

## SPECIAL ARTICLE

# Accuracy of Conflict-of-Interest Disclosures Reported by Physicians

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## ABSTRACT

**BACKGROUND**

The recent public reporting of payments made to physicians by manufacturers of orthopedic devices provides an opportunity to assess the accuracy of physicians' conflict-of-interest disclosures.

**METHODS**

We analyzed the reports of payments made to physicians by five manufacturers of total hip and knee prostheses in 2007. For each payment recipient who was an author of a presentation or served as a committee member or board member at the 2008 annual meeting of the American Academy of Orthopaedic Surgeons, the disclosure statement was reviewed to determine whether the payment had been disclosed. To ascertain the reasons for nondisclosure, a survey was administered to physicians who had received payments that were not disclosed.

**RESULTS**

The overall rate of disclosure was 71.2% (245 of 344 payments). For payments that were directly related to the topic of the presentation at the meeting, the rate was 79.3% (165 of 208); for payments that were indirectly related, the rate was 50.0% (16 of 32); and for payments that were unrelated, the rate was 49.2% (29 of 59) ( $P=0.008$ ). In the multivariate analysis, payments were also more likely to have been disclosed if they exceeded \$10,000 ( $P<0.001$ ), were directed toward an individual physician rather than a company or organization ( $P=0.04$ ), or included an in-kind component ( $P=0.002$ ). Among the 36 physicians who responded to the survey regarding reasons for nondisclosure (response rate, 39.6%), the reasons most commonly given for nondisclosure were that the payment was unrelated to the topic of presentation at the annual meeting (38.9% of respondents) and that the physician had misunderstood the disclosure requirements (13.9%); 11.1% reported that the payment had been disclosed but was mistakenly omitted from the program.

**CONCLUSIONS**

In this study of self-reported conflict-of-interest disclosure by physicians at a large annual meeting, the rate of disclosure was 79.3% for directly related payments and 50.0% for indirectly related payments.

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**F**INANCIAL CONFLICT OF INTEREST IN BIO-medical research has been associated with a number of potential pitfalls, including an increased likelihood of positive (pro-industry) conclusions,<sup>1-25</sup> the suppression of negative results,<sup>26-30</sup> restrictions on the behavior of the investigators,<sup>19</sup> and the use of biased study designs.<sup>19</sup> Although some academic medical centers have sought to manage the financial relationships of their investigators, most interested parties — including the U.S. government, professional organizations, and medical journals — have required only that potential conflicts of interest, including those that were present at the time of publication or presentation of the research, be fully disclosed.<sup>31</sup> Historically, these disclosures have nearly always been reported by physicians, and there have been no means of confirmation or verification. However, there is reason to believe that this policy may change in the near future, since there is legislation currently pending in the U.S. Congress that would require companies to publicly disclose payments made to physicians.<sup>32</sup>

Recently, the five companies that account for nearly 95% of the market for total hip and knee prostheses — Biomet, DePuy, Smith and Nephew, Stryker, and Zimmer — were required, as part of a settlement with the U.S. Department of Justice,<sup>33</sup> to make public all payments that were made to physicians during the 2007 calendar year (see the Supplementary Appendix, available with the full text of this article at NEJM.org). We used these disclosures to collect information on company payments to physicians that were not reported by the physicians.

The purpose of this study was to assess the extent to which conflict-of-interest disclosures made by physicians reflected payments made to these physicians, as reported by for-profit companies. To this end, we analyzed the payments that were made to physicians in 2007, as reported by five leading manufacturers of orthopedic devices, and compared them with conflict-of-interest disclosures made by physicians who were authors of presentations or served as board members or committee members at the 2008 annual meeting of the American Academy of Orthopaedic Surgeons. Our primary outcome measure was the accuracy of conflict-of-interest disclosures as reported by physicians. Secondary research questions centered on factors that are potentially associated with conflict-of-interest disclosure.

