

Orthopaedic Surgeons Receive the Most Industry Payments to Physicians but Large Disparities are Seen in Sunshine Act Data

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Abstract

Background Industry payments made to physicians by drug and device manufacturers or group purchasing organizations are now reported to the Centers for Medicare and Medicaid Services (CMS) as a part of the Physician

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Each author certifies that his or her institution approved or waived approval for the reporting of this investigation and that all investigations were conducted in conformity with ethical principles of research.

This work was performed at Yale School of Medicine, New Haven, CT, USA.

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Payments Sunshine Act. Initial reports from the program show that orthopaedic surgeons lead all physician specialties in total and average industry payments. However, before further discussion of these payments and their implications can take place, it remains to be seen whether these figures are a true reflection of the field of orthopaedic surgery in general, rather than the result of a few outlier physicians in the field. In addition, the nature and sources of these funds should be determined to better inform the national dialogue surrounding these payments.

Questions/Purposes We asked: (1) How do industry payments to orthopaedic surgeons compare with payments to physicians and surgeons in other fields, in terms of median payments and the Gini index of disparity? (2) How much do payments to the highest-receiving orthopaedic surgeons contribute to total payments? (3) What kind of industry payments are orthopaedic surgeons receiving? (4) How much do the highest-paying manufacturers contribute to total payments to orthopaedic surgeons?

Materials and Methods We reviewed the most recent version of the CMS Sunshine Act Open Payments database released on December 19, 2014, containing data on payments made between August 1, 2013 and December 31, 2013. Data on total payments to individual physicians, physician specialty, the types of payments made, and the manufacturers making payments were reviewed. The Gini index of statistical dispersion was calculated for payments made to orthopaedic surgeons and compared with payments made to physicians and surgeons in all other medical specialties. A Gini index of 0 indicates complete equality

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of payments to everyone in the population, whereas an index of 1 indicates complete inequality, or all income going to one individual.

Results A total of 15,376 orthopaedic surgeons receiving payments during the 5-month period were identified, accounting for USD 109,846,482. The median payment to orthopaedic surgeons receiving payments was USD 121 (interquartile range, USD 34–619). The top 10% of orthopaedic surgeons receiving payments (1538 surgeons) received at least USD 4160 and accounted for 95% of total payments. Royalties and patent licenses accounted for 69% of all industry payments to orthopaedic surgeons.

Conclusions Even as a relatively small specialty, orthopaedic surgeons received substantial payments from industry (more than USD 110 million) during the 5-month study period. Whether there is a true return of value from these payments remains to be seen; however, future ethical and policy discussions regarding industry payments to orthopaedic surgeons should take into account the large disparities in payments that are present and also the nature of the payments being made. It is possible that patients and policymakers may view industry payments to orthopaedic surgeons more positively in light of these new findings.

Level of Evidence Level III, Economic and Decision Analysis.

Introduction

The field of orthopaedic surgery has long had strong ties with the medical device manufacturing industry, as implants and surgical tools play an integral role in musculoskeletal surgery. The close surgeon-industry relationships foster continual development of novel ideas and techniques by manufacturers [16, 19, 25], which ultimately require the input of the end user, the orthopaedic surgeon. As a result, industry payments to orthopaedic surgeons, mostly from medical drug or device manufacturers and group-purchasing organizations (GPOs) for consulting services, reimbursement for travel, or ownership royalties, are not irregular [23, 33]. A nationwide survey of physicians of all specialties reported 94% of physicians received some form of payment from drug or device manufacturers during the previous year [9].

However, as with any financial relationships with industry, there are risks for conflicts of interest and bias [2, 5, 6, 20, 22, 25, 30, 38, 43]. As a result, increased transparency in these relationships has been stressed. Previous studies of self-disclosure of financial relationships have shown substantial reporting inaccuracies among orthopaedic surgeons [7], and other physician specialties [36, 39]. To address this, the newly passed Physician Patient Sunshine Act, part of the larger Patient Protection and Affordable Care Act, mandates

that all industry payments made to physicians from drug or device manufacturers or GPOs be reported to the Centers for Medicare and Medicaid Services (CMS) [1, 31]. The initial release of data was made on September 30, 2014, containing data on payments made between August 1, 2013 and December 31, 2013, with a second release on December 19, 2014 providing additional initially disputed payment data from the same period.

