

GYNECOLOGY

Sunshine Act: shedding light on inaccurate disclosures at a gynecologic annual meeting

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BACKGROUND: Physicians and hospital systems often have relationships with biomedical manufacturers to develop new ideas, products, and further education. Because this relationship can influence medical research and practice, reporting disclosures are necessary to reveal any potential bias and inform consumers. The Sunshine Act was created to develop a new reporting system of these financial relationships called the Open Payments database. Currently all disclosures submitted with research to scientific meetings are at the discretion of the physician. We hypothesized that financial relationships between authors and the medical industry are underreported.

OBJECTIVES: We aimed to describe concordance between physicians' financial disclosures listed in the abstract book from the 41st annual scientific meeting of the Society of Gynecologic Surgeons to physician payments reported to the Center for Medicaid and Medicare Services Open Payments database for the same year.

STUDY DESIGN: Authors and scientific committee members responsible for the content of the 41st annual scientific meeting of the Society of Gynecologic Surgeons were identified from the published abstract book; each abstract listed disclosures for each author. Abstract disclosures were compared with the transactions recorded on the Center for Medicaid and Medicare Services Open Payments database for concordance. Two authors reviewed each nondisclosed Center for Medicaid and Medicare Services listing to determine the relatedness

between the company listed on the Center for Medicaid and Medicare Services and abstract content.

RESULTS: Abstracts and disclosures of 335 physicians meeting inclusion criteria were reviewed. A total of 209 of 335 physicians (62%) had transactions reported in the Center for Medicaid and Medicare Services, which totaled \$1.99 million. Twenty-four of 335 physicians (7%) listed companies with their abstracts; 5 of those 24 physicians were concordant with the Center for Medicaid and Medicare Services. The total amount of all nondisclosed transactions was \$1.3 million. Transactions reported in the Center for Medicaid and Medicare Services associated with a single physician ranged from \$11.72 to \$405,903.36. Of the 209 physicians with Center for Medicaid and Medicare Services transactions that were not disclosed, the majority (68%) had at least 1 company listed in the Center for Medicaid and Medicare Services that was determined after review to be related to the subject of their abstract.

CONCLUSION: Voluntary disclosure of financial relationships was poor, and the majority of unlisted disclosures in the abstract book were companies related to the scientific content of the abstract. Better transparency is needed by physicians responsible for the content presented at gynecological scientific meetings.

Key words: financial disclosures, Open Payments database, Sunshine Act

Physicians and hospital systems often have relationships with biomedical manufacturers. These relationships are established to promote and develop innovative ideas and products and support physician education. Companies often provide funding for these efforts.

Industry's share of total investment in biomedical research and development increased substantially from 32% in 1980 to 62% in 2000.¹ In 2001, US

pharmaceutical companies spent more than \$21 billion promoting prescription drugs, and 84% of the marketing was directed toward physicians.² In 2007, 94% of US physicians surveyed nationally reported that they had a relationship with industry.³

Industry's financial influence leaves a significant impact on physicians' practice and research results. Physicians who have accepted money from pharmaceutical companies are more likely to request additions to the hospital formulary including drugs manufactured by those same companies.⁴

Prescribing practices are also influenced by interactions between physicians and pharmaceutical companies. Physicians who receive financial support from industry are more likely to prescribe those industries' medications.⁵⁻⁸

Industry-sponsored studies are more likely to reach conclusions that were favorable to the sponsor than nonindustry studies.^{1,9}

Despite evidence that industry relationships influence physician decision making, the majority of physicians deny that their own industry relationships influence their practice.¹⁰⁻¹³ Although physician-industry relationships are valuable, transparency is key to maintaining a professionalism. Disclosing financial relationships or other invested interest in companies reveals potential biases in physician behavior. Currently physician scientists are asked to divulge industry alliances when presenting scientific work, including presentations at scientific meetings and on publications to ensure transparency and reveal potential biases. Until recently, all

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disclosures were at the discretion of the physician.

The Physician Payments Sunshine Act was created from the Patient Protection and Affordable Care Act passed in 2010. This national disclosure program requires public reporting of payments to physicians and teaching hospitals from applicable manufacturers and group purchasing organizations.