## METHODS

### COMPANY PAYMENTS AND RECIPIENTS

In December 2007, we accessed the Web pages for Biomet,<sup>34</sup> DePuy,<sup>35</sup> Smith and Nephew,<sup>36</sup> Stryker<sup>37</sup> and Zimmer<sup>38</sup> on which company consultants are listed. For each recipient identified on the Web pages, we recorded the recipient's last name, first name, middle initial (when available), and country, as well as the amount of monetary and in-kind payments the consultant received during the 2007 calendar year. Monetary payments included "any and all compensation or remuneration paid to or for the benefit of Consultants, including but not limited to payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, clinical studies, professional meetings, product training, medical education, research funding, product development services, . . . advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property."<sup>39</sup> In-kind payments, defined as payments that were made "in other than dollar form," included lodging, meals, transportation, conference tuition, gifts, and corporate assistance for a clinical study.<sup>39</sup>

To calculate total payment amounts, the monetary and in-kind payments were summed for each recipient. For payments that were reported as a range (e.g., \$1 to \$24,999), the average of the minimum and maximum values was recorded. Payments were categorized as having been made directly to an individual person or indirectly to one or more persons through payment to a company or organization. For a payment that was made to more than one person, we estimated the amount each person received by dividing the total payment by the number of recipients. For recipients who were identified multiple times by the same company (e.g., as an individual and as a member of a group), payments were summed and collapsed into a single value. Nonphysicians were excluded from the analysis, as were recipients who were identified only by group name (e.g., a hospital department or a practice group in which no individual physicians were listed).

### THE ANNUAL MEETING

The 2008 annual meeting of the American Academy of Orthopaedic Surgeons was held from

March 5 through March 9 in San Francisco. To determine whether a payment recipient attended the annual meeting, we compared the names of all payment recipients with the names of physicians who were authors of presentations or served as board members or committee members at the annual meeting, as listed in the final meeting program. This comparison was made on the basis of last name, first name, and middle initial (when available). For each payment recipient who was found to have participated in the annual meeting, the participant was classified as an author of a podium presentation, an author of a poster presentation, a presenter at a symposium, a lecturer at an instructional course, a presenter at a multimedia education program, a presenter at a scientific exhibit, a board member, or a member of an annual-meeting committee or subcommittee.

#### PAYMENT RELATEDNESS

To assess the relationship between the company payment and the topic of the presentation at the annual meeting, one of us reviewed the abstracts of all presentations for which payment recipients were identified as authors. In addition, the abstracts associated with one third of the payments were reviewed by a second, independent reviewer so that interobserver reliability could be assessed. During this review process, each reviewer was unaware of all information on any conflict of interest the author of each abstract may have had, as well as on the author's conflict-of-interest disclosure, and was also unaware of the responses of the other reviewer.

Since the five companies in question specialize in the manufacture of hip and knee prostheses, a payment was considered to be directly related to the presentation at the annual meeting if total hip or knee implants, or both, were the specific focus of the presentation (e.g., in a report on a follow-up study of total joint replacements). A payment was considered to be indirectly related if the presentation involved hip or knee arthroplasty but focused on something other than hip or knee implants (e.g., a report on a study of antibiotic prophylaxis in total joint-replacement surgery). A payment was considered to be unrelated if the presentation in question did not involve total hip or knee arthroplasty. In the case of 13.1% of the payments (45 of 344), no presentation abstract was available, and relatedness was classified as unknown. In the case of annual-meeting participants who were authors of more than one presentation, the highest level of relatedness was used to determine the overall payment relatedness. For example, if a participant was an author of one directly related presentation and one unrelated presentation at the meeting, the payment was considered to be directly related to the topic of the presentation.

