



Financial Disclosures in Academic Publications and the Sunshine Act: A Concordance Study

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Authors' contributions

This work was carried out in collaboration between all authors. Authors PBG and CEM designed the study. All authors collected and analyzed data. Author CY drafted the manuscript. All authors revised the manuscript and approved the final version.

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ABSTRACT

Aims: To assess the concordance between conflicts of interest reported by physicians in three major scientific journals and industry-reported payments available through the Open Payments Program (OPP) database.

Study Design: Comparative cross-sectional surveys.

Place and Duration of Study: United States allopathic and osteopathic physicians with publications in *American Journal of Ophthalmology*, *JAMA Ophthalmology*, and *Ophthalmology* accepted after January 1, 2014 and published from May 2014 through October 2014.

Methodology: We compared physicians' self-reported conflicts of interest in their academic publications to industry-reported payments in the Centers for Medicare & Medicaid Services OPP

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database. Authors were categorized based on concordance between self-reported disclosures and payments listed in the database. Payments were designated as disclosed or undisclosed.

Results: Of the 670 authors surveyed, 367 (54.8%) were in perfect concordance with the OPP database; 68 (10.1%) authors made disclosures beyond those in the database but had no undisclosed ties; 235 (35.1%) authors had one or more undisclosed payments. Disclosed and undisclosed payments totaled \$1.46 million and \$1.81 million, respectively.

Conclusion: In three major ophthalmology journals, a significant discrepancy exists between conflicts of interest reported by physician authors and payments found in the OPP database. This lack of concordance raises concerns about incomplete physician disclosure, inaccurate reporting, inadequate vetting, and ambiguity over financial relevance, all of which undermine confidence in the disclosure process.

Keywords: Conflict of interest; sunshine act; financial disclosure; transparency.

1. INTRODUCTION

The Centers for Medicare & Medicaid Services (CMS) released the Open Payments Program (OPP) database with the intent of increasing transparency of financial relationships between physicians and industry [1]. Released in fulfillment of the Physician Payments Sunshine Act initiative of the Affordable Care Act, the OPP database publicly reports payments to United States-licensed physicians by manufacturers of federally covered drugs, devices, biological, or medical supplies. Individual payments less than \$10.00 are exempt, unless the annual aggregate exceeds \$100.00. The database has been criticized for being difficult to use, not thoroughly vetted, and incomplete [2]; nevertheless it contains information that may shape opinion about conflict of interest (COI) in research and medicine.

Accurate COI reporting is essential to the integrity of scientific research as well as trust in the physician-patient relationship. Currently, most peer-reviewed scientific journals rely on authors to self-report COI. As the OPP database shows payments made by manufacturers to physicians, it offers the opportunity to evaluate the accuracy of financial disclosures. This study examined the agreement between physician-reported COI in three major ophthalmology journals and payments recorded in the OPP database.

2. METHODOLOGY

The OPP data we analyzed included payments made between August 1 and December 31, 2013. Thus one inclusion criterion for journal manuscripts was an acceptance date on or after January 1, 2014, which ensures that payments would have transpired during the time of the

work. Our review of OPP data also occurred subsequent to the December 2014 update, which included any previously disputed claims.

Original scientific studies or editorials accepted for publication after January 1, 2014 and published between May and October 2014 from *American Journal of Ophthalmology*, *JAMA Ophthalmology*, and *Ophthalmology* were included in our study. American allopathic and osteopathic physician authors from these papers were the subjects of our survey. We performed a Google search in situations where MD/OD status was ambiguous. A single reviewer abstracted each paper for qualified physicians, self-reported financial disclosures and conflicts of interest, including sources. We then searched the General, Research, and Ownership databases on the OPP website by physician name and verified by Physician Profile ID for financial payments to each author during the study period [3]. Information about the amount, source, nature of the payment, and whether it was contested, were collected; payments within the same category and manufacturer were summed and considered as one payment. Physicians who authored multiple papers were counted as new authors with each original paper since each study offered the potential for different financial disclosures. To confirm completeness and accuracy of data collection, we selected a third of the papers for independent second review by three co-authors. We then compared payments in the database to self-reported conflicts of interest and categorized the payments as disclosed or undisclosed. Authors were categorized based on concordance between self-reported financial disclosures and payments listed in the database. We analyzed results collectively for the three journals using descriptive statistics.