This early release of Sunshine Act data, while subject to criticisms regarding completeness and accuracy [34, 42, 46], suggests that orthopaedic surgeons lead all medical specialties in industry payments from drug and device manufacturers. As previously reported [15, 26, 44], orthopaedic surgery leads all fields in per capita industry payments at more than USD 5000 per surgeon, and in total industry payments, with more than USD 109 million paid to more than 15,000 surgeons during the 5-month reporting period. The next closest field, internal medicine, received approximately USD 34 million paid to more than 55,000 physicians.

Although musculoskeletal surgery lends itself to close ties with industry representatives, the differences in industry payments between orthopaedics and other fields are striking. However, further exploration of these data is warranted before discussion of these payments and their implications can take place. It remains to be seen whether the large sums paid to orthopaedic surgeons are a true reflection of the majority of surgeons in the field rather than the result of a few outliers. In addition, the nature and sources of these funds are largely not described. Patients and policymakers will likely form opinions based on previous summaries of Sunshine Act data. Therefore, while the national dialogue surrounding these payments increases, thoroughly characterizing these data is critical.

We asked: (1) How do industry payments to orthopaedic surgeons compare with payments to surgeons and physicians in other fields, in terms of median payments and the Gini index of disparity? (2) How much do payments to the highest-receiving orthopaedic surgeons contribute to total payments? (3) What kind of industry payments are orthopaedic surgeons receiving? (4) How much do the highest-paying manufacturers contribute to total payments to orthopaedic surgeons?

Methods

Study Design and Setting

We conducted a retrospective study of prospectively collected industry payment data. The publically available Sunshine Act Open Payment database was accessed on December 20, 2014 via the CMS website [12].

Participants and Study Subjects

The publically available Sunshine Act Open Payment database contains records of all payments made to physicians or teaching hospitals by applicable medical manufacturers or GPOs operating in the United States [14]. All payments made to orthopaedic surgeons released during the first two releases of data on September 30, 2014 and December 19, 2014, were reviewed. These releases contain payments made between August 1, 2013 and December 31, 2013. A total of 15,376 orthopaedic surgeons were identified in the database as having received industry payments from a total of 388 manufacturers and GPOs during the 5-month period.

Description of Experiment, Treatment, or Surgery

Only the CMS Sunshine Act general payments database was accessed, which includes all “payments or other transfers of value not made in connection with a research agreement or research protocol” [13]. Additional databases for research payments and physicians’ ownership interests are available but were not reviewed in this study owing to concerns of data quality [27] and less perceived risk for conflicts of interest, specifically with indirect research payments. Applicable manufacturers and GPOs report payment data directly to CMS. After submission, there is a 45-day dispute period during which physicians may report inaccuracies in data. Only payments that have completed the 45-day dispute period are included in the database with physician identifiers. Payments with ongoing or unresolved disputes are reported as deidentified in the Sunshine Act database and are not included in this analysis.

Variables, Outcome Measures, Data Sources, and Bias

Physicians in the database were grouped by medical specialty and the total payments to individual physicians and to each medical specialty were tabulated. Medical specialties and subspecialties were reported by CMS as Healthcare Provider Taxonomy Codes, as originally reported by the applicable manufacturers or GPOs. Specialties then were converted to 35 medical specialties based on those reported in the Association of American Medical Colleges 2012 Physician Specialty Data Book [11]. The total number of practicing physicians in each medical specialty and in each US Census region also was obtained from this source.

Statistical Analysis and Study Size

All statistical analyses were performed using Stata[®] version 13.0 (StataCorp LP, College Station, TX, USA).

Several separate analyses were performed for this study. First the median and interquartile range of payments to orthopaedic surgeons were computed. The Gini index, the most commonly used measure of statistical dispersion [10], was computed for payments made to all 35 medical specialties. A Gini index of 0 indicates complete equality of payments to everyone in the population, whereas an index of 1 indicates complete inequality, or all income going to one individual. Another often-used example is that if 80% of wealth is concentrated in only 20% of the population, this correlates with a Gini index of 0.6.

