On June 30, 2017, the Centers for Medicare and Medicaid Services released the 2016 Open Payments data, which (as required by the Physician Payments Sunshine Act of the Affordable Care Act) disclose payments and any other “transfers of value” to physicians from commercial entities (https://openpaymentsdata.cms.gov). This was the third complete year of the availability of this information. It now includes payment information from over 2000 companies that have made ~40 million payments to over 900,000 physicians for a total of nearly 25 billion dollars. The vast majority of these payments are for relatively small dollar amounts (<$100) related to the provision of food and beverages. Each year, before the release of the information, physicians have the opportunity to refute their own personal data; however, relatively few corrections have been requested or made.

At its inception, the Sunshine Act (named in honor of Supreme Court Justice Louis D. Brandeis, who famously wrote, “Sunlight is said to be the best of disinfectants…”[1]) was expected to better inform the public about their physicians’ financial dealings with pharmaceutical and medical device manufacturers. For example, in an analysis of payments accepted by pediatricians in 2014, it was discovered that most payments were associated with medications that treat attention-deficient/hyperactivity disorder and vaccinations.[2] This may lead parents and child advocates to question the true intent of these types of prescriptions. But, despite this original intention, there has been no indication that the lay public is prepared to use this information to influence their medical decision-making.[3] The specific reasons for the payments are unclear, and patients seem to have a general lack of desire to know this type of information about the doctors they already know and trust. Nevertheless, the public availability of these data has proven useful in numerous other ways that give an indication of its future use and the implications it portends for physicians. The most salient of these implications includes the following.

ENFORCEMENT OF FRAUD

The Department of Justice and other law or regulatory enforcement agencies have and will continue to mine these data by cross-referencing it with prescriber databases, such as those provided by the Centers...
for Medicare and Medicaid Services for Medicare patients, to identify relationships that violate antikickback and False Claims Act (FCA) statutes. Shortly after the beginning of the Open Payments collection process, the Food and Drug Administration’s Office of Criminal Investigations issued a request for a proposal for an outside party to create a prescription drug data and marketing database.4 Because the mission of this office is to investigate suspected criminal violations of the Food, Drug, and Cosmetic Act, the implications for detection of fraud are apparent.

The intersection of the Sunshine Act, antikickback statutes, and the FCA has resulted in a powerful prosecutorial triumvirate with which to penalize drug manufacturers and physicians who are found to enter into mutually rewarding financial relationships. Historically, prosecutions have resulted in large civil penalties levied against pharmaceutical manufacturers, but recent prosecutions of pain management physicians and other health care providers have sent a strong message that prescribers will now also be targeted and prosecuted for selectively and inappropriately prescribing drugs of companies that provide them with compensation.5 Furthermore, potential whistleblowers will be able to use information gleaned from the database to establish and reinforce antikickback and FCA allegations. On the basis of the Park doctrine, which holds corporate executives liable for the actions of their employees, hospital or University C-suite executives may be liable for their employees’ antikickback or FCA violations if the officers had the responsibility and authority to prevent the misconduct or knew about the violation but failed to promptly correct it. One would expect that these prosecutions will have a chilling effect on the relationships between prescribers and manufacturers, but this will become more apparent in the coming years as parties on both sides reevaluate these mutually beneficial transactions that are now publicly transparent. Although the existence of payments to prescribers does not establish a quid pro quo relationship, inordinately large payments that are beyond the norm can initiate a more detailed investigation into the nature of those payments and the discovery of fraudulent behavior.

**VERIFICATION OF VOLUNTARY FINANCIAL CONFLICT OF INTEREST DISCLOSURES**

Medical centers will now be able to screen their employee prescribers to verify their financial conflict of interest disclosures in an attempt to decrease risk to the hospital’s reputation and prevent loss of federal grants due to the concealment of financial conflict of interest. For example, in my own institution, staff from the compliance office routinely examine Open Payments to verify voluntary disclosures by medical faculty (no purposeful omissions have been found thus far). Journal editors and peer reviewers will be able to use the database to verify the disclosures of authors of clinical trials6 or guidelines.7 For now the database contains information only on prescribers who practice in the United States, but global regulatory agencies have begun to take notice of our disclosure laws and are expected to follow suit.8

Federal and private granting agencies will be able to use the database to verify financial relationships of grant applicants and initiate inquiries into the nature of these relationships. In some cases it may influence or even disqualify applicants. Likewise, governmental regulatory agencies such as the Food and Drug Administration can use the database to screen for financial conflicts of special government employees, such as consultants who serve as members of advisory committees as well as speakers hired by pharmaceutical companies who present data at advisory committee meetings.

**MEDICAL MALPRACTICE**

Attorneys will be able to use the Open Payments database to search for advantages on either side of a medical malpractice case. Plaintiff attorneys will find it useful when, in a case involving a medication or device-related complication, the defendant physician has accepted payments from the manufacturer of that drug or device. Although the payment may not have been materially linked to the complication, the appearance of a relationship may hamper the defendant’s prospects at trial and could encourage a settlement beneficial to the plaintiff. Conversely, defense attorneys will be able to use information from the database to discredit the plaintiff’s experts who have accepted payments from drug or device companies in an attempt to demonstrate that the expert’s opinion can be bought.

**STATE DISCLOSURE LAWS**

States will continue to develop disclosure laws that target consumer protection from physicians who accept pharmaceutical payments. These laws have been used in Oregon to prosecute physicians who failed to disclose their financial relationships to their patients and will likely be increasingly used throughout the country in a similar manner.9

**CONCLUSIONS**

The information contained in the Open Payments database has not provided the reassurance to the public as originally thought, but it is influencing areas of medicine that depend on the disclosure of financial
relationships with industry. Because these disclosures may reveal quid pro quo fraudulent behavior, influence whether an investigator acquires or retains a grant, or even benefit 1 side of a medical malpractice claim, the implications of this new transparency will change the way in which prescribers and manufacturers approach these mutually beneficial relationships.

### Abbreviation

- FCA: False Claims Act

### References


The Physician Payments Sunshine Act: Implications and Predictions
Ronald S. Litman
Pediatrics 2018;141;
DOI: 10.1542/peds.2017-1551 originally published online January 23, 2018;

Updated Information & Services
including high resolution figures, can be found at:
http://pediatrics.aappublications.org/content/141/2/e20171551

References
This article cites 5 articles, 1 of which you can access for free at:
http://pediatrics.aappublications.org/content/141/2/e20171551#BIBL

Subspecialty Collections
This article, along with others on similar topics, appears in the following collection(s):
Administration/Practice Management
http://www.aappublications.org/cgi/collection/administration:practice_management_sub
Compliance
http://www.aappublications.org/cgi/collection/compliance_sub

Permissions & Licensing
Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
http://www.aappublications.org/site/misc/Permissions.xhtml

Reprints
Information about ordering reprints can be found online:
http://www.aappublications.org/site/misc/reprints.xhtml
The Physician Payments Sunshine Act: Implications and Predictions
Ronald S. Litman

Pediatrics 2018;141;
DOI: 10.1542/peds.2017-1551 originally published online January 23, 2018;

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://pediatrics.aappublications.org/content/141/2/e20171551