#### CONFLICT-OF-INTEREST DISCLOSURE

Each author of a presentation, board member, and committee member who participated in the 2008 annual meeting was required to disclose "if he or she has received something of value from a commercial company or institution, which relates directly or indirectly to the subject of their presentation"<sup>40</sup> (see the Supplementary Appendix). Disclosures had to be submitted by October 15, 2007, and participants were required to disclose all potential conflicts of interest that had occurred within the preceding 12 months. In accordance with the existing policy of the American Academy of Orthopaedic Surgeons, conflicts of interest were to be categorized as research or institutional support (code a); miscellaneous nonincome support, commercially derived honoraria, or other funding unrelated to research (code b); royalties (code c); stock or stock options (code d); or consultant or employee payments (code e). Completion of the disclosure form was mandatory, and participants with no conflicts of interest were required to indicate that nothing of value had been received. Self-reported conflict-of-interest disclosures were printed in the final program of the annual meeting under a section entitled "Disclosure."

**Table 1. Payments Made by Five Manufacturers of Hip and Knee Prostheses to 1162 Consultants in 2007.\***

Variable	Payment (N=1347)
Payment type — no. (%)	
Monetary and in-kind	834 (61.9)
Monetary only	389 (28.9)
In-kind only	124 (9.2)
Payment amount — \$	
Median	17,181.00
Mean	150,758.16
Minimum	6.13
Maximum	7,026,617.00

\* Several physicians received payments from more than one company. Data were obtained from the Web pages of each of the five companies on which company consultants are listed.

In the case of each payment recipient who was an author of a presentation or who served as a board member or committee member at the annual meeting, the disclosure statement that was printed in the final program was compared with the payment reports from the company. If the meeting participant reported having received something of value from the company in question (code a, b, c, d, or e), the conflict of interest was considered to have been disclosed. If the company had reported a payment to a participant but that participant did not report having received anything of value from the company in question, the conflict of interest was considered not to have been disclosed. The accuracy of disclosure was assessed independently by two investigators.

#### SURVEY

To ascertain the reasons for nondisclosure, a survey was administered to the 91 physicians who did not disclose payments in the final program of the 2008 annual meeting. Survey recipients were informed that participation was voluntary and that all responses would be kept confidential and would be reported only in aggregate form. The survey was administered by the McMaster University Division of Orthopaedic Surgery, with all elements approved by the research ethics board at McMaster University.

Survey recipients were asked to choose from a list of potential reasons for nondisclosure that included the following: the payment was unrelated to the presentation topic, the payment was unknown at the time of disclosure, the payment had been received after the disclosure deadline, the payment was not large enough to warrant disclosure, the payment was unintentionally omitted, the payment was intentionally omitted, the payment was disclosed but was mistakenly omitted from the annual-meeting program; the requirement for disclosure was not known; and other reason (open-ended response; see the Supplementary Appendix). Open-ended responses that were considered to be similar to an existing category were included in that category for the analysis.

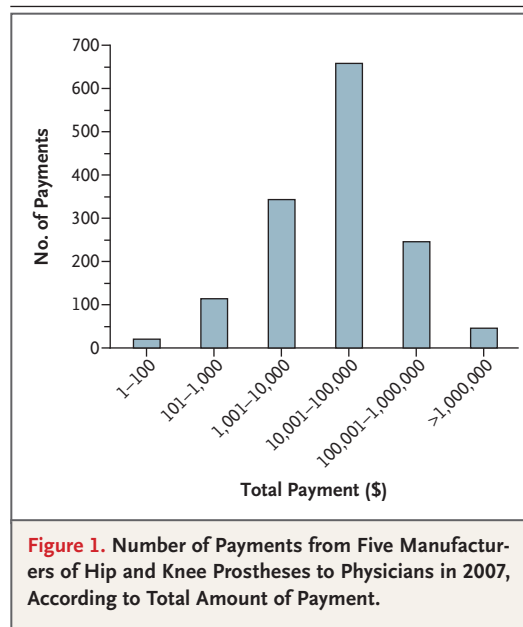
The surveys were initially administered by e-mail in February 2009. If no response was received, the survey was sent again 3 weeks later. In a final attempt to increase the number of responses, survey recipients who had not responded by March 2009 were contacted by telephone.