The Centers for Medicare and Medicaid Services was assigned to collect information from these companies in a publicly available database called the Open Payments Program (<http://www.cms.gov/openpayments>). The purpose of this system is to improve transparency to consumers of possible biases in physician practice and research.

Applicable manufacturers or group purchasing organizations are included in the Centers for Medicare and Medicaid Services database if they are located and/or conduct activities within the United States and produce, purchase, arrange, and/or negotiate the purchase of pharmaceuticals, devices, biological agents, or medical supplies. At least 1 product must be reimbursed by Medicare, Medicaid, or the Children's Health Insurance Program, and either the product must require the physician's authorization/prescription to administer or the product requires premarket approval/notification by the Food and Drug Administration.¹⁴

All transactions including single payments greater than \$10 and multiple payments exceeding \$100 qualify for reporting. The Centers for Medicare and Medicaid Services lists all transactions with applicable companies including company names, number of transactions, physician payment amounts, and types of payments. Data collection began Aug. 1, 2013, and 2014 was the first year this information became publicly available.

One way to measure physician transparency is to compare industry relationships reported in the Open Payment Program with physician self-disclosure. We aimed to evaluate the concordance of authors' self-reported disclosures at the 41st annual scientific meeting of the Society of Gynecologic Surgeons in 2015

compared with those published in the Centers for Medicare and Medicaid Services Open Payments Program in the same year. We hypothesized that financial relationships between authors and medical industry are underreported at a scientific meeting, and many physician undisclosed associations with companies were directly related to the subject of the research being presented.

Materials and Methods

We performed a retrospective cohort study to compare the financial disclosures between those physicians responsible for the scientific content of the 41st annual scientific meeting of the Society of Gynecologic Surgeons in 2015 and disclosures published on the online Centers for Medicare and Medicaid Services database.

This was an institutional review board-exempt study because all data were publicly available. The *Journal of Minimally Invasive Gynecology*, published in March/April 2015, listed the scientific program committee members as well as all abstracts presented at the annual meeting. Abstracts included oral presentations, oral poster presentations, nonoral poster presentations, video presentations, video fest, and the video café. The Society of Gynecologic Surgeons instructs all authors to disclose conflicts "whether or not this relationship is directly related to the material being presented," and physician self-disclosures were published with their abstracts.

The authors and Society of Gynecologic Surgeons scientific committee members responsible for the content at the meeting were identified from the abstract book. Demographic information including sex, specialty, level of training, type of institution (ie, private practice, teaching hospital) was collected by searching publicly available Internet sites using the authors' name and institution. All presenters except for those who were identified as nonphysicians and physicians practicing medicine outside the United States were included in this study. Physicians meeting eligibility criteria were searched in the Centers for Medicare and Medicaid Services Open Payments database.

Centers for Medicare and Medicaid Services payment information was compared with self-reported financial disclosures to determine the disclosure rate. If an author was listed on more than one abstract, disclosures were summed across abstracts and compared in total with the companies listed on the Centers for Medicare and Medicaid Services.

Abstracts do not include a monetary value with the self-disclosed companies. To determine the monetary value of nondisclosed affiliations, the total amount of money from companies listed on the Centers for Medicare and Medicaid Services and self-disclosed by the authors in the abstracts was subtracted from the total amount reported in the Centers for Medicare and Medicaid Services.

Others have proposed a cutoff value for associations because associations of very low value may have been disclosed by a company without the author's awareness, and small amounts may not have as strong an influence as larger amounts on physician behavior. We performed a subanalysis by excluding all Centers for Medicare and Medicaid Services total value listings less than \$100.

Relatedness of nondisclosed conflicts was also evaluated. Two authors each independently reviewed each nondisclosed Centers for Medicare and Medicaid Services listing to determine whether the company's product line was related to the content of the abstract. The companies were categorized by their products or services into pharmaceutical, surgical, or medical relevant to the treatment of pelvic floor dysfunction. Abstracts were similarly categorized.

A disclosure was determined related to the content of the abstract if the company produced a product in the same category as the abstract. For example, a company involved with producing medications for overactive bladder was determined relevant to a study evaluating the outcomes of overactive bladder treatments. Both reviewers agreed on the relatedness assignment. If reviewers did not agree, discrepancies were adjudicated with a third party.

Study data were entered into REDCap.¹⁵ Descriptive statistics were

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