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, including 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 $94,940 [$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)
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. 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 pro-industry conclusions or restrict publication and data sharing.

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. Undisclosed FCOI has received significant attention from both the scientific community and lay press media, especially for relationships between physicians and manufacturers of treatments for cancer and orthopedics. 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. 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.

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 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.

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 α = .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 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 $111,399,987 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 1,116 during the study period. The majority of transactions (97.8%) had a value below $5,000 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 = 7 [13%]; 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)

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<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant</td>
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<td>33.8</td>
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<tr>
<td>Advisory board</td>
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<td>15.3</td>
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<td>Honoraria</td>
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<td>13.1</td>
</tr>
<tr>
<td>Lecture fee</td>
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<td>6.4</td>
</tr>
<tr>
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<td>5.9</td>
</tr>
<tr>
<td>Shareholder</td>
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<td>5.6</td>
</tr>
<tr>
<td>Personal fees</td>
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<td>4.8</td>
</tr>
<tr>
<td>Committee</td>
<td>18</td>
<td>4.8</td>
</tr>
<tr>
<td>Travel expenses</td>
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<td>2.9</td>
</tr>
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<td>Patent</td>
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</tr>
<tr>
<td>Royalties</td>
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<td>1.6</td>
</tr>
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</table>

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 $94,944 [$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 ($2,355,918). 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 ($2,500 [$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, 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. 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. 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...
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. Even free meals have demonstrated influence on physicians’ opinions of pharmaceuticals and other medical products. 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. 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. 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. 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 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

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

<table>
<thead>
<tr>
<th>Self-reported primary specialty</th>
<th>No.</th>
<th>Median total payment</th>
<th>Interquartile range</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional cardiology</td>
<td>19</td>
<td>57,998.84</td>
<td>636,574.43</td>
<td>824.86</td>
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<tr>
<td>Vascular surgery</td>
<td>14</td>
<td>3764.17</td>
<td>43,972.76</td>
<td>735.88</td>
<td>339,881.03</td>
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<td>Thoracic surgery (cardiothoracic vascular surgery)</td>
<td>9</td>
<td>19,470.01</td>
<td>77,700.78</td>
<td>442.57</td>
<td>169,276.00</td>
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<td>Cardiovascular disease</td>
<td>7</td>
<td>14,511.16</td>
<td>49,323.82</td>
<td>552.14</td>
<td>511,544.26</td>
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<tr>
<td>Vascular and interventional radiology</td>
<td>4</td>
<td>173,610.40</td>
<td>298,075.33</td>
<td>2315.43</td>
<td>404,277.14</td>
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<td>Surgery</td>
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<td>16,487.09</td>
<td>285,127.44</td>
<td>6352.12</td>
<td>291,479.56</td>
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</table>

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.

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**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.
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. 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

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

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<td>Travel and lodging</td>
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<td>240.16</td>
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<td>14,302.20</td>
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Values represent transaction values in U.S. dollars by form of payment or transfer during a 4-year period from 2013 to 2016.
with clinical trials evaluating robotic surgery in a recent analysis of CMS Open Payments Data. 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 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.

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, 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.

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
concerns.

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 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
Analysis and interpretation: TB, CH, KSB, JS, MC
Data collection: TB, CH, MC
Writing the article: TB, KSB, JS, MC
Critical revision of the article: TB, CH, KSB, JS, MC
Final approval of the article: TB, CH, KSB, JS, MC
Statistical analysis: TB, MC
Obtained funding: Not applicable
Overall responsibility: MC

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119. McCoy MS, Emanuel EJ. Why there are no “potential” conflicts of interest. JAMA 2017;317:1721-2.