#### STATISTICAL ANALYSIS

Agreement between reviewers on the assessment of disclosure accuracy and on payment relatedness was assessed through reliability analysis with the use of the intraclass correlation coefficient (two-way random single measures). To analyze the factors associated with disclosure, univariate and multivariate logistic regressions were performed. Factors that were found to be significant in the univariate analysis were retained in the multivariate model. In the multivariate analysis, all variables were simultaneously entered into the model, with adjustment of each variable for all the others. Associations were initially estimated on the basis of odds ratios and 95% confidence intervals. To derive estimates of relative risk, odds ratios and 95% confidence intervals were corrected for common outcomes with the use of methods described by Zhang and Yu.<sup>41</sup> P values of less than 0.05 were considered to indicate statistical significance. All reported P values are two-sided and have not been adjusted for multiple comparisons. Statistical analysis was performed with the use of SAS software, version 9 (SAS).

#### RESULTS

From the Web pages listing company consultants, we identified 1347 payments that were made to 1162 physicians during the 2007 calendar year (Table 1). A total of 166 physicians received payments from multiple companies, including 147



**Table 2. Payments to Presentation Authors, Board Members, and Committee Members Who Participated in the Annual Meeting of the American Academy of Orthopaedic Surgeons.**

Variable	Payment (N=344)
Company — no. (%)	
Biomet	40 (11.6)
DePuy	81 (23.5)
Smith and Nephew	49 (14.2)
Stryker	54 (15.7)
Zimmer	120 (34.9)
Amount of payment — no. (%)	
<\$10,000	63 (18.3)
\$10,000–\$100,000	135 (39.2)
>\$100,000	146 (42.4)
Payment made to an individual physician — no. (%)	
No	74 (21.5)
Yes	270 (78.5)
Payment included an in-kind component — no. (%)	
No	82 (23.8)
Yes	262 (76.2)
Role of payment recipient at annual meeting — no. (%)*	
Author of podium presentation	197 (57.3)
Author of poster presentation	163 (47.4)
Symposium presenter or instructional-course lecturer	154 (44.8)
Multimedia-education or scientific-exhibit presenter	76 (22.1)
Member of board of directors or annual-meeting committee or subcommittee	43 (12.5)
Relationship between company payment and recipient's topic of presentation at annual meeting — no./total no. (%)†	
Unrelated	59/299 (19.7)
Indirectly related	32/299 (10.7)
Directly related	208/299 (69.6)

\* Several payment recipients had multiple roles at the annual meeting.

† A total of 45 payments for which presentation abstracts were unavailable and relatedness was classified as unknown are not included.

who received payments from two companies, 18 who received payments from three companies, and 1 who received payments from four companies. All payment recipients were from the United States. There were 282 payments that exceeded \$100,000 during the 2007 calendar year, including 47 payments that totaled more than \$1 million (Fig. 1).

Approximately one quarter (25.5%) of the

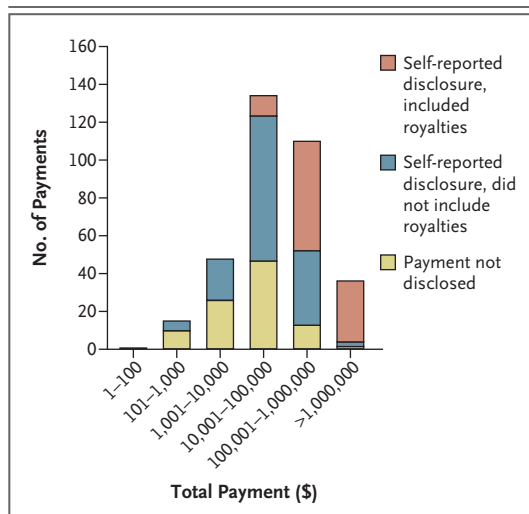
payments that were made in 2007 (344 of 1347 payments) were made to physicians who were authors of presentations or who served as committee members or board members at the 2008 annual meeting of the American Academy of Orthopaedic Surgeons. In the majority of cases (69.6%; 208 of the 299 payments that could be evaluated for relatedness), the payment in question was directly related to the topic of the presentation at the annual meeting (Table 2). In the case of most of the large payments, the recipient's reported disclosure statement included the disclosure of royalties (Fig. 2).

