From the Southern Association for Vascular Surgery

Industry compensation and self-reported financial conflicts of interest among authors of highly cited peripheral artery disease studies

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ABSTRACT

Objective: Industry compensation to authors may influence the interpretation of study results. Scientific journals often require author disclosure of a relevant financial conflict of interest (FCOI) but seldom quantify compensation and leave reporting up to the author's discretion. Professional and public concerns related to potential bias introduced into medical research by FCOI have arisen, especially when physician compensation from manufacturers is not disclosed. Little is known, however, about the prevalence of industry compensation to authors of related publications, payment amounts, or how this information compares with self-reported FCOI. The objective of this study was to compare industry compensation and disclosed FCOI among highly referenced publications related to treatment of peripheral artery disease, a disease that affects approximately 8.5 million Americans and is often treated with medications and devices.

Methods: "Peripheral artery disease" was used as a Web of Science search term to identify publications from 2013 to 2016, excluding review articles, conference proceedings, book chapters, abstract publications, and non-English language publications. The top 99 most cited publications were abstracted for self-reported FCOI by author. Industry compensation to authors was queried using a ProPublica Dollars for Docs custom data set based on Centers for Medicare and Medicaid Services Open Payments data. Providers practicing in the United States in any of the following specialties were included: cardiology, cardiothoracic surgery, vascular and interventional radiology, or vascular surgery. Payment transactions were matched to physician authors on the basis of provider name, specialty, and geographic location. Statistical analysis included descriptive statistics and categorical tests. Descriptive statistics are reported as frequency (percentage) or median (interquartile range).

Results: Among 1008 vascular specialist authors identified, 218 (22%) self-reported FCOI. Fifty-six physician authors had compensation reported to the Centers for Medicare and Medicaid Services by industry during the study period. Among those identified as recipients of industry compensation, 28 (50%) self-reported FCOI. Industry payments to the 56 authors totaled $11,139,987, with a median total payment of $18,827 (interquartile range, $152,084) per author. Food and beverage was the most frequently identified nature of payment (n = 8981 [74%]), promotional speaking involved the largest total amount of payments ($3,256,431), and royalty or license was the highest median payment ($51,431 [$72,215]). Physicians reporting FCOI received a total of $9,435,340 during the study period vs $1,706,647 for those who did not report any FCOI. Median total payments were higher among authors reporting FCOI vs not ($81,224 [$324,171] vs $9494 [$43,448]; $P < .001$).

Conclusions: Nondisclosed author compensation from industry is relatively uncommon among highly cited peripheral artery disease research studies but may be associated with substantial payments. These results suggest that self-reported FCOI does not provide a comprehensive overview of industry compensation. Reporting all payments rather than only those deemed relevant by the author might provide a more complete and transparent report of potential FCOI, allowing independent assessment of relevance in interpreting study findings. (J Vasc Surg 2020;72:673-84.)

Keywords: Financial disclosure; Conflict of interest; Industry payment; Peripheral artery disease; Cardiovascular specialists

Many important scientific publications are authored by physicians who have received significant compensation from industry because of their relationship with a for-profit manufacturer of drugs, devices, or even newly developed techniques. Although many medical journals require disclosure of financial conflict of interest (FCOI)

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before publication, this information is usually self-reported, and the relevance of industry compensation is usually left up to the discretion of the authors. FCOI information is rarely checked or audited. Moreover, self-reported disclosures are often incomplete and may be omitted from the published manuscript.[1] Even when FCOI is fully disclosed, it does not exclude bias favoring companies compensating authors. Industry sponsorship of clinical research trials in particular may bias results toward proindustry conclusions or restrict publication and data sharing.[2]

Currently, there is no uniform process across journals that guarantees disclosure of FCOI by physician authors of medical research manuscripts. This is especially problematic when study participants and the scientific community are unaware of undisclosed FCOI.[3] Undisclosed FCOI has received significant attention from both the scientific community and lay press media, especially for relationships between physicians and manufacturers of treatments of cancer and orthopedics.[1,4,5] Professional and public concerns have arisen to potential bias and safety issues, and there is no reason to suspect that vascular specialists are immune to similar problems. However, despite widespread industry sponsorship for trials of treatments for vascular disease, little is known about the prevalence of disclosed FCOI in subsequent research publications or compensation to authors paid by industry.

