A Closer Look at the Relationship Between Industry and Orthopaedic Sports Medicine Surgeons

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Background: A recent study demonstrated that discrepancies exist between disclosures reported by authors publishing in *The American Journal of Sports Medicine* and disclosures listed in the Physician Payments Sunshine Act–initiated Open Payments database, managed by the Centers for Medicare & Medicaid Services (CMS). However, no study to date has explored the relationship between the biopharmaceutical and device industry (industry) and the membership base of the American Orthopaedic Society for Sports Medicine (AOSSM).

Purpose: To critically examine the relationship between orthopaedic sports medicine surgeons and industry.

Study Design: Cross-sectional study.

Methods: The publicly available CMS Open Payments database website was accessed to search for sports medicine orthopaedic surgeons in the United States who were members of the AOSSM. Financial data, specifically general, research, and ownership payments for 2015, were recorded for each surgeon. The American Academy of Orthopaedic Surgeons (AAOS) disclosures of each surgeon were then obtained. Descriptive statistics and simple proportions were calculated to summarize the collected data, including years in practice and amount of payment. Median values for general payments were compared to provide a more accurate reflection of payments transferred to a "typical" sports medicine surgeon.

Results: A total of \$58,113,561 in general payments, \$3,996,051 in research payments, \$72,481,814 in money invested, and \$144,552,383 in interest earned from money invested were identified as being paid to 2274 surgeons (all amounts in US\$). The distribution of total general payments received was skewed: 10% of surgeons received 95.4% (\$55,463,183) of the total general payments. A total of 1433 surgeons had completed, up-to-date AAOS disclosures. Although 44% (635 surgeons) self-reported no financial conflict to the AAOS, the Open Payments database indicated some level of industry support to these surgeons. Unreported general payments totaled \$1,393,212, or a median of \$561 per surgeon (interquartile range, \$10-\$200,048).

Conclusion: Although orthopaedic sports medicine surgeons received substantial payments from industry, most of the total general payments were given to a small proportion of people. The regional distribution of these payments did not differ significantly. Summary reports of data are largely skewed by outliers and should be interpreted with caution. However, a large percentage of these surgeons failed to reveal industry support of any kind in their AAOS disclosures, including meals and educational funding, demonstrating the importance of transparency and accuracy when completing financial disclosures.

Keywords: Sunshine Act; sports medicine; industry; AOSSM

The relationship between physicians and the biopharmaceutical and device industry (industry) has received considerable attention over the past several years. A recent national survey demonstrated that 94% of physician respondents across all specialties reported some form of industry relationship. However, industry relationships have the potential to hinder clinical decision making and

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increase health care costs. ^{1-3,6,7} In 2010, the Physician Payments Sunshine Act (PPSA) was enacted to regulate and provide a transparent avenue for reporting these physician-industry relationships. The PPSA mandates that all pharmaceutical and device companies annually report financial payments made to physicians and teaching hospitals. As part of the PPSA, all physicians are required to report their financial relationships each year. This includes reporting even minor payments for meals, educational funding for textbooks, or attendance to continuing medical education events. These reports are publicly available online.

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Orthopaedic surgeons are offered the unique opportunity to work closely with industry to advance current technology and improve patient outcomes. A corollary of this opportunity is demonstrated by a recent study showing that orthopaedic surgeons, when compared with other specialists, accounted for 44.6% of payments equaling >\$10,000 and 61.5% of payments equaling >\$100,000.9 Another study demonstrated that payments provided to orthopaedic surgeons were greater than to other surgical subspecialties. The American Orthopaedic Association, with support from the Orthopaedic Institute of Medicine, recently created a task force to explore the relationship between industry and orthopaedic surgeons. It recognized that the skills and expertise of orthopaedic surgeons can bolster the advancement of implant technology and improve patient care. Within its report, the task force produced 16 recommendations to protect the integrity of the profession, prevent gratuitous relationships, and ensure that patient care is not hindered by this relationship.¹