3. RESULTS

There were 493 original papers and editorials published during the 6-month study period that met inclusion criteria. These articles had 670 American physician authors; 260 (38.8%) had payments listed in the OPP databases, and 146 (21.8%) had self-reported financial disclosures. Only one author had contested payments.

Concordance status for all 670 authors is reported in Table 1. The 367 (54.8%) authors that had complete agreement between self-reported financial disclosures and payments in the OPP database are listed as concordant. Another 68 (10.1%) authors reported financial disclosures that were not in the database but had no undisclosed payments. The remaining 235 (35.1%) authors had at least one undisclosed payment in the database.

Of the 146 authors who reported COI, only 2 had perfect agreement between self-reported financial disclosures and payments listed in the database. The 2 authors with perfect agreement along with 365 additional authors who did not report financial disclosures and had no payments listed in the database are listed in Table 1 as concordant.

Another 23 (3.4% of total) authors reported all relationships listed in the database and additional relationships not in the database. Forty-five authors disclosed COI but had no payments recorded in OPP. These two groups (68 [10.1%] authors) are listed in Table 1 as non-concordant with excess self-reporting. There were 235 authors who made disclosures that either did not match reports or under reported records in the OPP database. This group is listed in the non-concordant under reporting section of Table 1. One hundred fifty-nine authors in this category (23.7% of total) reported no financial disclosures but had payments listed in the database. The remaining 76 authors reported COI but had one or more discrepancies when compared to payments listed in the database.

Table 2 contains payment distribution information from the OPP database during the six-month study period. Disclosed payments and undisclosed payments totaled \$1.46 million and \$1.81 million, respectively. Payments fell into 13 categories, with the most number of payments in the Food and Beverage category (560 summed payments) and the highest value in Research (\$1.21 million). For every category, the number of undisclosed payments was greater than the number disclosed; the amount of undisclosed payments was also greater for all categories except Research.

Table 1. Concordance between self-reported financial disclosures and industry-reported payments in the Open Payments Program (OPP) database

Agreement category	Number of authors (%)
Concordance	
No self-reported financial disclosures and no payments listed in OPP database	365 (54.5)
Perfect agreement between self-reported financial disclosures and payments listed in OPP database	2 (0.3)
Total	367 (54.8)
Non-concordance with excess self-reporting	
Self-reported financial disclosures but no disclosures listed in OPP database	45 (6.7)
Self-reported financial disclosures in agreement with payments listed in OPP database AND self-reported disclosures in excess of payments listed in OPP database	23 (3.4)
Total	68 (10.1)
Non-concordance with under self-reporting*	
No self-reported financial disclosures but payments listed in OPP database	159 (23.7)
Self-reported financial disclosures not in agreement with payments listed in OPP database AND self-reported disclosures in excess of payments listed in OPP database	37 (5.5)
Some self-reported financial disclosures in agreement but fewer than payments listed in OPP database AND self-reported disclosures in excess of those listed in database	30 (4.5)
Some self-reported financial disclosures in agreement but fewer than disclosures listed in OPP database	9 (1.3)
Total	235 (35.1)
Total	670 (100)

*Authors with both excess and under-reporting were listed in the under-reporting category

4. DISCUSSION

Our survey of COI statements from three major US eye journals from May through October 2014 showed a lack of concordance between authors' acknowledged COI and their financial payments in the OPP database. One hundred fifty-nine (23.7%) authors with payments listed in the database reported no financial disclosures. Only 10.4% of the authors surveyed fully disclosed their financial reimbursements in their publications (i.e., perfect agreement plus those with agreement and excess self-reporting). Undisclosed payments during this 6-month period exceeded disclosed payments by \$350,000.

Contrary to some opinions that the CMS website is difficult to use [2,4], we found the search engine workable and information easily extractable. The difficulty arises in distinguishing what type and amount of payment differentiates worrisome from trivial interactions [5]. The CMS describes the dilemma this way: "Sharing information about financial relationships alone is not enough to decide whether they're beneficial or improper" [6].