The objective of this study was to evaluate industry compensation and self-reported FCOI among highly cited publications related to treatment of peripheral artery disease (PAD), a condition that affects >8.5 million Americans and is often treated with medications and devices.[6,7] The intent was to identify the scope and prevalence of industry-related payments received with or without author self-reporting of FCOI within published articles. Self-reported FCOI was compared with payments authors received from industry manufacturers during a four-year period from 2013 to 2016.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of scientific literature and publicly reported industry payments to physicians
- **Key Findings:** Industry payments to vascular specialist authors of highly cited peripheral artery disease manuscripts totaled $11,139,987 during a 4-year period with a median total compensation of $18,827. Of 56 authors identified as recipients of industry compensation, 28 (50%) self-reported a financial conflict of interest (FCOI).
- **Take Home Message:** Compensation from industry is uncommon among authors of highly cited peripheral artery disease research studies but is not consistently self-reported. Self-reported FCOI may be incomplete or inaccurate, resulting in potential for author bias that may be unapparent to readers. Reporting all industry payments, rather than only compensation deemed a relevant FCOI by the author, might avoid nonreporting bias and provide a more comprehensive and transparent perspective in interpreting study results.

METHODS

This research study was reviewed by the University of Michigan Institutional Review Board and determined to fall under the policy for research using publicly available data sets. Institutional Review Board approval therefore was not required.

Literature search and data analyzed. A literature search was performed with librarian assistance using Web of Science version 5.31 (Clarivate Analytics, Philadelphia, Pa). Peer-reviewed scientific articles published in English language were identified using the search term "peripheral artery disease," restricting publication dates to January 2013 through December 2016. Meeting or conference proceedings, review articles, book chapters, and abstract publications were excluded from analysis. Articles were included regardless of whether the investigation was related primarily to PAD (eg, as the primary or single study population, treatment intervention, hypothesis, or pathophysiologic mechanism) or instead secondarily (eg, as a comorbidity, shared experimental model, comparison population, or analogous experimental conditions) to minimize selection bias related to subjective or arbitrary exclusion criteria. Results were then sorted from most to least cited.

The top 99 most cited publications were abstracted by two authors (C.H. and T.B.) for authors' self-reported conflict of interest. Self-reported FCOI was identified using disclosures reported or referenced within the published articles. Disclosures were identified from information within the manuscripts or from supplementary Internet resources if this information was listed separately on the publisher's website. Articles were categorized as either basic science or clinical science. Clinical science articles were further subcategorized as observational, medical (pharmaceutical) interventional, or procedural interventional studies. The number of self-reported disclosures per author and the category of FCOI based on authors' self-reported descriptions were collected from published manuscripts and referenced journal websites, including consultant fees, honoraria, lecture fees, personal fees, and advisory board or board of directors compensation. Authorship on a study directly sponsored by industry was not considered FCOI unless author-specific compensation was separately disclosed. Author employment by manufacturers was recorded when disclosed but was not categorized as FCOI on the basis of

the rationale that industry employees would not also be engaged in direct patient care (so related compensation would not be subject to reporting requirements).