Although some of these studies delve into various orthopaedic subspecialties, such as trauma, arthroplasty, and spine, there is a paucity of research on the relationship between industry and the orthopaedic sports medicine subspecialty. Therefore, the purpose of this study was to critically examine the relationship between orthopaedic sports medicine surgeons and industry using the online Open Payments database. We sought to (1) report the total payments to orthopaedic sports medicine surgeons, (2) assess what percentage of total payments are made to surgeons receiving the largest industry payments, (3) compare geographic/ regional differences in the distribution of payments made to surgeons, (4) look for a correlation between the duration of practice and amount of payment, and (5) compare the disclosures in the Open Payments database with the disclosures that surgeons self-reported through the American Academy of Orthopaedic Surgeons (AAOS) website. Our null hypothesis was that an equal distribution of payments would be made among surgeons. We also hypothesized that a normal distribution of payments would be made between the various geographic/regional areas, that the duration of practice would not influence the amount of payments, and that surgeon-reported disclosures would match those in the Open Payments database.

METHODS

The publicly available, PPSA-initiated Open Payments database (https://openpaymentsdata.cms.gov/search),

which is federally mandated and supported, reports financial relationships between physicians and applicable manufacturers. The drug or device manufacturers or group-purchasing organizations report payment data directly to the US Centers for Medicare and Medicaid Services. After a 45-day dispute period, the data and physician identifiers are made public via the Open Payments database. Available information includes general payments, research payments, and ownership. General payments include food/beverage, travel/lodging, consulting fees, royalties for physician-invented medical devices, education, and speaking services. Research payments include indirect or direct payments for research endeavors, and ownership includes ownership or investments in a device or pharmaceutical company.

We accessed the website during the last week of December 2016 to search for sports medicine orthopaedic surgeons. The list of orthopaedic surgeons was generated through the American Orthopaedic Society for Sports Medicine's (AOSSM) membership directory. Full-time surgeons who are active AOSSM members were chosen as an appropriate population because they demonstrate a continuing interest in sports medicine. Many also are pioneers in the field and are responsible for advancing procedures and instruments. Surgeons from outside the United States were excluded because the Open Payments database does not include their information. In the Open Payments database, the geographic location and specialty search functions were used to accurately identify data for surgeons with common names.

Financial data, specifically general payments, ownership, and research funding for the calendar year of 2015, were recorded for each surgeon. Additionally, the number of disputed payments was tallied. Using the duration of AOSSM membership as a surrogate for the number of years in practice, the correlation between the duration of practice and the payment amount was analyzed. A regional comparison of industry payments to surgeons was also conducted. We categorized the states into 8 regions (New England, Mideast, Great Lakes, Plains, Southeast, Southwest, Rocky Mountains, and Far West), as defined by the Bureau of Economic Analysis (BEA) for the comparison of economic data (Figure 1).14 The total payments, proportion of surgeons receiving payments, and median payments were compared between regions. Each surgeon's information stored in the AAOS Orthopaedic Disclosure Program online database (http://www7.aaos .org/education/disclosure/search.aspx) was then accessed and compared with the reported payments from the Open Payments database.

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Ethical approval was not sought for the present study.

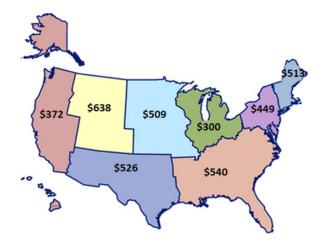


Figure 1. Median general industry payment to surgeon by US Bureau of Economic Analysis region. The median general payment per surgeon was lowest in the Great Lakes region (US\$300) and highest in the Rocky Mountains region (US\$638). There was no statistical difference between the regions in payments received by surgeons (P = .13). Data obtained from the Open Payments database.

Statistical Analysis

Descriptive statistics and simple proportions were calculated to summarize the collected data, including years in practice and amount of payment. Median values were compared to provide a more accurate reflection of general payments transferred to a "typical" sports medicine surgeon.^{9,13} To measure statistical dispersion, the Gini index was calculated for payments transferred to all people. A Gini index of 1.0 indicates complete inequality (ie, a single person possesses 100% of wealth), whereas an index of 0 indicates a completely equal payment to everyone. 12 Sample characteristics were described using descriptive statistics. Frequencies and percentages were used to describe categorical variables. Means and standard deviations (or medians and ranges where appropriate) were used to describe continuous variables. The chi-square test (or Fisher exact test when low counts were present) was used to test for associations in comparisons of 2 categorical variables. The Wilcoxon rank-sum test was used to test for differences in continuous variables between 2 groups. The Kruskal-Wallis test was used to test for differences in continuous variables between >3 groups. Results were considered statistically significant at P < .05. All statistical analyses were performed using GraphPad (version 5.01; GraphPad Software).

