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Association of Compensation From the Surgical and Medical Device Industry to Physicians and Self-declared Conflict of Interest

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IMPORTANCE Surgical and medical device manufacturers have a cooperative relationship with clinicians. When evaluating published works, one should assess the integrity and academic credentials of the authors, who serve as putative experts. A relationship with a relevant manufacturer may increase the potential risk for bias in relevant studies.

OBJECTIVE To characterize the association of industrial payments by device manufacturers, self-declared conflict of interest (COI), and relevance of publications among physicians receiving the highest compensation.

DESIGN, SETTING, AND PARTICIPANTS This population-based bibliometric analysis identified 10 surgical and medical device manufacturing companies and the 10 physicians receiving the highest compensation from each company using the 2015 Open Payments Database (OPD) general payments data. For each of the 100 physicians, the total amount of general payments, number of payments, institution type, and academic rank were recorded. Royalty or license payments were excluded. A search of PubMed identified articles published by each physician from January 1 through December 31, 2016, and their associated COI declaration. Scopus was used to identify bibliometric data reported as the h index (number of papers by a researcher with at least h citations each). **MAIN OUTCOMES AND MEASURES** Discrepancy between self-declared COI and industry payments.

RESULTS The 100 physicians included in the sample population (88%men) were paid a total of \$12 446 969, with a median payment of \$95 993. Fifty physicians (50.0%) were faculty at academic institutions. The mean (SD) h index was 18 (18; range, 0-75) for the authors. In 2016, 412 articles were published by these physicians, with a mean (SD) of 4 (6) publications (range, 0-25) and median of 1 (36 physicians had no publications). Of these articles, 225 (54.6%) were relevant to the general payments received by the authors. Only in 84 of the 225 relevant publications (37.3%) was the potential COI declared by the authors.

CONCLUSIONS AND RELEVANCE A high level of inconsistency was found between self-declared COI and the OPD among the physicians receiving the highest industry payments. Therefore, a policy of full disclosure for all publications, regardless of relevance, is proposed. No statistically significant association was demonstrated between academic rank or productivity and industrial payments.

Key Points

Question What is the association between the physicians receiving the top compensation from surgical and/or medical device manufacturers and their academic affiliation, expertise, and disclosure of conflicts of interest?

Findings A bibliometric analysis of the 100 physicians receiving the highest compensation from 10 large surgical and medical device manufacturers used payment information from the Centers for Medicare & Medicaid Services Open Payments Database. Conflicts of interest were declared by the authors in only 84 of 225 of the relevant 2016 publications (37.3%).

Meaning A large discrepancy between self-declared conflict of interest and the Open Payments Data among the physicians receiving the highest compensation from surgical and medical device manufacturers needs to be addressed.

Substantial financial ties between health care professionals and the pharmaceutical and medical device industry are common. Device manufacturers have a symbiotic relationship with clinicians. Compensation is often appropriate for the work and intellectual capital provided to the companies and can be an important source of revenue for a clinician or an investigator. Moreover, many academic institutions have restrictions and/or reporting requirements with regard to compensation for consulting and speaking owing to concerns about conflict of interest (COI) and/or reputation.

When evaluating published works, it is important to assess the integrity and academic credentials of the authors, who serve as putative experts. Are lationship with a relevant manufacturer may increase the potential risk forbias in relevant studies. Research has shown that as many as 94% of physicians in the United States receive a form of benefit from an external company, with food and beverage being the most common. Financial ties to industry can result in a COI in the research authored by physicians. A COI can potentially lead to favorable outcomes in reporting and prejudice study reports. Inaccurate COI statements can result in biased perception of the study results by readers, ranging from patients to health care professionals.

The International Committee of Medical Journal Editors (ICMJE) requires all authors to disclose any potential COI that is directly or indirectly related to the publication ormay be perceived as relevant by the readers during the 3 years before ubmission.² However, before the SunshineAct3 came into effect in 2010, no reliable source was available to validate the credibility and accuracy of COI statements. In 2010, the government mandated reporting of any and all payments made to physicians through surgical and medical device, pharmaceutical, and technology companies. In 2013, the Centers for Medicare & Medicaid Services established the Open Payments Database (OPD) to house this information and increase transparency into the reporting of payments. The intended effect was to allow access to scrutinize potential COIs.³

The present study was undertaken to assess the credibility and accuracy of COI statements in articles published by the physicians receiving the top compensation and to evaluate the discrepancy between these reports and the industrial supports reported to the

Centers for Medicare & Medicaid Services. We also sought to evaluate the relevance of publications to payments received by these physicians.

Methods

We extracted the data from the 2015 OPD general payments regarding 10large surgical and medical device companies. Each year, payment information is released by the Centers for Medicare & Medicaid Services in the following 3 categories: general payments, research payments, and ownership or investment interests. General payments include food and beverage, consulting fees, nonpublicly traded ownership interests, honoraria, gifts, travel and lodging, entertainment, royalty or license, compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program, compensation for serving as faculty or as a speaker for an accredited or certified continuing education program, and education.3 Institutional review board approval was deemed unnecessary and the need for informed consent was waived for the use of publicly available data.

Sample Selection

The companies sampled included Medtronic, Inc, Stryker Corporation, Intuitive Surgical Inc, Covidien Ltd, Edwards Lifesciences Corporation, Ethicon, Inc, Olympus Corporation, W. L. Gore & Associates Inc, LifeCell Corporation, and Baxter Healthcare. The search tool on the Centers for Medicare & Medicaid Services OPD website (https://openpaymentsdata.cms.gov) was used to search each company. We extracted the 10 physicians receiving the highest compensation from each company, regardless of their specialty. All subdivisions of the companies were considered in the process of selecting the physicians. Royalty or license payments were excluded, and data were collected accordingly. For each of the 100physicians, the total amount of general payments, number of payments, institution type, and academic rank were recorded.

Publication Selection

We searched PubMed using each physician's first and last name. If the search was inconclusive, we used the physician's middle name and affiliated institution. We recorded the total number of publications, the number of articles published from January 1 through December 31, 2016, the presence or absence of financial funding disclosure, and the relevance of the 2016 publications to the financial funding made by the associate company in 2015. The full text of each article was reviewed for COI disclosure. We examined 2016 studies to ensure that the payments preceded the publication of the article. If the electronic version of the article (i.e., published online ahead of print) was available sooner than the print version, the date of the electronic article release was considered. In our sample group, 36 physicians had no publications in 2016andwere excluded from the COI analysis (eFigure in the Supplement).

To establish the relevance of publications to the payments, the ICMJE guidelines were used. The ICMJE suggests that "interactions with ANY entity that could be considered broadly relevant to the work" should be disclosed. ^{2(p1)} Fontanarosa andBauchner⁴ further clarified these guidelines, suggesting that disclosures are not limited to the specific products, devices, tests, and services mentioned in a manuscript, and that all relationships with products, devices, tests, and services used in management of a condition are considered relevant and should be disclosed. Based on these guidelines, we considered any equipment made by a surgical or medical device manufacturer that was directly or indirectly used, tested, investigated, or discussed in an article as relevant to the payments received by the author.

An attempt was made to extract the data using Google Scholar and ResearchGate. However, owing to the reporting nature of these websites, we could not have a clean and accurate data set of all publications.

Bibliometric Data

The Scopus scholarly database (https://www.scopus.com) was used to determine bibliometric data, specifically the h index, for each physician. The h index is defined as "the number of papers (Np) that have at least h citations each and the other (Np - h) papers that have no more than h citations each." We used these data to further evaluate the association among Industrial payments, scholarly influence, and COI in our sample group.

Outcome Assessment

All 100 physicians were considered to have potential COIs owing to the payments received from the mentioned companies. Next, we processed each 2016 article published by these physicians for declaration of the financial ties with the associated company and relevance of their research to the payments received by surgical and medical device companies.

We considered that a discrepancy existed between self-declared COI and the actual potential COI when an author received any payments (regardless of the value or the nature of the payments) that directly or indirectly relevant to the 2016 publications and did not declare all the financial ties with the device companies. For example, a vascular surgeon is listed in the 10 highest-paid physicians by Medtronic, Inc. He also has a financial relationship with W. L. Gore & Associates, Inc. He recently published an article evaluating the Gore endoprosthesis in the repair of aortic arch aneurysms. The ICMJE guidelines require that this surgeon not only declare his financial ties with W.L.Gore & Associates, Inc, but also Medtronic, Inc, because these financial ties can indirectly result in a bias in the study. However, if this physician only declares his financial ties with W. L. Gore & Associates, Inc, we consider that the potential COI has not been fully declared and that discrepancy between the self-declared COI and the actual potential COI exists.

Statistical Analysis

We used SPSS software (version 22;IBM Corporation)and Excel (version 15.21.1; Microsoft Corp) for data analysis. We used paired and independent t tests, depending on the variables, to determine the differences in mean values for 2 groups and the $\tau 2$ test for comparison of proportions between groups. We used analysis of variance for comparison of the means of 3 or more groups.

Results

In 2015, 570524 payments with the total value of \$326 863 647 were made to 139 087 physicians by the 10 large surgical and medical device companies analyzed in this study. Of these, a total of \$12 446 969 was paid to the 100 physicians with the highest compensation included in the sample population (88 men [88%] and 12 women [12%]), with a median payment of \$95 993. This median payment constitutes 3.81% of the total payments made to physicians by these 10 large surgical and medical device companies. Our sample group received a significantly higher mean amount per payment compared with physicians receiving at least 1 payment from these companies (\$1303 vs \$414.60; 95%CI, \$526-\$1251; P < .001). None of the physicians made the top 10 list for more than 1 company among the companies evaluated. Among these companies, Medtronic, Inc, paid the highest amount to physicians, accounting for 263 372 total general payments with the total value of \$187 446 742.81 and a mean value of \$711.72 per payment. Stryker Corporation paid the next highest amount (mean value, \$693.46per payment), followed by Intuitive Surgical Inc (mean value, \$422.46 per payment) (Table 1).

Table 1. Overview of Payments by the 10 Large Surgical and Medical Device Companies

Company Name	Total General Payments, \$	Total No. of Payments	Mean Value per Payment, \$
Medtronic, Inc ^a	187446742.81	263 372	711.72
Stryker Corporation	61956818.91	89 344	693.46
Intuitive Surgical, Inc	25643934.77	60 701	422.46
Covidien, Ltd ^b	13505546.92	29 158	463.18
Edwards Lifesciences Corporation	9430247.10	29 097	324.10
Ethicon, Inc ^c	7677437.86	25 763	298.00
Olympus Corporation ^d	6407590.06	13 044	491.23
W. L. Gore & Associates, Inc	6313408.24	27 732	227.66
LifeCell Corporation	5565706.02	19817	280.86
Baxter Healthcare	2916215.08	12 496	233.37

^a Includes Medtronic Minimed, Neurovascular, Medtronic Sofamor Danek USA, Inc, Medtronic Vascular, Inc, and Medtronic Xomed, Inc.

^b Includes Covidien Caribbean, Inc, Covidien LP, and Covidien Sales, LLC.

^c Includes Ethicon Endo-Surgery, Inc, and Ethicon US, LLC.

^d Includes Olympus America, Inc, Olympus Corporation of the Americas, Olympus Medical System Corporation, Olympus Latin America, Inc, and Olympus Winter & Ibe GmbH.

Among the 100 highest-paid physicians, Stryker had the highest contribution at \$2 517 043, followed by Intuitive Surgical Inc, at \$1 987 156 and LifeCell Corporation at \$1 914 215 (Table 2).

Table 2. Overview of Payments to the Top 100 Highest-Paid Physicians

Company Name	Total General Payments, \$	Total No. of Payments	Mean Value per Payment, \$
Stryker Corporation	2 517 043	1686	1492.91
Intuitive Surgical, Inc	1 987 156	2174	914.06
LifeCell Corporation	1914215	1487	1287.30
Medtronic, Inc	1 453 451	1145	1269.39
W. L. Gore & Associates, Inc	1 224 707	517	2368.87
Ethicon, Inc	859 050	632	1359.25
Edwards Lifesciences Corporation	835 016	816	1023.30
Covidien, Ltd	677 704	862	786.20
Olympus Corporation	608 479	503	1209.70
Baxter Healthcare	370 147	280	1321.96

After a comprehensive search of PubMed and Scopus, we identified a total of 7362 articles published by the 100 physicians, with a mean (SD) of 73 (95) publications (range, 0-431) and a median of 37. In 2016, 412 articles were published by these physicians with a mean (SD) of 4 (6) publications (range, 0-25) and a median of 1. Of the 2016 articles, 225 (54.5%) were relevant to the general payments received by the authors, for a mean (SD) of 2 (3) publications (range, 0-14) and a median of 1. However, the COI was declared by the authors in only 84 of the 225 relevant publications (37.3%). The mean (SD) for COI declaration by authors in association with their relevant publications in 2016 was 41.1% (37.9%) (Table 3). At the author level, of the 64 authors with publications in 2016, 55 (85.9%) had at least 1 publication without declaring the associated COI.

