CLINICAL RESEARCH STUDY

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Author Self-disclosure Compared with Pharmaceutical Company Reporting of Physician Payments

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ABSTRACT

BACKGROUND: Industry manufacturers are required by the Sunshine Act to disclose payments to physicians. These data recently became publicly available, but some manufacturers prereleased their data since 2009. We tested the hypotheses that there would be discrepancies between manufacturers' and physicians' disclosures.

METHODS: The financial disclosures by authors of all 39 American College of Cardiology and American Heart Association guidelines between 2009 and 2012 were matched to the public disclosures of 15 pharmaceutical companies during that same period. Duplicate authors across guidelines were assessed independently. Per the guidelines, payments <$10,000 are modest and ≥$10,000 are significant. Agreement was determined using a κ statistic; Fisher's exact and Mann-Whitney tests were used to detect statistical significance.

RESULTS: The overall agreement between author and company disclosure was poor ($\kappa = 0.238$). There was a significant difference in error rates of disclosure among companies and authors ($P = .019$). Of disclosures by authors, companies failed to match them with an error rate of 71.6%. Of disclosures by companies, authors failed to match them with an error rate of 54.7%.

CONCLUSIONS: Our analysis shows a concerning level of disagreement between guideline authors' and pharmaceutical companies' disclosures. Without ability for physicians to challenge reports, it is unclear whether these discrepancies reflect undisclosed relationships with industry or errors in reporting, and caution should be advised in interpretation of data from the Sunshine Act.

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KEYWORDS: Conflict of interest; Practice guidelines

SEE RELATED EDITORIAL p. 3

Pharmaceutical companies spent more than 27 billion dollars for promotional purposes in 2012, 4 billion of which went to the cardiovascular field.[1] The Patient Protection and Affordable Care Act, signed in 2010, requires pharmaceutical and medical industry manufacturers to disclose their financial relationships with physicians.[2] This policy, known as the Sunshine Act, serves to enhance the transparency of financial relationships without determining their appropriateness.[3] The Sunshine Act data became available in 2014, though some manufacturers have self-reported data since 2009. Physicians did not have the opportunity to review and request corrections to these self-reported data. On the other hand, the Centers for Medicare and Medicaid Services' website allows physicians to challenge the reports and request corrections of the Sunshine Act data, though these requests were limited by a narrow time window and compounded by website difficulties. Therefore,

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we expect that the prereleased data would provide a representative sample of the data from the Sunshine Act.

As published in the "Policy and Procedure" manual by the American Heart Association (AHA), guideline authors are instructed to disclose any relevant financial relationships within the prior 2 years and encouraged to report "any and all relationships that could be perceived as real or apparent Conflicts of Interests."[4] Furthermore, the disclosure is not limited to the writer only; it should include all members of the person's household. Although persons with relevant financial relationships are not banned from being in the writing group, a balance is maintained in which more than 50% are free of relationships with industry.[5] The group chair, however, is not allowed to assume this role when relevant financial relationships with industry do exist. In this study, we tested the hypothesis that there would be discrepancies between manufacturers and physician disclosures according to the prereleased data.

CLINICAL SIGNIFICANCE

- There is a concerning level of disagreement between clinical practice guideline authors' self-disclosure and pharmaceutical companies' reporting of payments to physicians.
- The sources of disagreement may be from differences in methodology or could represent true conflicts of interest.
- In light of our results, caution is advised in the interpretation of Sunshine Act data and accuracy of guideline authors' relationships with industry.

METHODS

Fifteen pharmaceutical companies disclosed their payments to physicians between 2009 and 2012; these disclosures were assembled into a single, comprehensive queryable database.[6] During this period, there were 39 American College of Cardiology (ACC) and AHA guidelines published. Non-US and nonphysician authors were excluded from the analysis because pharmaceutical companies did not provide data for these types of authors. Disclosures by guideline authors were matched to the disclosures of these 15 pharmaceutical companies. To avoid mismatching authors' names, matches were affirmed if first name, middle name (when available), last name, city, and state were all exact matches. For authors who may live in one state and work in another, we searched surrounding states in which interstate commuting is common; for instance, for authors in New York, Connecticut and New Jersey also were searched, and for authors in the Washington, DC area, Maryland and Virginia also were analyzed.

Duplicate authors across guidelines were assessed independently, assuming that in each guideline there is a responsibility upon authors to fully disclose their financial relationships. The dollar amounts of the 15 companies' payments for a single author in a single guideline were summed together, giving an author credit for disclosing a relationship if any payment from 1 of the 15 companies was disclosed. The guidelines organize these relationships into the following categories: Speaker's Bureau, Consultant, Personal Research, Ownership/Partnership/Principal, Other Financial Benefit, and Expert Witness, whereas the companies' disclosures uses the following categories for organization: Speaking Fees, Consulting Fees, Research, Travel Fees, Meals, Gifts, and Royalties/License Fees.

To create matching categories, we assumed equivalence for "Speaker's Bureau" and "Speaking Fees," "Consultant" and "Consulting Fees," "Personal Research" and "Research."

We elected to combine the guidelines' categories "Ownership/Partnership/Principal," "Other Financial Benefit," and "Expert Witness" into one category named "Other" and similarly combined the companies' categories of "Travel Fees," "Meals," "Gifts," and "Royalties/License Fees" into a single "Other" category. Whenever a company reports financial relationships with an author that an author does not report, we designated this as an author error. Conversely, we defined a company error for those relationships that an author discloses and a company does not.

The ACC/AHA Guidelines designate payments $<$\$10,000 as modest and those $\geq$\$10,000 as significant.[5] These definitions were used to determine cut-off points to convert the continuous data into nominal data. Group chairs also were studied as a separate cohort. Agreements between authors and pharmaceutical companies were determined using a κ statistic. The statistical significance was estimated by χ^2 or Fisher's exact tests for dichotomous variables as well as Mann-Whitney test for continuous variables. Statistical significance was defined as a P value of $<.05$. Analysis was performed using SPSS version 22.0 (IBM, Armonk, NY).

RESULTS

The joint ACC/AHA guidelines spanning 2009 to 2012 featured a total of 588 authors. Of these authors, 51 were

Table 1 Means ± Standard Deviation (SD) and Ranges of Companies' Payments

Variable	Speaking	Consulting	Research	Other	Overall
n	13	32	11	49	64
Mean ± SD ($)	26,332 ± 51,992	11,714 ± 12,189	66,347 ± 176,901	2,752 ± 4560	24,716 ± 79,067
Range ($)	350-186,000	2,000-60,562	665-598,808	15-18,130	15-598,849