Next the total payments made to orthopaedic surgeons in the 10th percentile and the 1st percentile of total payments were computed. Additionally the minimum total payments to surgeons in the 10th percentile and 1st percentile were reported. Total payments to orthopaedic surgeons made by the top 10, top five, and top single manufacturer or GPO then were computed.

Next, the types of payments made to orthopaedic surgeons were assessed based on data given in the CMS database. Reasons given for industry payments include: charitable contributions, consulting fees, education, entertainment, faculty/speaker fees for continuing medical education events, fees for other nonconsulting services, food and beverage, gifts, grants, honoraria, ownership/investment interests, royalty or license fees, and travel and lodging costs.

Finally, as a secondary analysis, regional comparison of industry payments to orthopaedic surgeons was conducted. The percentage of surgeons receiving payments, total payments to the region, and per capita payments were computed for surgeons in each of the four US Census regions (Midwest, Northeast, South, and West).

Results

A total of 15,376 orthopaedic surgeons receiving payments from applicable manufacturers and GPOs, accounting for USD 109,846,482 in payments made during a 5-month period in 2013, were included in the December 19, 2014 release of Sunshine Act data. The median total industry payment to orthopaedic surgeons was USD 121 (interquartile range, USD 34–619) (Fig. 1). The median industry payment in the other surgical subspecialties ranged from USD 71 (otolaryngology) to USD 181 (thoracic surgery) (Fig. 2). The Gini index of disparity for industry payments to orthopaedic surgeons was 0.956. For comparison, a Gini index of 1.0 indicates complete inequality, or one individual possessing 100% of the wealth while all others have none. Notably, orthopaedic surgery had the highest Gini index of all physician specialties with more than 500 physicians receiving payments (Fig. 3).

Although preventative medicine, with a Gini index of 0.959, had a higher disparity in payments than orthopaedic surgery, only 421 physicians were reported to have received payments in preventive medicine. However, sampling bias or temporal bias may influence these raw cross-sectional observations, and no statistically significant

conclusions could be drawn. Overall, orthopaedic surgery has a similar-to-higher Gini index compared with other surgical subspecialties, which ranged from 0.850 (vascular surgery) to 0.942 (neurosurgery).

The top 10% of orthopaedic surgeons receiving payments (n = 1538 surgeons) each received at least USD 4160 and accounted for USD 104.7 million, or 95% of total payments to the field (Fig. 4). The top 1% (n = 154 surgeons) each received at least USD 120,506 and accounted for 66% of total payments. The surgeon receiving the highest total payments from manufacturers or GPOs accounted for 7% of all payments to orthopaedic surgeons (USD 7.4 million).

Royalties and license fees for patents and intellectual property accounted for USD 74.7 million or 69% of all industry payments to orthopaedic surgeons (Table 1). Consulting fees accounted for the next greatest share at USD 13.9 million (13%), followed by fees for nonconsulting services at USD 5.8 million (5%). The most commonly occurring payments were for food and beverage, accounting for 53,431 individual payments (68%) and for travel and lodging accounting for 13,981 individual payments (18%).

The top 10 manufacturers accounted for 80% of payments to orthopaedic surgeons (USD 87 million) (Table 2). The top five manufacturers accounted for 63% of payments

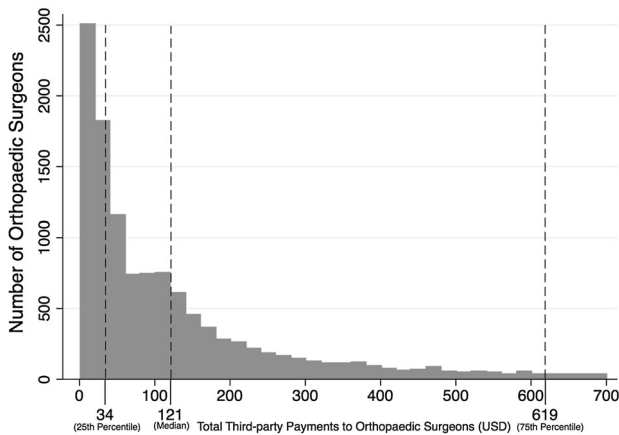


Fig. 1 The median payment was USD 121 (interquartile range, USD 34–619), based on the initial release of Sunshine Act data for August 2013 to December 2013. Only payments less than USD 700 are included in the histogram.