RESULTS

A total of 2312 sports medicine surgeons were identified on the AOSSM website. Of these, 2274 surgeons were identified as being from the United States. Over the study period, \$58,113,561 in general payments were made (all amounts in US\$). The median total industry payment amount to surgeons was \$460 (interquartile range, \$114-\$2301).

TABLE 1 Frequency of Industry Payments to Surgeons^a

Total Value, US\$	Surgeons, n (%)	
Nothing reported	110 (4.8)	
≤10,000	1906 (83.8)	
>10,000 to <100,000	202 (8.9)	
>100,000 to <500,000	43 (1.9)	
>500,000	13 (0.6)	

 $^a\mathrm{Data}$ obtained from the Open Payments database. Only 10% of surgeons received 95.4% of total payments, while 5% accounted for 90.5% of the overall value.

Because of outliers, the mean payment amount (\$25,556) was almost 56-fold greater than the median value. The distribution of total payments received was skewed because 10% of surgeons received 95.4% (\$55,463,183) of the total general payments. Only 5% accounted for 90.5% (\$52,583,634) of the overall value (Table 1). A single surgeon who received \$19,421,951 was a significant outlier, making up approximately one-third of the total combined payments of all surgeons. A small proportion of surgeons (4.8%) did not receive any payment. The Gini index for industry payments was 0.962.

Any form of payment a surgeon receives from industry, even a meal or funding for educational expenses, should be disclosed as a potential conflict of interest. A total of 1433 surgeons had completed, up-to-date AAOS disclosures, while the other 841 surgeons did not have completed disclosures. Of the 1433 surgeons, 635 (44%) had documented industry support in the Open Payments database, but they self-reported no financial conflict to the AAOS. Unreported general payments totaled \$1,393,212, or a median of \$561 per surgeon (interquartile range, \$10-\$200,048). The Wilcoxon rank-sum test was used to assess the difference in the total general payments between surgeons with disclosed and nondisclosed payments; a significant difference was detected (P < .0001) (Table 2).

Over the study period, \$3,996,051 in research payments was made to 2274 surgeons. The mean research payment amount to surgeons was \$1637 (range, \$0-\$341,475). There was a significant difference in total research payments between surgeons with disclosed and nondisclosed payments (P < .0001) (Table 3). The total amount of money invested by sports medicine surgeons was \$72,481,814, with a mean total amount invested of \$1429 (range, \$0-\$600,018). The total value of interest with regard to money invested was \$144,552,383, with a mean total value of interest of \$2381 (range, \$0-772,893). The total value of interest payments between surgeons with disclosed and nondisclosed payments was significantly different (P = .001) (Table 4).

Industry Payments by Region

When comparing the BEA regions (Figure 1), the median general payment per surgeon was lowest in the Great Lakes (\$300) and highest in the Rocky Mountains (\$638). When looking at the total distribution of general payments

 ${\it TABLE~2} \\ {\it Difference~in~General~Payments~Between~Surgeons~With~Disclosed~and~Nondisclosed~Payments}^a$

Conflict of Interest	No. of Surgeons	Median (Interquartile Range), US\$	Mean ± SD (Range), US\$
Nondisclosed	635	441 (116-1701)	$2194 \pm 11,\!217 \; (0\text{-}200,\!047) \\ 41,\!348 \pm 294,\!501 \; (0\text{-}6,\!475,\!336)$
Disclosed	798	1782 (260-11,689)	

^aData obtained from the Open Payments database. There was a significant difference in total general payments between surgeons with disclosed conflicts of interest on the American Academy of Orthopaedic Surgeons website and those with no disclosures reported (P < .0001).