The combined list of authors from all 99 highly cited PAD publications was then used to query the ProPublica Dollars for Docs data set[8] to identify industry payments from 2013 to 2016. The ProPublica database contains payments from pharmaceutical and medical device companies to physicians and teaching hospitals. Companies are required to disclose these payments under the Sunshine Act, established in 2010 as part of the Patient Protection and Affordable Care Act. Medical doctors, osteopaths, optometrists, podiatrists, and chiropractors are included in the database. Nonphysician health care providers (ie, nurse practitioners, physician assistants) and PhDs who are not health care providers are excluded. To create its data sets, ProPublica compiles the reports released by the Centers for Medicare and Medicaid Services (CMS) on physician payments and matches them to National Provider Identifier numbers. ProPublica data include standardization of how each company, drug, and device is listed. Payments data include total payments in U.S. dollars relegated to 15 categories, including consulting fees, promotional speaking, honoraria, gifts, entertainment, food and beverage, travel and lodging, education, research, charitable contributions, royalty or license, ownership or investment interest, and compensation for serving as a speaker for either accredited or unaccredited continuing medical education programs.[9]

This study used a custom data set obtained for providers (and related payments) defined as physician vascular specialists in any of the following specialties: cardiology, cardiothoracic surgery, vascular and interventional radiology, or vascular surgery. Duplicate author names within the ProPublica data set were reviewed to reconcile which should be identified as manuscript authors by matching state, ZIP code, and specialty information contained in the published manuscripts. To link the providers to detailed payment data, those authors who received payments reported by industry were matched to the payment transaction data set using their National Provider Identifier numbers. For author-based comparisons between self-reported FCOI and industry compensation, those authors with multiple highly cited publications were categorized as having self-reported if at least one FCOI was disclosed on any highly cited article published during the study period.

Statistical analysis. Descriptive statistics were displayed for continuous variables as either mean ± standard deviation or median (interquartile range), depending on data distributions, and as frequency (percentage) for categorical variables. Industry compensation to physician authors was reported rounded to the nearest whole dollar amount (U.S. currency). Nonparametric methods (including Wilcoxon rank sums and the Kruskal-Wallis test) were used to evaluate payments data stratified by provider subgroups. Statistical significance was evaluated at $\alpha = .05$. Statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC), Excel (Microsoft Corp, Redmond, Wash), and Prism (GraphPad Software, San Diego, Calif).

RESULTS

Self-reported FCOI. The 99 highly cited PAD articles[6,10-107] were published in 55 different journals and written by a total of 1008 individual authors, including both physicians and nonphysicians. Among these, 218 authors (22%) self-reported 373 conflicts of interest. Grants (33.8%), advisory boards (15.3%), and honoraria (13.1%) were the three most common categories of self-reported FCOI (Table I). Twenty authors identified themselves as employees of industry manufacturers on a total of 11 manuscripts. Studies evaluating medical (pharmaceutical) treatment interventions for PAD had the highest mean self-reported FCOI per author (3.2 ± 6.6), followed by clinical observational studies (1.0 ± 3.4), studies evaluating procedural interventions (0.9 ± 2.9), and basic science studies (0.5 ± 3.1).

Industry compensation to physician authors. Industry compensation to vascular specialist physicians included 1,186,609 payment transactions to 14,480 individuals totaling $327,315,078 from 2013 to 2016. Fifty-six of the physicians receiving industry compensation were authors of at least one of the 99 highly referenced PAD articles. These 56 authors received a total of 12,178 payment transactions totaling $11,139,987 during the study period. The median value of total payments per author was $18,827 ($152,084), ranging from $443 to $2,629,021. All physician authors received multiple payments; the number of transactions per individual physician author ranged from a minimum of 2 to a maximum of 1116 during the study period. The majority of transactions (97.8%) had a value below $5000 each.

Specialties of those authors receiving industry payments during the study period included interventional cardiology (n = 19 [34%]), vascular surgery (n = 14 [25%]), cardiothoracic surgery (n = 9 [16%]), cardiovascular disease (n = 7 [13%]), and vascular and interventional radiology (n = 4 [7%]; Table II). No association between provider specialty and total payments was observed ($P = .321$).