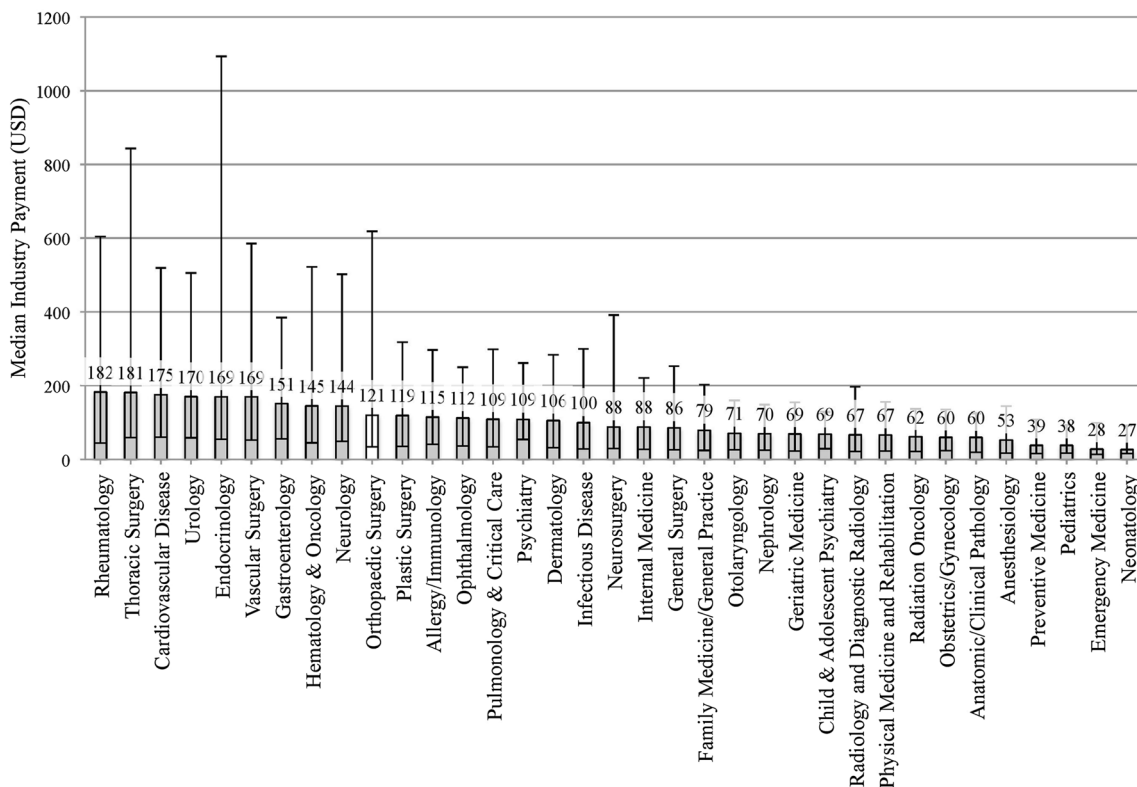


Fig. 2 The median industry payment to orthopaedic surgeons (USD 121) was comparable to payments to other surgical subspecialties (ranging from USD 71–181). Interquartile ranges are indicated with error bars.