Payments in the OPP database fell into 13 categories (Table 2). However, the limited contextual framework for the individual financial payments makes details about particular commercial relationships largely speculative. This shortcoming is important as the amount of

money industry bestows to ophthalmologists is not inconsequential: during the last five months of 2013 (after the OPP made records available), ophthalmologists received just under \$11 million with 42% (\$4.6 million) for consulting work [4].

Problems with vetting the OPP database have been raised, including a backlog of disputed records [2]. Delays in the vetting process, however, would result in payments being listed as "disputed." Although we encountered just one disputed claim, it is possible other physicians may have considered the effort to contest a claim too burdensome to pursue. In addition, we came across several cases where physician specialty was mislabeled for different payments to the same physician. Regardless, physicians will bear the burden of dissonant reports due in large part because their names are listed on a public website as having had a financial interaction with industry.

Further complicating the discussion of transparency are observations that the Sunshine Act contains loopholes such as exemptions from reporting rebates given to physicians as incentives to use expensive drugs and the "unrestricted grants" provided by industry for accredited continuing medical education [5]. Besides certain loopholes, it is possible that legal ambiguities surrounding the definition of an OPP-delineated industry could have kept some businesses from reporting financial relationships.

Table 2. Distribution of disclosed and undisclosed payments to authors

Category	Number of payments	Total payments (\$)	Disclosed payments	Disclosed amount (\$)	Undisclosed payments	Undisclosed amount (\$)
Compensation for services other than consulting	44	222,365.	20	83,912.	24	138,453.
Compensation for serving as faculty or speaker for CME program	18	49,287.	5	12,700.	13	36,587.
Consulting Fee	143	1,059,450.	55	472,278.	88	587,172.
Education	73	77,835.	14	24,269.	59	53,566.
Entertainment	13	657.	3	109.	10	547.
Food and Beverage	560	87,102.	107	23,037.	453	64,065.
Gift	26	11,626.	6	4,673.	20	6,953.
Grant	1	1,000.	0	0	1	1,000.
Honoraria	7	9,958.	1	1,000.	6	8,958.
Ownership	2	179,250.	0	0	2	179,250.
Research	19	1,209,001.	7	663,648.	12	545,353.
Royalty or License	8	129,075.	6	98,136.	2	30,939.
Travel and Lodging	116	235,429.	39	80,923.	77	154,506.
Totals	1,030	3,272,036.	263	1,464,686.	767	1,807,350.

Another consideration when evaluating discrepant results is ambiguous financial disclosure statements. The International Committee of Medical Journal Editors (ICMJE) disclosure form, which is used by the three journals evaluated herein, requests “relevant financial activities” be divulged [7]. The form defines “relevant” as activities “that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work.” [7]. The ICMJE form does request disclosures not specially related to a submitted work for 36 months prior to submission, but that too is couched in the term *relevant*. The money or gifts physicians receive from industry may seem to have no *relevant* relationship to the research they perform, but patients and physicians have been shown to have differing perspectives on what constitutes an unacceptable financial tie [8,9].

There are limitations of this study. One is the relatively brief sample period of 6 months, which provides only a snapshot of the concordance between authors’ acknowledged COI and their financial payments in the OPP database. Another is that authors from these three journals may not be representative of authors who publish in other eye journals, particularly those with less clinical orientation. Finally, it is possible that authors whose disclosures were not listed in OPP were reporting activities that pre-dated the government-mandated reporting date.

5. CONCLUSION

This study suggests that the laudable goals of financial transparency in medical research and clinical practice are confounded by a lack of concordance in self-reported COI and payments recorded in the OPP database. This lack of concordance could be due to incomplete disclosures by physicians, inaccurate reporting, inadequate vetting, or ambiguity over what is financially relevant. Unless some means of distinguishing beneficial financial interactions from conflicts of interest exist, medical editors may recommend that authors confirm the accuracy of self-reported financial disclosures against those found in the OPP database before papers are published, or fully disclose all industry payments regardless of perceived relevance [10].

CONSENT

This study was granted exemption by the Providence Veterans Affairs Medical Center Institutional Review Board.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and granted an exemption by the Providence Veterans Affairs Medical Center Institutional Review Board and have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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