Among the 56 physician authors receiving payments from industry, 28 (50%) self-reported FCOI related to a highly cited PAD research study published during the same period. Physicians reporting FCOI received a total of $9,435,340 during the study period vs $1,706,647 for those who did not report any FCOI (Fig). Median total payments were higher among authors reporting FCOI

Table I. Authors' self-reported financial conflict of interest (FCOI)

Category	Frequency	%
Grant	126	33.8
Advisory board	57	15.3
Honoraria	49	13.1
Lecture fee	24	6.4
Employee	22	5.9
Shareholder	21	5.6
Personal fees	18	4.8
Committee	18	4.8
Travel expenses	11	2.9
Patent	11	2.9
Board of directors	10	2.7
Royalties	6	1.6

Categories are based on self-reported disclosures published with highly referenced peripheral artery disease studies. Disclosures are displayed by frequency and percentage of total disclosures.

vs not ($81,224 [$324,171] vs $9494 [$43,448]; $P < .001$). In-kind items and services were the most common form of payment or transfer (n = 8670 [71%]), followed by cash or cash equivalent (n = 3504 [29%]) and stock, stock options, or any other ownership interest (n = 4 [<1%]). Industry compensation transactions stratified by form of payment or transfer and author self-report of FCOI are displayed in Table III.

The nature of industry payments or transfers to authors was varied. The most frequent nature of payment or transfer was food and beverage (n = 8981 [74%]), followed by travel and lodging (n = 1857 [15%]) and consulting (n = 704 [6%]). Promotional speaking (ie, serving as faculty or speaker at an event other than a continuing education program) was not among the top three most frequent transactions based on nature of payment but was the category with the highest total compensation amount ($3,252,430), followed by consulting ($2,633,022) and royalty or license payments ($2,335,918). Royalty or license payments had the highest median payment ($51,431 [$72,215]), followed by ownership or investment interest payments ($19,704 [$67,977]) and compensation for promotional speaking ($2500 [$1450]). Payment transactions stratified by both nature of payment or transfer and author self-report of FCOI are shown in Table IV.

Payments were reported by 170 different manufacturers, some of which had shared parent companies. There were 138 payments (1% of total payment transactions to the 56 authors) made to physicians with ownership interests in the submitting manufacturer, and physician ownership was associated with higher median payments ($96.51 vs $50.00; $P < .001$). Seventeen payments (0.1%) were disputed by physicians before publication, and no association was observed between dispute status and payment amount ($P = .11$). None of the payments had prepublication requests for delayed reporting.

DISCUSSION

Industry financial support for research, accounting for approximately 25% of clinical trials,[3] often benefits patients through rapid advances that frequently outpace progress within the academic sector. Collaboration with industry is often a necessity for both premarket development and postmarket distribution of pharmaceuticals and medical devices. Scientific publications involving industry-sponsored research are usually subjected to peer review as part of the evidence dissemination process. Nonetheless, our observations suggest several important considerations for readers in interpreting clinical research findings.

Discordance between published FCOI and industry compensation identified in this study, although uncommon, suggests that the current system of self-reported disclosure does not consistently provide a comprehensive overview of industry compensation to authors of influential publications. Currently, assessment of the relevance of industry compensation to a study is left up to the authors, and under most circumstances, FCOI information is neither verified nor audited by a third party. Previous reports have identified that denial and rationalization are common among physicians attempting to reconcile conflicts and may contribute to nondisclosure of FCOI.[108,109] Nondisclosed compensation may be irrelevant to a given study and should not always be considered tantamount to FCOI. Objective assessment of the relevance of compensation, however, can be challenging or impossible, given the complexities of corporate structures (where a given manufacturer may have multiple subsidiaries with multiple products) and the volume and variety of payment transactions per author.