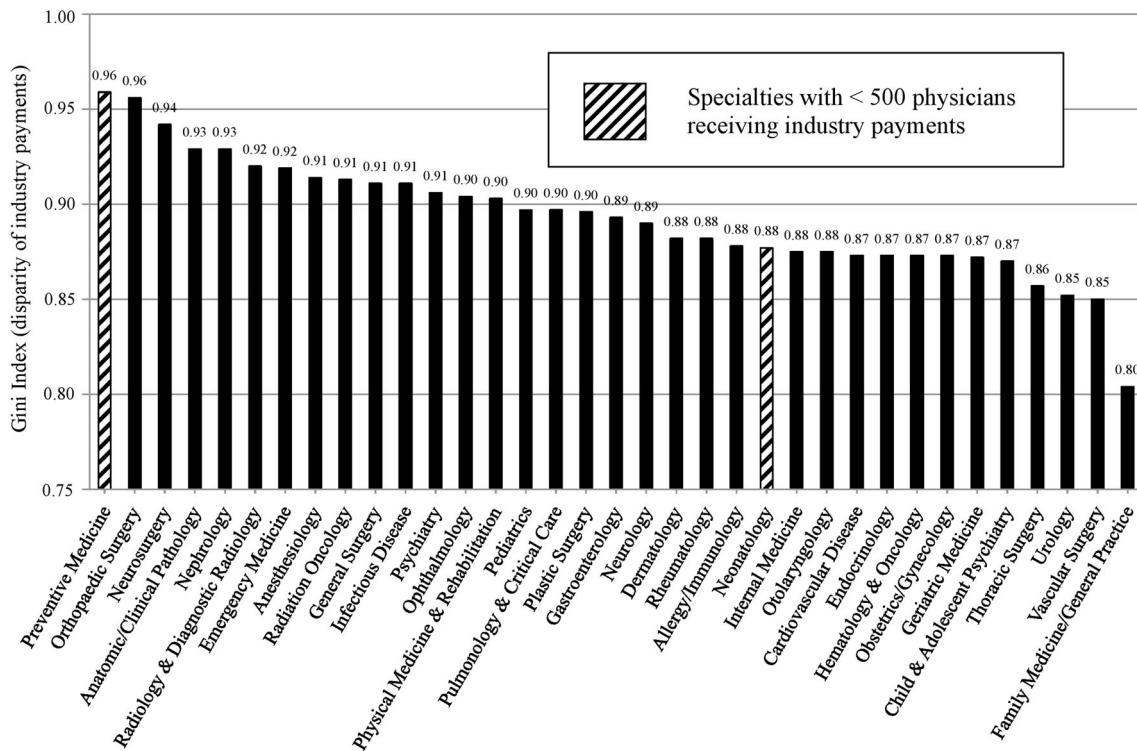


Fig. 3 Orthopaedics is second among all medical specialties in terms of Gini index of disparity for industry payments to physicians, based on the September 30, 2014 and December 19, 2014 Sunshine Act data

releases. Specialties indicated in stripes had fewer than 500 physicians receiving industry payments.

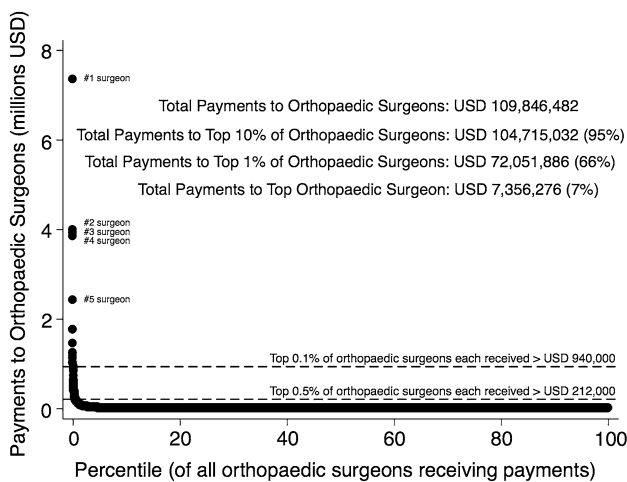


Fig. 4 The top 10% of orthopaedic surgeons accounted for 95% of total payments while the top 1% accounted for 66% of total payments to orthopaedic surgeons.

(USD 69 million) (Fig. 5). The highest-paying manufacturer accounted for 9%, or USD 33 million in payments to orthopaedic surgeons.