Agreement between the reviewers in the assessment of disclosure accuracy and payment relatedness was excellent (intraclass correlation coefficient, 1.00 [344 of 344 payments, or 100%] for disclosure accuracy; and 0.88 [112 of 118, or 94.9%] for payment relatedness). The overall disclosure rate was 71.2% (245 of 344 payments), including 79.3% (165 of 208) for directly related payments, 50.0% (16 of 32) for indirectly related payments, and 49.2% (29 of 59) for unrelated payments ( $P=0.008$ ). In the multivariate analysis, payments were also more likely to be disclosed if they totaled between \$10,000 and \$100,000 ( $P<0.001$ ) or were in excess of \$100,000 ( $P<0.001$ ), were directed toward an individual physician ( $P=0.04$ ), included an in-kind component ( $P=0.002$ ), were made to a symposium presenter or instructional-course lecturer ( $P<0.001$ ) at the annual meeting, or were made to a board or committee member ( $P=0.009$ ) (Table 3).

The response rate for the survey on nondisclosure was 39.6% (36 of 91 physicians). The reasons most commonly given for nondisclosure were that the payment was unrelated to the topic of the presentation at the annual meeting (38.9%; 14 of 36 physicians) and that the disclosure requirements were misunderstood (13.9%; 5 of 36); 11.1% of the survey respondents (4 of 36) reported that the payment had been disclosed but was inaccurately printed in the program (Table 4).

## DISCUSSION

In this observational study of conflict-of-interest disclosure by physicians, payments were more likely to be disclosed if they were directly related to the topic of presentation, exceeded \$10,000, were directed to an individual recipient, included



**Figure 2. Number of Company Payments in 2007 to Physicians Who Participated in the 2008 Meeting of the American Academy of Orthopaedic Surgeons, According to Physicians' Reported Disclosure.**

Data are for payments made by five manufacturers of hip and knee prostheses to presentation authors, board members, and committee members at the annual meeting of the American Academy of Orthopaedic Surgeons.

an in-kind component, or were made to a symposium presenter, instructional-course lecturer, or board or committee member.

The most notable finding of our study, however, was the high rate of nondisclosure. A total of 20.7% of directly related payments and 50.0% of indirectly related payments received during the 2007 calendar year were not disclosed, despite instructions directing each participant to make a disclosure "if he or she has received something of value from a commercial company or institution, which relates directly or indirectly to the subject of their presentation."<sup>40</sup> The size of these undisclosed payments was substantial: the 43 directly related payments that were not disclosed totaled \$4,320,563, and the 16 indirectly related payments that were not disclosed totaled \$7,772,105.

There are many possible explanations for this high rate of nondisclosure. One possibility is that the physicians in question did not consider the undisclosed payments to have been related to the subject of their presentation. In our survey of physicians who did not disclose payments, the leading reason for nondisclosure was the lack of

relatedness between the payment and the presentation topic. However, even among payments that we found to be directly related to the topic of presentation, the rate of disclosure was only 79.3%. Current criteria for determining what constitutes a related payment can be somewhat subjective and open to interpretation, and this may have contributed to the observed discrepancies. In situations of uncertainty, physicians are encouraged to err on the side of overdisclosure, because disclosure gives audience members the opportunity to assess the material being presented with the most complete information available. