

Interactions with industry under the Sunshine Act: an example from gynecologic oncology

David I. Shalowitz, MD; Monique A. Spillman, MD, PhD; Mark A. Morgan, MD

Introduction

As part of the Affordable Care Act, the Centers for Medicare and Medicaid Services (CMS) issued final regulations in February 2013 implementing the Physician Payments Sunshine Act. In an attempt to improve transparency of financial connections between manufacturers and health care providers, the Sunshine Act requires manufacturers of drugs, devices, and other medical supplies to report all payments or in-kind compensation of significant value (defined as >\$10 per instance or totaling >\$100 in a year) to CMS. CMS, in turn, maintains a public, searchable database with details regarding the reporting company, the physician receiving payment, and the nature and purpose of the payment. Separate databases are maintained for hospitals and physicians. Payments to physicians are further separated into direct funding for clinical research, ownership of stock and investments, and “general payments,” which include compensation for consulting, travel and lodging, educational lectures, meals, and honoraria.^{1,2} In this article, we focus on the general payments database, as there is

From the Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, University of Pennsylvania, Philadelphia, PA (Drs Shalowitz and Morgan); and Texas Oncology—Baylor Charles A. Sammons Cancer Center, Dallas, TX (Dr Spillman).

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Disclosure: Dr Shalowitz is a current member of the Committee on Ethics of the American Congress of Obstetricians and Gynecologists, and Dr Spillman is a former chair of the same committee. The opinions expressed in this article are the authors' own.

Corresponding author: David I. Shalowitz, MD. david.shalowitz@uphs.upenn.edu

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THE PROBLEM: Clinicians may be unaware that industry payments to physicians are now publicly searchable under the Physician Payments Sunshine Act. Furthermore, the extent of industry's financial involvement in subspecialty practice has not been previously accessible. As an example, 6948 direct, research-unrelated payments totaling \$1,957,004 were made to 765 gynecologic oncologists in 2014, the first full year of data available. A total of 153 companies reported at least 1 payment; however, the 10 manufacturers reporting the highest total payment amount accounted for 82% of all payments to physicians. In all, 48 gynecologic oncologists received >\$10,000 from manufacturers, accounting for \$1,202,228, or 61%, of total payments.

A SOLUTION: Obstetrician-gynecologists, including gynecologic oncologists, should be aware of their publicly reported payments from industry and ensure reports' accuracy. Professional organizations, including the Society of Gynecologic Oncology (SGO), should strongly consider proactively developing guidelines regarding interactions with industry for their general memberships.

Key words: conflict of interest, ethics, gynecologic oncology, Sunshine Act

less guidance available to clinicians on how to manage these interactions with industry, compared to existing oversight of research funding and stock ownership. Given the potential influence on the opinions and behavior of patients, physicians, and the public, it is critical for obstetrician-gynecologists and subspecialists to be aware of publicly available data connecting physicians to industry.

An analysis of payment data from the fourth quarter of 2013 suggested that the median payment from industry to gynecologic oncologists may be particularly high compared to other specialties.³ As a case in point, we therefore considered compensation data from 2014, the first full year released by CMS. Statistics for individual gynecologic oncologists are available through the CMS Web site; summary data and implications are presented in this article. Of note, physicians who are not named in disclosures from manufacturers do not appear in the CMS database.

Materials and Methods

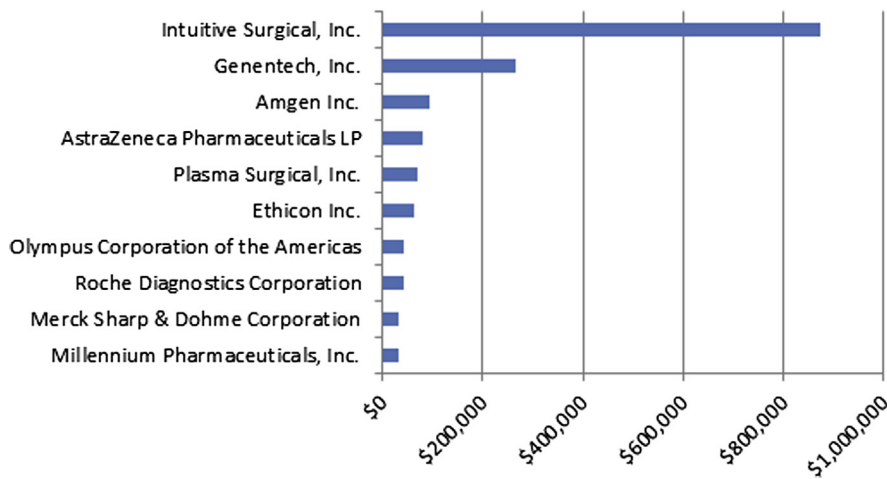
Industry-reported payments to gynecologic oncologists were extracted from

the open payments database, maintained by the CMS (<https://www.cms.gov/openpayments/index.html>). Data collection was limited to the general payments data set from 2014, the first full year of data collected. This data set, released by CMS on June 30, 2015, includes payments made by applicable manufacturers to physicians for purposes not connected to a research agreement or protocol, and not related to investment or ownership. The general payments data summarize payments totaling \$2.02 billion from 1444 companies to 607,000 physicians across all specialties. The data set includes, among other items, the names of the manufacturer reporting payment; the name, specialty, and a unique identifier for the physician receiving payment; the nature of payment received (eg, honorarium, consultant's fee); and the amount of the payment. Analysis was limited to physicians identified as specialists in gynecologic oncology. Standard descriptive statistics were utilized.