Table 3. Publications by the 100 Physicians Receiving Top Payments

Publication Information	All Publications	Mean (SD)	Median (Range)
All	7362	73 (95)	37 (0-431)
All 2016	412	4 (5.54)	1 (0-25)
All 2016 relevant	225	2 (3.13)	1 (0-14)
COI declaration for relevant publications, No. (%)	84 (37.3)	41.1%(37.89%)	NA (0%-100%)

Abbreviations: COI, conflict of interest; NA, not applicable.

Of the 100 physicians, 50 (50.0%) were faculty at academic institutions. No statistically significant difference for the COI declarations was found between academic faculty vs community physicians (mean, 34.8%vs 31.6%; 95%CI, – 14.41% to 20.95%; P = .71). Of these 50 physicians, 27 (54.0%) were professors, 8 were associate professors (16.0%), and 15 were assistant professors (30.0%). The mean payments for associate

professors was \$156 615, followed by \$124 680 for professors and \$109 769 for assistant professors. We found no statistically significant association between academic rank and the payments in our sample group.

The mean (SD) h index for the authors was 18 (18; range, 0-75), with a median of 11. To evaluate the association among the h index, declaration of COI, and industry payments, we divided our sample into 2 groups based on the median h index, including one group with an h index of less than 11 and another with an h index of at least 11. We found no significant difference between the 2 groups on declaration of COI (0.40 vs 0.30; 95% CI, -0.65 to 0.85; P = .77). We also found no statistically significant association between high h index and payments from surgical and medical device companies (\$113 296 vs \$201 565; 95% CI, -\$198 732 to \$22 194; P = .11).

Of the 100 physicians, obstetricians and gynecologists (n = 15) constituted the highest frequency. This specialty was followed by anesthesiologists (n = 9), general surgeons (n = 8), and orthopedic surgeons (n = 8) (Table 4). We found no association between physician specialty and COI declaration (P = .18).

Table 4. Distribution of Specialties Among the Highest-Compensated Physicians

Specialty	Frequency, No. of Authors
Emergency medicine	1
IM/critical care	1
IM/endocrinology, diabetes, and metabolism	1
IM/nephrology	1
Pathology	1
Psychiatry and neurology	1
Diagnostic radiology	1
Critical care surgery	2
Surgical oncology	2
Allergy and immunology	3
IM/pulmonary disease	3
Interventional radiology	3
Neurologic surgery	3
Colorectal surgery	4
IM/cardiovascular disease	4
Pediatrics	4
Vascular surgery	4
Bariatric surgery	5
IM/gastroenterology	5
Cardiothoracic surgery	5
Plastic surgery	6
General surgery	8
Orthopedic surgery	8
Anesthesiology	9
Obstetrics and gynecology	15

Abbreviation: IM, internal medicine.

Discussion

This study is the first, to our knowledge, of the physician industry relationship to evaluate the highest-compensated physicians across specialties. Our study design allowed for a large sample size with more than 400 articles. Our study showed that among the physicians receiving the highest compensation, no statistically significant association existed between scholarly influence and payments. Of the 225 relevant articles, the COI with the surgical or medical company was declared in only 37.3%. Fifty-five of the 64 authors (85.9%) had at least 1 publication without declaring the associated COI. This high rate of discordance raises concern regarding the accuracy and credibility of self-declared COI.

In a recent review, Patel et al⁶ examined 458 robotics studies published in 2015 and assessed the accuracy of self-declared COI statements in the studies using the 2013 and 2014 OPD. These authors found discrepancy between industry payments by Intuitive Surgical Inc, and COI statements in 240 cases (52.4%). Of the 303 studies in which at least 1 author received a general payment from Intuitive Surgical Inc, only 63 (20.8%) declared the payments in the COI statement. In another study by Cherla et al,⁷ 500 publications were analyzed from January 2014 through June 2016. They reported 65%discordance between the OPD and self-disclosed COI (P < .001). Our study findings are in line with the findings of these articles and the fact that a very high discordance exists between the OPD and self-declared COI.

During recent years, the h index has been proposed as a better measure of scholarly influence compared with the number of publications and total number of citations. Significantly included in industrial contributions have higher h indices compared with otolaryngologists receiving less than \$1000 (h index, 17.8 vs 10.9; P < .001). They also found that mean payments and the proportion of academic otolaryngologists receiving more than \$1000 in payments significantly increased with higher academic rank (P < .05). We found no difference in h indices when we compared payments by the 10 large surgical and medical device companies studied and self-declared COI. Our study also showed no statistically significant association between academic rank and payments.

The high discordance between COI disclosure and the OPD observed in our assessment and other similar studies may be the result of several factors. One major factor is the difference in policies of different journals, meetings, and institutions on COI disclosure. These policies can be overwhelming and puzzling for authors. Another factor to consider is the authors' perception of relevance of COI in a study. Some industrial payments might not be perceived as relevant to the reporting author, whereas in reality they are indirectly associated with the study. We agree with Olavarria et al10 that the first step toward achieving full transparency should be standardizing the COI disclosure process among different journals, meetings, and institutions. We further agree that to avoid authors' errors on reporting relevant COI, authors should disclose all of their financial ties, and an unbiased third party should decide on relevance of the disclosures.

Access to COI statements in a study abstract rather than only the full text can move us 1 step closer to full transparency. Access to the full article text is sometimes difficult and costly, especially for the general population. In a letter on March 30, 2016,

scientists from the United States, Latin America, Europe, and Australia and 5democraticUS Senators asked the National Library of Medicine to add COIs to article abstracts on PubMed.¹¹ In the study by Cherla et al,⁷ 17 articles were excluded owing to inability to access the full text. In addition to increasing transparency for the general population, this process can help researchers in data gathering and assessing credibility of an article. However, PubMed has not yet included COI data in article abstracts.

Limitations

Our study is limited by potential inaccuracies of the OPD. Several studies have shown inaccuracies within the OPD for different specialties. ¹²⁻¹⁵ In a study of the accuracy of the 2014 OPD for neurosurgeons, 1232% of the neurosurgeons were misclassified for other specialties. Nevertheless, the OPD is the only available source on physicians' industrial payments and the only available data to validate self-declared COI. An additional limitation of this study was that 36 of the 100 physicians evaluated did not publish any articles in 2016. Oursample size was therefore restricted to 64 physicians for analyzing the association between COI declaration and the industrial payments. However, owing to high numbers of publications by these 64 physicians in 2016, we believe that this fact did not have a significant influence on our study results. Another limitation of this study was that establishment of relevance and presence of COI is subjective.

Conclusions

We found that a high level of inconsistency exists between self-declared COI and the OPD among the physicians who receive the highest compensation from surgical and medical device companies. Such inconsistencies should be addressed to decrease the risk of potential bias in studies. A single standardized disclosure process used for all scholarly activities, implementation of a COI statement in article abstracts, and full disclosure of all financial ties, whether relevant or not, would eliminate any inconsistencies in disclosures and could help us move 1 step closer to full transparency.

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ARTICLE INFORMATION

Author Contributions: Drs Ziai and Jafari had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: Ziai, Pigazzi, Smith, Carmichael, Jafari.

Acquisition, analysis, or interpretation of data: Ziai, Pigazzi, Nouri-Nikbakht, Nepomuceno, Mills, Stamos.

Drafting of the manuscript: Ziai, Pigazzi, Nouri-Nikbakht, Carmichael, Stamos. Critical revision of the manuscript for important intellectual content: Pigazzi, Smith, Nepomuceno, Mills, Jafari.

Statistical analysis: Ziai, Nouri-Nikbakht.

Administrative, technical, or material support: Ziai, Smith, Mills, Stamos. Supervision: Pigazzi, Smith, Carmichael, Mills, Stamos, Jafari.

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