This study identifies a diverse array of activities associated with financial payments from industry to physicians, each of which may have unique nuances.[110] The skewed distributions of dollar amounts by form of compensation and nature of related activities demonstrate that any given industry payment is not necessarily equivalent to another. Although stock, stock options, or ownership interests were identified as the least common transactions (accounting for <1%), these forms of compensation were associated with highest payments. Similarly, specific activities, such as ownership or investment interest, royalties and licenses, or promotional speaking, may indicate situations in which payments may be particularly significant and influential. Accordingly, many academic institutions prohibit physician faculty participation in such activities to avoid potential conflicts with patient care and institutional purchasing.

Physicians are not exempt from the potential influence of industry payments, even if this compensation is only a

Table II. Physician authors receiving industry compensation from 2013 to 2016 stratified by specialty

Self-reported primary specialty	No.	Median total payment	Interquartile range	Minimum	Maximum
Interventional cardiology	19	57,998.84	636,574.43	824.86	2,629,021.11
Vascular surgery	14	3764.17	43,972.76	735.88	339,881.03
Thoracic surgery (cardiothoracic vascular surgery)	9	19,470.01	77,700.78	442.57	169,276.00
Cardiovascular disease	7	14,511.16	49,323.82	5521.40	511,544.26
Vascular and interventional radiology	4	173,610.40	298,075.33	2315.43	404,277.14
Surgery	3	16,487.09	285,127.44	6352.12	291,479.56

The number is providers for each specialty listed as authors of highly cited peripheral artery disease research studies. Median, interquartile range, minimum, and maximum payments per physician are displayed in U.S. dollars.

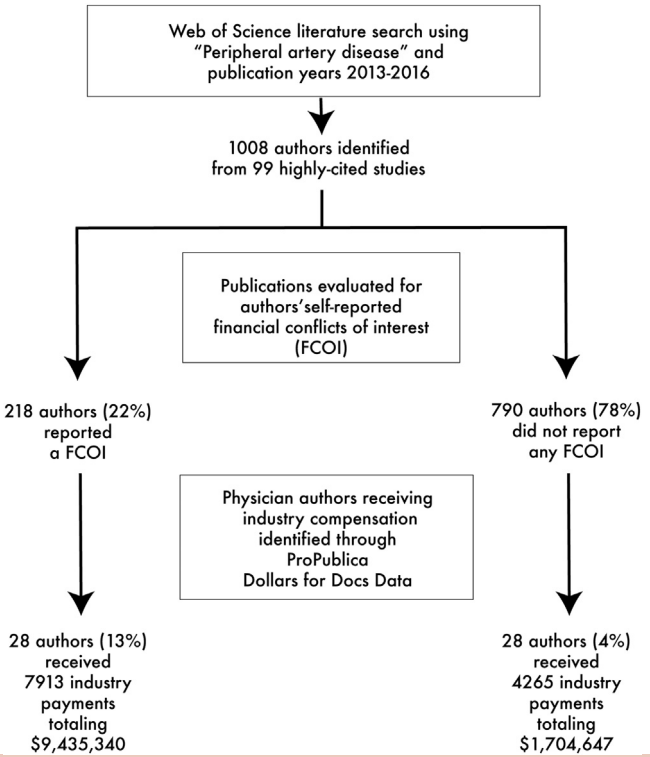

Fig. Summary of study data collection, analysis, and results. Data collection and analysis steps are summarized within *boxes*. Percentages within results are based on the result of the preceding step as the denominator. Payments are shown in U.S. currency rounded to the nearest dollar. *FCOI,* Financial conflict of interest.

small fraction of their total income. Studies of physician and nonphysician behavior noted that even small gifts may induce a sense of gratitude and reciprocity that the recipient may not be consciously aware of.[108] Even free meals have demonstrated influence on physicians' opinions of pharmaceuticals and other medical products.[111] These findings suggest that there is no safe compensation threshold below which corporate influence is implausible.