Discussion

The initial release of data from the Physician Payment Sunshine Act showed that orthopaedic surgery led all medical specialties in total and per capita industry payments from drug and device manufacturers. Although orthopaedic surgeons maintain strong ties with device manufacturers owing to the need for physician input in the development of new and innovative surgical devices, previous analyses of the Sunshine act data revealed a large difference between the field and others. While previous research has shown that industry payments may affect provider practices [3, 4, 10, 18, 21, 30, 40] and patient perceptions of their physicians [32, 48], our study showed that substantial disparities in payments do exist among orthopaedic surgeons and that the median orthopaedic surgeon does not receive a large sum. The majority of total payments to orthopaedic surgeons are for royalties and licenses for intellectual property, which actually foster device innovations and are viewed more positively by patients and physicians [8]. While the increased transparency afforded by the Sunshine Act is enlightening, a cursory look at the raw data overstates the payments made

Table 1. Industry payments made to orthopaedic surgeons*

Type of industry payment to orthopaedic surgeons	Number of individual payments	Median payment (interquartile range), USD	Total payments, USD	%
Royalty or license	1922	5702 (1481–21,591)	74,700,000	69%
Consulting fees	3823	2000 (750–4800)	13,900,000	13%
Other nonconsulting services	1450	2000 (775–5200)	5,769,592	5%
Travel and lodging	13,981	171 (65–393)	5,307,289	5%
Food and beverage	53,431	23 (13–62)	2,401,952	2%
Faculty/speaker for CME	305	3600 (1500–9500)	1,812,143	2%
Ownership/investment interest	23	20,000 (2100–87,400)	1,601,756	1%
Education	3569	9 (2–196)	1,333,316	1%
Grant	130	2174 (1042–8803)	1,048,295	1%
Honoraria	98	1000 (1000–2250)	186,561	< 1%
Gift	306	32 (20–60)	20,882	< 1%
Charitable contribution	6	500 (475–1000)	12,891	< 1%
Entertainment	35	68 (28–125)	4660	< 1%

* In descending order of total amount; CME = Continuing Medical Education.

Table 2. Top 10 manufacturers or GPOs making payments to orthopaedic surgeons

Manufacturer or GPO	Total payments (USD)	Number of individual payments	Median individual payment (USD)
DePuy Synthes Sales Inc	33,000,000	10,744	38
Arthrex Inc	14,300,000	2497	375
Smith & Nephew Inc	9,801,744	5942	79
Biomet Inc	6,965,842	4607	81
Stryker Corporation	6,216,288	8658	49
Zimmer Holding Inc	5,538,171	4165	82
MAKO Surgical Corporation	4,367,827	1030	96
Wright Medical Technology Inc	3,523,279	1868	110
NuVasive Inc	3,021,099	2539	31
Medtronic Sofamor Danek Inc	2,167,673	1807	25

GPO = group purchasing organization.

to the average orthopaedic surgeon and also overlooks the types of financial relationships that may exist, some of which may be viewed as beneficial by patients.

Our study has limitations and the findings must be interpreted in light of them. As was seen with early release of Medicare Part B data [49], the initial Sunshine Act dataset has clear shortcomings [34, 42, 46]. Most notably, USD 2.3 billion in payments currently are deidentified in the Sunshine Act database owing to ongoing disputes of accuracy [46], however these mostly are research payments and were not analyzed in the current study of the CMS Sunshine Act general payments database only. As of the December 2014 data release, only USD 11,800,000 in general payments remain deidentified compared with the total USD 693,000,000 identified general payments.

Another limitation of the database is that only a small fraction of payments initially were reviewed for validity before publication. A complicated online vetting system was cited as a common difficulty for potential users [25]. Finally, the data presented in the 2014 data releases include only payments to physicians made during the final 5 months of 2013, failing to provide a full picture of annual payments to physicians or to account for seasonal variations in payments. Beginning in 2015, Sunshine Act data releases will contain full-year data and subsequent analyses of industry payments to physicians should use this to monitor annual trends.

Nevertheless, patients, practitioners, and policymakers will still draw conclusions using this initial release of data, and analysis of the trends seen is warranted. It is reasonable

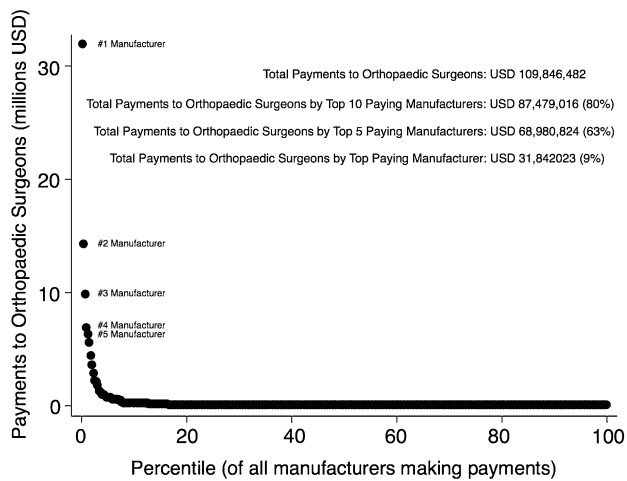


Fig. 5 The 10 highest-paying manufacturers accounted for 80% of payments to orthopaedic surgeons, while the five highest-paying manufacturers accounted for 63% of payments during August 2013 to December 2013.

to assume that the currently deidentified data will not substantially alter the trends currently seen and that orthopaedic surgeons will continue to maintain their hold on the highest total and per capita payments of any specialty once all currently deidentified payments are included. Since the initial release of Sunshine Act data in September 2014, the majority of the previously disputed general payments have been resolved and either were excluded from the database or identified and published in the December 2014 data release. The addition of these new payments did not substantially alter the position of orthopaedic surgeons as the top recipients of industry payments or the Gini index of disparity for the field (0.956 based on the September 2014 data release versus 0.959 based on the December 2014 data release). With only a small fraction of general payments remaining deidentified for the 2013 period, the conclusions drawn with our analysis are likely valid. These data also are a substantial improvement over previous state-mandated disclosures of industry payments. Previous industry disclosure data from Vermont had 61% of payments withheld as “trade secrets” and a remaining 75% of payments deidentified because of missing recipient data [45]. In Minnesota only 25% of required companies reported their payments to physicians [45]. Furthermore, the differences seen between medical specialties in the Sunshine Act data mirrors trends seen in more complete industry payment data obtained from the Massachusetts Department of Health and Human Services [28]. In addition, while a full year of payment data have yet to be released, the total of almost USD 110 million paid to orthopaedic surgeons during this 5-month period, while partially incomplete, is a substantial sum that might pose risks for conflicts of interest and warrants thorough characterization.

Although the total and per capita industry payment to orthopaedic surgeons has been reported to be high compared with other fields [15, 26, 44], the median industry payment of USD 121 is comparable to that of other surgical subspecialties and illustrates a different reality for the majority of orthopaedists receiving industry payments. In addition, orthopaedic surgeons have one of the highest Gini indexes of disparity at 0.959 compared with other fields, indicating substantially skewed payment data and the inadequacy of using the mean as an accurate measure of central tendency. Opinions regarding perceived inappropriate payments to orthopaedic surgeons should take into account this more in-depth analysis. Nevertheless, while the risk of conflicts of interest in the field of orthopaedic surgery may be lower than previously stated, it cannot be overlooked, as even small payments may influence provider practices [27]. Although the increase in transparency of industry payments has mostly highlighted the large sums paid to a minority of surgeons, additional study may be better focused on the effects of payments as low as USD 121 on surgeon practices, and whether better policies regarding receipt of even these payments may or may not be warranted.

When considering only the top recipients of industry payments, a clearer picture of disparity emerges. The top 10% of surgeons receiving payments account for 95% of the more than USD 109 million paid to the orthopaedic surgeons. Similar disparities in industry payments have been shown to a lesser extent in the field of otolaryngology, with the top 10% of surgeons receiving 86% of total industry payments to the field [44]. Nevertheless the total sums of payments are much greater in the field of orthopaedic surgery (USD 109 million vs USD 2.2 million). It remains to be seen who the top-payment recipients are compared with the average surgeon. One analysis of physicians receiving at least USD 100,000 from industry revealed that they were, on average, more active in research, however none of the reported industry funding was received for research purposes, but rather consulting or speaking fees [36]. These physicians also frequently underreported industry funds in disclosures for publications [7, 17, 36, 39]. It also was shown that top orthopaedic implant manufacturers have shifted physician payments to more published surgeons and those with academic affiliations [23]. Physicians involved in training medical students or developing clinical practice guidelines have been shown to be more likely to report receiving payments from industry [9]. This is consistent with previously described methods of targeting highly-regarded “thought leaders” in various fields as spokespersons for industry [35]. Whether research production and academic standing increases the likelihood of financial relations with industry remains to be seen. However, the larger effect of industry payments to

highly visible academic and research-active orthopaedic surgeons warrants further investigation.