Conflict of Interest	No. of Surgeons	Mean \pm SD (Range), US\$
Nondisclosed Disclosed	635 798	$218 \pm 4297 \ (0\text{-}106,500) \\ 4140 \pm 21,311 \ (0\text{-}341,475)$

^aData obtained from the Open Payments database. There was a significant difference in total research payments between surgeons with disclosed conflicts of interest on the American Academy of Orthopaedic Surgeons website and those with no disclosures reported (P < .0001).

Conflict of Interest	No. of Surgeons	Mean ± SD (Range), US\$	
Nondisclosed Disclosed	635 798	$946 \pm 19,141 \ (0-472,273) \ 4164 \pm 42,215 \ (0-772,893)$	

^aData obtained from the Open Payments database. There was a significant difference in the total value of interest payments between surgeons with disclosed conflicts of interest on the American Academy of Orthopaedic Surgeons website and those with no disclosures reported (P=.001).

according to regions, the Southwest had the highest (\$21,101,802). There was no statistical difference detected in total general payments between regions (P = .13).

When comparing the BEA regions, the mean research payment per surgeon was lowest in the Southwest (\$928) and highest in the Rocky Mountains (\$3323). The Kruskal-Wallis test was used to assess the difference in the total research payments between regions; a significant difference was not detected (P=.52). The mean total value invested was lowest in the Southwest (\$0) and highest in New England (\$3544). There was no statistical difference in the total value invested between regions (P=.09). The mean total value of interest was lowest in the Southwest (\$0) and highest in New England (\$5535), which was not statistically different (P=.14).

Correlation With Years in Practice

The Wilcoxon rank-sum test was used to assess the difference in the years of practice between disclosed and

 ${\it TABLE~5} \\ {\it Industry~General~Payments~According~to~Years~in~Practice}^a \\$

Years in $Practice^{b}$	No. of Surgeons	Mean (Range), US\$	Median (Interquartile Range), US\$
1-10	1118	5301 (0-383,134)	653 (156-2431)
11-20	813	25,292 (0-6,475,336)	384 (102-2337)
21-30	235	40,651 (0-4,279,584)	291 (56-1720)
31-41	108	206,508 (0-19,421,951)	136 (24-522)

^aData obtained from the Open Payments database. Although the mean industry general payment received increased with each additional decade in practice, the median general payment received decreased every decade.

 b The duration of American Orthopaedic Society for Sports Medicine membership was used as a surrogate for the number of years in practice.

nondisclosed surgeons; a significant difference was detected (P < .0001). Although the mean industry payment increased with each additional decade in practice, in contrast, the median general payment decreased every decade (Table 5).

Disputed and Undisputed Payments

There was 1 disputed payment recorded, by a surgeon who had reported no disclosures on the AAOS website. There were 28,386 total undisputed payments. The median number of undisputed payments for surgeons who reported no disclosures on the AAOS website was 6 (interquartile range, 0-118), while the median for surgeons who reported disclosures on the AAOS website was 11 (interquartile range, 0-176).

DISCUSSION

The results of this study demonstrate a wide variation in industry payments to orthopaedic sports medicine surgeons. Although sports medicine surgeons received large sums of payments from industry (\$58,113,561), only a small proportion of these surgeons received most of the payments. Although the funding distribution between regions did not differ significantly, the median general payment per surgeon and mean research payment per surgeon were greatest in the Rocky Mountains, while the mean value of investments and value of interest per surgeon were

greatest in New England. The mean value of general payments to surgeons increased with each decade of practice. Additionally, 44% of surgeons self-reported no financial conflict to the AAOS, while the Open Payments database indicated industry support of some capacity.

A strong majority of the public is either supportive of or neutral toward industry financial support of surgeons when they perceive that such support is likely to benefit care. One study surveyed patients after they underwent arthroplasty and found that only 6% were worried about their surgeons' possible financial relationships, while 69% believed that it was appropriate for surgeons to receive royalties for inventions as long as the devices benefited patients. However, most of these patients believed that it was inappropriate for surgeons to receive gifts, highlighting the complexity of the surgeon-industry relationship. Therefore, this relationship must remain transparent, with a full commitment to patient care and altruism.

Despite much attention and research devoted to their negative aspects, surgeon-industry relationships can serve an important positive role in physician development and patient care. Industry provides educational support at the level of residency and fellowship and sponsors professional meetings for practicing surgeons. Technological advancements of devices have revolutionized the orthopaedic field and improved patient outcomes. Orthopaedic surgeons are a key component of this advancement, as they improve and optimize the technology through surgical experience and promote the products to their patients and peers. Finally, surgeons who develop products that positively change practice and patient care should be incentivized fairly. Without such a relationship, technological advancement could falter and ultimately affect future patient care.

An important element of this relationship is consistent and honest reporting by the physician. Before the formation of the PPSA, a study published in The New England Journal of Medicine critically examined the financial disclosures reported by industry manufacturers for arthroplasty surgeons attending the 2008 AAOS Annual Meeting. This study found a disclosure rate of 79% for directly related payments and 50% for indirectly related payments. 11 Even after the passage of the PPSA, 1 study demonstrated a 35% rate of inconsistency when disclosures from presenters at the 2014 AAOS National Meeting were compared with the Open Payments database.8 Studies also have demonstrated variability between surgeon-reported disclosures and industryreported payments in the spine and trauma subspecialties.^{3,15} A recent study demonstrated that 82.9% of authors publishing in The American Journal of Sports Medicine had discrepancies between disclosures that they self-reported to the journal and industry-reported disclosures found in the Open Payments database. In addition, 25.3% of the authors had inconsistencies between disclosures found in the AAOS and Open Payments databases.2 Along with consistent, honest reporting, surgeons must self-regulate their actions and focus on improving patient care and outcomes. The task force created by the American Orthopaedic Association produced recommendations to maximize these surgeonindustry relationships while ensuring improved patient care. However, it ultimately is the responsibility of orthopaedic surgeons to self-report and self-regulate their industry relationships while they maintain their ethical duty to serve patients. This includes reporting all forms of industry support, including meals, educational funding, and reimbursement for attendance to continuing medical education events. An alternative solution to this may be requiring the AAOS website to prompt members to verify their payments on the Open Payments database before completing the form.

Honest reporting should also apply to editorial board members and clinical practice guideline contributors. A recent study demonstrated that 78% of editorial board members of various orthopaedic surgery journals receive industry support. 10 The editors of top orthopaedic journals can influence the content of their journals and inadvertently induce bias into the current literature by publishing (or rejecting) articles that contain data on device performance and outcomes. That bias can extend to patient care because many surgeons use a literature-based treatment approach. Another recently published study indicated that contributors to the AAOS clinical practice guidelines received a mean of \$93,000 per person in industry payments and that many of their disclosure statements did not match the financial payments reported in the Open Payments database. 6 The authors stated that their findings could negatively affect patient care because these people recommend appropriate-use criteria and clinical practice guidelines that many surgeons implement in their practices.⁶

Limitations

This study has several limitations. Despite PPSA-initiated regulations, inconsistencies between physician-reported and industry-reported disclosures remain prevalent. Because it is a cumbersome endeavor for most surgeons, each financial disclosure in the database might not be verified in all cases. As a result, there are limitations to the accuracy of the Open Payments database. A recent study demonstrated that of surgeons who reported disclosures and attended the 2014 AAOS Annual Meeting, 11% were not included in the Open Payments database, and 23% had ≥1 disclosures either improperly categorized or not included in the database.8 A second limitation is that our study sample consisted only of those sports medicine surgeons registered through the AOSSM, which may not account for all practicing sports medicine surgeons. Moreover, this study utilized duration of AOSSM membership for years in practice, which may not accurately depict the duration of an individual surgeon's time in practice. Additionally, the specifics of each physician-industry relationship were not studied, including types of payments and the appropriateness of the relationships.

CONCLUSION

Although orthopaedic sports medicine surgeons received substantial payments from industry, most of the payments were given to a small proportion of people. No significant differences existed in the regional distribution of these payments. Summary reports of data are largely skewed by outliers and should be interpreted with caution. However, a large percentage of surgeons failed to disclose industry support of any kind to the AAOS, including minor support such as meals and educational funding, demonstrating the importance of transparency and accuracy when completing financial disclosures.

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