The International Committee of Medical Journal Editors has proposed that authors disclose all potential FCOI directly related to the work being considered for publication, any relevant financial activities outside the submitted work, and any other relationships that readers might perceive to have influenced or might have the appearance of potentially influencing the submitted work during the past 3 years.[112] Quantifying financial payments per author, rather than just reporting FCOI categorically, might provide both the reader and scientific community with greater precision in weighing the potential influence of payments on the study's design, analysis, and conclusions. In addition to the quantity of payment, the nature of the compensated activity may alter a reader's judgment about an author's potential bias. It is important to acknowledge that unbiased analysis and presentation of results are achievable in the setting of industry sponsorship or significant author compensation, but transparent disclosure is extremely important under these circumstances and grants readers a more comprehensive perspective in interpreting results.

Knowing nondisclosure of a relevant FCOI is considered a form of author scientific misconduct that carries responsibilities to both editors and institutions.[9,113] For instance, industry-sponsored trials increase a journal's impact factor and may generate sales of article reprints that represent a source of substantial income.[114] Several high-impact medical journals do not include FCOI within the published articles, relegating this information to a separate document or listing on the journal's website instead. From a practical perspective, omission of FCOI from the published article is likely to equate to nondisclosure for readers who are unaware of this distinction or fail to take the extra steps necessary to seek out the FCOI. Disclosure of FCOI within the published article is a more direct and transparent means to alert readers to FCOI when it exists.

The association between higher levels of industry compensation and reporting of FCOI identified in this study has been observed in other specialties and areas of medical research. Okike et al[1] audited financial payments from the top five manufacturers of hip and joint prostheses and identified a nondisclosure rate of 29% among physician participants at a major 2008 meeting of the American Academy of Orthopaedic Surgeons. These authors observed that disclosures were more likely for payments >$10,000, for payments directed to an individual

Table III. Industry-reported compensation transactions stratified by form of payment or transfer and author self-report of financial conflict of interest (FCOI)

Form of payment or transfer	Financial conflict disclosed	No. of payments	Median	Interquartile range	Minimum	Maximum
Cash or cash equivalent	No	1215	51.98	154.04	0.25	66,935.60
	Yes	2289	191.35	1959.75	0.13	366,971.37
In-kind items and services	No	3048	18.78	60.50	0.24	9753.40
	Yes	5622	54.58	109.40	0.06	450,584.05
Stock, stock option, or any ownership interest	No	2	349,312.30	565,389.59	66,617.50	632,007.09
	Yes	2	851,941.54	1,690,883.07	6500.00	1,697,383.07

Values represent transaction values in U.S. dollars by form of payment or transfer during a 4-year period from 2013 to 2016.

Table IV. Industry-reported compensation transactions stratified by nature of payment or transfer and author self-report of financial conflict of interest (FCOI)

Nature of payment or transfer	Financial conflict disclosed	No. of payments	Median	Interquartile range	Minimum	Maximum
Accredited training	No	1	1750.00	0.00	1750.00	1750.00
	Yes	1	2500.00	0.00	2500.00	2500.00
Consulting	No	128	1337.50	2300.00	81.25	25,550.00
	Yes	576	2500.00	3910.00	21.56	97,656.25
Education	No	51	14.25	94.95	0.45	4500.00
	Yes	89	32.96	118.88	2.09	7500.00
Entertainment	No	6	23.45	36.52	11.23	149.51
	Yes	11	37.14	454.13	13.64	2500.00
Food and beverage	No	3612	18.72	46.12	0.24	867.54
	Yes	5369	35.84	81.69	0.06	4720.50
Gift	No	1	73.87	0.00	73.87	73.87
	Yes	5	73.87	0.00	10.92	73.87
Grant	No	0	—	—	—	—
	Yes	6	701.53	424.95	374.00	1379.09
Honoraria	No	44	2000.00	2912.50	435.00	24,539.35
	Yes	66	2175.00	2437.96	250.00	44,000.00
Nonaccredited training	No	3	1500.00	1000.00	1000.00	2000.00
	Yes	17	1500.00	2900.00	36.27	12,027.80
Ownership or investment interest	No	1	66,935.60	0.00	66,935.60	66,935.60
	Yes	11	15,408.23	74,915.04	1150.22	450,584.05
Promotional speaking	No	37	2400.00	1500.00	95.85	632,007.09
	Yes	257	2500.00	1425.00	19.54	1,697,383.07
Royalty or license	No	1	51,431.59	0.00	51,431.59	51,431.59
	Yes	28	51,954.50	73,847.13	262.71	366,971.37
Travel and lodging	No	380	207.05	343.12	4.40	9753.40
	Yes	1477	240.16	373.52	0.70	14,302.20