The majority of industry payments to orthopaedic surgeons were found to be for royalties and patent licenses rather than for gifts or travel expenses. Previous studies of industry payments to physicians did not show substantial royalty payments, likely owing to either nonspecific data on payment types or incomplete dataset populations [10, 28, 45]. One previous study of payments by orthopaedic implant manufacturers noted that in 2008, 88% of the USD 124 million paid by Zimmer Inc, was for royalty buyouts [23]. These payments for intellectual property that physicians have had significant contributing roles in developing are undoubtedly important for continued innovation in our field, and are viewed favorably by patients and physicians alike [8]. One study suggested that physicians are a key contributor to medical device innovation, as physician-founded startups eventually contribute to more than double the number of FDA-approved devices produced by four incumbent device firms, compared with nonphysician founded startups [47]. Although there are concerns for clinical conflicts of interest [50], restriction of physician-device innovation may reduce innovation across the industry. After royalties, the second largest category of payments made to orthopaedic surgeons was for consulting fees. As opposed to industry payments for food, travel, or gifts, which are viewed negatively by patients [8, 32, 41], patients mostly support physicians serving as industry consultants [29]. However, concerns remain for conflicts of interest in this type of financial relationship, and further study of the larger influence of industry consultants is needed [24].

The effect of a select few device manufacturers on payments made to orthopaedics surgeons is of interest as well. The 10 highest-paying companies account for 80% of all payments. In light of the 2007 Department of Justice action against the “Big Five” orthopaedic joint implant manufacturers for financial kickbacks to surgeons, it is notable that the field is still dominated by a few select organizations maintaining financial relationships with physicians. Previous analysis of the early effects of the 2007 reforms showed an increase in total payments but a reduction in the number of orthopaedic surgeons receiving payments from the top five joint implant manufacturers, although conclusive results of the federal action could not yet be made [15]. Followup analysis of financial practices of these “Big Five” manufacturers and other top paying firms identified here is warranted to determine the effects of these reforms and the possible need for further policy changes to limit inappropriate financial relationships.

Although early Sunshine Act data showed that orthopaedic surgeons receive a large proportion of industry payments to physicians, our study showed that the median payment to orthopaedic surgeons is comparable to payments to other specialties and is much less than suggested by the

total industry payments to the field. Furthermore, the majority of payments to orthopaedic surgeons are for royalties and patent licenses, rather than gifts, food, or travel, which are more commonly viewed as sources of potential conflicts of interest. This shows that the true practices of the majority of orthopaedic surgeons may be difficult to interpret from a “bird’s eye view” of Sunshine Act data. Previous summary reports of the data, which may influence opinions of patients and policymakers, are largely skewed by the practices of select outliers in the field. Although complete transparency of financial relationships of physicians provided by the Sunshine Act is enlightening, these limitations make it difficult for identification of potential conflicts of interest in the field of orthopaedic surgery in general. However, there may be specific settings where this now-public resource may be highly beneficial. One potential positive use of these data is verification of individual physician disclosures to national meetings and publications [17]. Numerous studies have shown the inaccuracies of disclosures made in these academic, high-visibility settings [7, 17, 36, 39]. Another, perhaps more important, setting for disclosure is at the bedside. Prior focus group analysis revealed that whenever conflicts of interest may directly pertain to patient care, patients desire that they be discussed by the physician during treatment planning [37]. Ultimately, the true effects of disclosure of industry payment data are not yet known. Even with the median orthopaedic surgeon receiving only USD 121, further study of any effects of these payments on financial and clinical practices of physicians is needed.

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