Results

Applicable manufacturers reported a total of \$1,957,004 over 6948 direct,

FIGURE 1
Top-10 companies in total payments to gynecologic oncologists, 2014



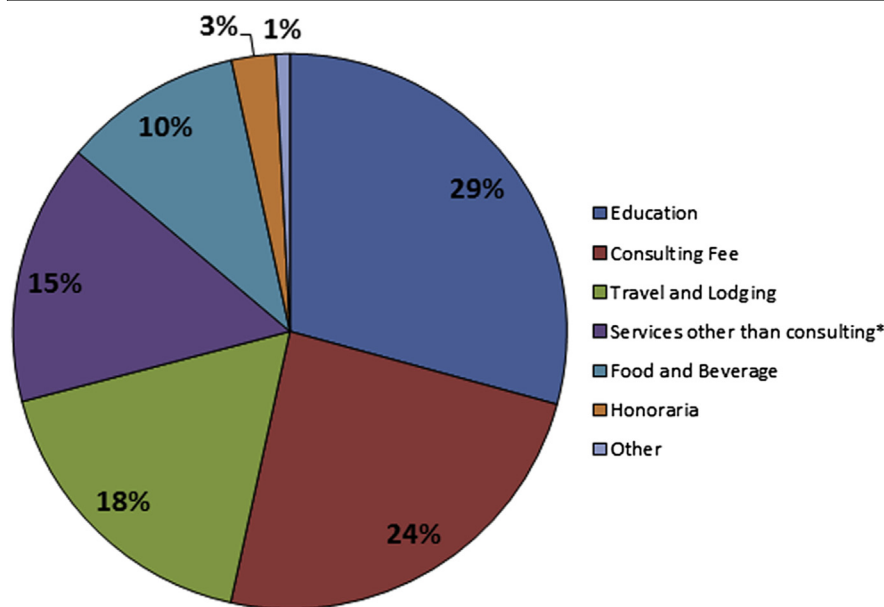
Top-10 companies in total payments to gynecologic oncologists, 2014.

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research-unrelated payments to gynecologic oncologists in 2014. A total of 153 companies reported at least 1 payment; however, the 10 manufacturers reporting the highest total payment

amount accounted for 82% of all payments to physicians (Figure 1). Furthermore, the 2 manufacturers reporting the highest total payments (Intuitive Surgical Inc and Genentech

FIGURE 2
Nature of payments from industry to gynecologic oncologists



*Includes faculty/speaker fees for non-educational events. For more detail on payment classification, see <https://www.cms.gov/OpenPayments/About/Natures-of-Payment.html>

Nature of payments from industry.

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Inc.) together account for \$1,137,647, or 58%, of the total payments reported by all 153 manufacturers. Median total payment per manufacturer was \$332, with 25th and 75th percentiles \$71 and \$4339, respectively. Of payments from manufacturers, 99% were categorized as related to an educational event (29%), consulting fee (24%), travel and lodging (18%), speaking fee unrelated to education (15%), food and beverage (10%), and honoraria (3%) (Figure 2).

In all, 765 gynecologic oncologists were identified as having received payments from manufacturers. This represents approximately 77% of gynecologic oncologists practicing nationwide; the Foundation for Women’s Cancer’s Find a Gynecologic Oncologist database⁴ identified 1007 board-certified and board eligible gynecologic oncologists in 2014. Median total payment to gynecologic oncologists identified in the general payments database was \$219, with 25th and 75th percentiles \$69 and \$1205, respectively. In all, 48 gynecologic oncologists received >\$10,000 in total payment from manufacturers (median \$17,158), accounting for \$1,202,228, or 61%, of the total payments. Another 48 physicians received between \$5000-10,000 (median \$6694), accounting for an additional 17% of total payments.

Comment

Three of every 4 gynecologic oncologists practicing in the United States received compensation from pharmaceutical or medical device manufacturers in 2014. This is consistent with a large, cross-sectional survey of multiple subspecialties estimating that annually upwards of 80% of physicians receive payment from industry.^{5,6} As the open payments database is increasingly accessed by patients, research participants, and the press, it is critical for physicians to verify the accuracy of entries under their names. Unfortunately, preliminary data released in 2014 contained significant inaccuracies. CMS reported later that year that the systemic errors accounting for the majority of these errors were corrected for the data to be released in 2015.^{7,8} Information on the process of disputing a disclosure

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