Values represent transaction values in U.S. dollars by form of payment or transfer during a 4-year period from 2013 to 2016.

physician (rather than to a company or organization), and for payments that included an in-kind component. Physicians' explanations for their own nondisclosures included a lack of perceived relationship between the payment and presentation topic, a misunderstanding of the disclosure requirements, and errant omission of reported disclosure information from the program.[1] Beyond FCOI disclosure, higher compensation may also affect interpretation and reporting. Remarkably, a similar cut point of $9557 was associated with reporting of positive results associated

with clinical trials evaluating robotic surgery in a recent analysis of CMS Open Payments Data.[115] Although explanations related to nondisclosure were not elicited as part of our study, there is little reason to suspect that authors of PAD articles or cardiovascular research studies in general are any different. We observed a large volume of payment transactions with individual values <$5000, suggesting that use of a per-transaction dollar amount as a cut point for FCOI designation would underrepresent industry compensation to many physician authors. Such an approach may have contributed to the observation that compensation unaccompanied by reported FCOI was associated with lower median payment amounts in the current analysis.

Industry compensation may also have an impact on patients participating in clinical trials or those receiving a different treatment because of an article authored by a physician with FCOI. Kim et al[116] observed that research study candidates consider FCOI important and potentially influential in their decisions to participate or not in a study. They reported that prospective participants considered individual conflicts more concerning than institutional conflicts. Although participants in cancer trials generally considered it ethical for researchers to receive speaking or consultant fees from companies sponsoring research trials, an important minority wanted reassurances about oversight to protect against FCOI.[114] Increased scrutiny of individual and institutional FCOI has received recent high-profile coverage in the lay media, with examples of rather dramatic actions after the public discovery of nondisclosed physician and institutional compensation from industry.[4,5]

There is currently no uniform mechanism for disclosure of financial associations with publications,[117] although a variety of approaches have been proposed by physician journal editor associations.[114,118] Recommendations have principally focused on what types of information should be disclosed but have not included quantifying compensation or auditing self-reported FCOI (or lack thereof). Resources such as the CMS Open Payments and ProPublica are helpful for identifying and quantifying industry compensation to physicians in the United States, including physician authors of scientific research manuscripts. Both ProPublica and CMS Open Payments data are easily queried on the basis of limited provider information through web-based search interfaces.[8] These resources make independent verification and transparent reporting of physician compensation possible and could potentially reduce risk of misinterpretation and related nonreporting bias. Distinction between real FCOI and potential FCOI has been characterized as rooted in misunderstanding by McCoy and Emanuel,[119] who suggested that there are no "potential" conflicts of interest. Reporting all payments to the journal on submission of an article, not just those deemed relevant by the author, would allow independent third-party assessment of reportable FCOI for the reader to consider in interpreting study results. The ongoing attention to FCOI such as reported in this study should increase awareness of resources available to investigate the role of industry compensation. Screening of payment information as a matter of routine during the process of peer review and publication would certainly reduce ambiguity and avoid the need for authors to interpret relevance of their own compensation to a given study, a process that fails at least some of the time. Whereas scientific publications are an inherently public venue where a lower threshold for disclosure of FCOI might be expected, decisions related to use of drugs and devices within medical practice are shielded from public view by comparison (and were not evaluated in this analysis).

