must have clinical trial proof of efficacy for approval of their drug by the Federal Drug Administration (FDA). On the one hand, the companies' sponsorship of trials is necessary because the National Institutes of Health (NIH) and other federal agencies pay for comparatively few clinical trials; moreover, such trials are very expensive to develop and conduct. On the other hand, it is certainly fair and appropriate for the company that will profit from the sales of its drugs to pay for the clinical trial studies.

Public Access to Pharmaceutical Payments to Physicians

Patients should know whether their physician has received payments from pharmaceutical or medical device companies, especially when they have been prescribed expensive drugs when a less expensive drug that is just as effective is available. Pharmaceutical companies spend millions of dollars for their representatives to "educate" physicians on the many wonders of their drugs. This is especially true for new (read expensive) drugs. Pharmaceutical companies' representatives pay for items such as food for the physicians' offices and staff; lavish dinners for the physicians; tickets for sports events, theater, and other entertainment events; and travel to meetings, especially when the physician presenters, also paid by the pharmaceutical companies, discuss diseases and treatments, often using slides made by the pharmaceutical company. In return, the physicians are expected to prescribe the drugs manufactured by the representative's pharmaceutical company. Physicians have stated that they are not affected by these gifts, but if they aren't, why would the pharmaceutical companies continue this expensive practice?

Pharmaceutical representatives also give physicians drug starter samples, most often for expensive new drugs that require many subsequent

prescriptions. This practice is the same with “direct-to-consumer advertisements,” which typically include coupons offering the first prescription free. The *modus operandi* of this tactic is that the patient will come to the physician with the coupon requesting that specific medication and that many physicians will fulfill the patient’s request instead of discussing a less expensive but equally effective medication.

Beginning in 2000, various bills dealing with this problem, including the 2007 Physician Payments Sunshine Act, were introduced in the US Congress without success. Several states, however, enacted variations on this Act, some pharmaceutical companies began to disclose payment data, and the Medicare Payment Advisory Committee and the Institute of Medicine supported the Act. In 2010, these elements of the Sunshine Act were incorporated into Title VI, the transparency and integrity component of the Patient Protection and Affordable Care Act (ACA).

As part of the ACA, the Centers for Medicare and Medicaid Services (CMS) began its Open Payment Program, which collected data on payments made by manufacturers of federally covered drugs, biologics, medical supplies, and devices to physicians and to teaching hospitals. The CMS has now released the database (<https://openpaymentsdata.cms.gov>), and not surprisingly, it contains some very interesting information.

The database includes information on 1,444 companies, 607,000 physicians and their payment records, and 1,121 teaching hospitals. In 2014, pharmaceutical and medical device manufacturers paid \$6.49 billion to US physicians and teaching hospitals. Of this, \$3.23 billion (49.8%) was for research-related activities, which might be necessary expenditures, as explained earlier. However, many of the large research payments were related to drugs that have been on the market for several years, which probably includes money for the drug samples discussed earlier.

Of special interest to patients, \$403.64 million was paid to physicians for food and beverages, travel, and lodging. The data also include some interesting payments for “miscellaneous entertainment.”

The top pharmaceutical companies in payouts to physicians and teaching hospitals were Genentech, \$373.4 million; Pfizer, \$287.4 million; and GlaxoSmithKline, \$213.1 million. However, virtually every pharmaceutical company provided some payments to physicians and teaching hospitals.

Indeed, this database is a treasure trove of information that demands to be reviewed by policymakers, health care professionals, and the public.

Patients finally have a resource where they can monitor physicians' payments from pharmaceutical and medical device manufacturers. Already, merely as a result of gathering these data with the promise of publishing them online, many physicians have stopped taking "gifts" from these companies, and pharmaceutical and medical device companies are sending fewer representatives to physicians.

The effect of the aptly named Sunshine Act has been to shed some light on shaded, or shady, practices so that they can be seen by the public. It's now up to them to use this revelation to help prevent such practices from affecting their health and pocketbooks.

Reference

1. Lundh A, Sismondo S, Lexchin J, Busuico OA, Bero L. Industry sponsorship and research outcome. *Cochrane Rev.* 2012. doi:10.1002/14651858.MR000033.pub2.

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