Physicians receiving compensation without reporting FCOI represented <3% of authors included in this study, indicating that >97% (the vast majority) had no industry compensation identified. These observations indicate that screening or comprehensive reporting would not affect disclosure status for most authors. Research grants from nonindustry sources were the most common category of self-reported disclosures identified in this analysis. In contrast to industry payments, which may be viewed with negative scrutiny by the academic sector (whether warranted or not), we believe that most authors are likely biased in favor of disclosing public or nonprofit grant funding that instead may be perceived as an indicator of academic accomplishment. This is one possible explanation for disclosure unaccompanied by industry payment observed in this study, which was far more common than industry compensation unaccompanied by reporting of FCOI.

Beyond allowing readers to consider potential influence of corporate compensation on physician authors, we hope that this analysis will also raise physicians' awareness of public reporting of industry payments. Physicians may not be notified directly when industry compensation to them is reported. For example, industry payments to groups may be attributed to everyone with potential to benefit regardless of their personal-level direct compensation or involvement. Payments therefore may go unrecognized by physicians who do not screen reporting through the CMS Open Payments website,[120] potentially resulting in missed opportunities to dispute or to correct this information. CMS Open Payments records are made available for review and dispute only during the calendar year in which they are submitted and attested to. A 45-day period following data publication is allotted by CMS for physicians and hospitals to review and to dispute information they believe is inaccurate; but if this window is missed, modification may not be possible.[121]

Several limitations of this analysis warrant specific mention. First, several common nonfinancial inducements that may also contribute to author bias could not be evaluated, such as authoring prestigious scientific articles, being recognized as an expert, and becoming a

key opinion leader.[108] Second, this study did not assess relevance of industry compensation to each specific article based on the journal's disclosure policy. It therefore is possible in many of these instances that nondisclosed compensation had no relevance and therefore was not FCOI. For reasons previously mentioned, however, objective assessment of the relevance of compensation on a per-study basis was not possible. Third, we restricted our analysis of industry compensation to vascular specialists enrolled as CMS providers. Payments to physicians who are not vascular specialists, nonphysician health care specialists, and authors outside the United States therefore were not captured. Thus, this study's findings cannot be generalized to nonphysician authors, authors residing outside the United States, or other specialties including primary care. Nevertheless, others have observed that some specialists may be more likely to establish financial relationships with industry. Campbell et al[117] identified a higher rate of self-reported industry financial relationships among cardiologists compared with primary care specialists, anesthesiologists, and surgeons, although family practice physicians had more frequent contact with industry representatives. Fourth, our analysis included publications from >50 different journals but did not include a survey of each journal's individual reporting requirements related to FCOI. We suspect that a comparison of the journals' reporting requirements would identify significant heterogeneity from one publication to the next, making self-reporting less intuitive and potentially increasing risk of inappropriate nondisclosure. Finally, this analysis did not distinguish between premarket and postmarket clinical studies or those directly sponsored by industry. Readers must be cognizant of the potentially greater relevance of industry influence when manufacturers compensate authors or sponsor studies evaluating new drugs or devices for introduction into clinical practice.

CONCLUSIONS

Nondisclosed author compensation from industry is relatively uncommon among highly cited PAD research studies but may be associated with substantial payments. Author reporting of all industry payments to journals at the time of article submission would allow third-party assessment of FCOI and potentially capture previously unreported FCOI. Greater transparency in industry payments and independent confirmation of FCOI in vascular research may allow readers to be more completely informed in judging the potential for bias in scientific reports.

In support of the comments within the discussion, the physician authors of this article (J.C.S. and M.A.C.) queried their own data using the ProPublica online search tool[8] and voluntarily disclose all identified industry payments:

- Dr Stanley received one payment for $98 in 2016.
- Dr Corriere received a total of 11 payments totaling $911 from 2013 to 2016 and $1500 in 2018 (a year not yet available through ProPublica) as an expert panel advisor for AIM Specialty Health, Inc.

AUTHOR CONTRIBUTIONS

Conception and design: TB, KSB, MC
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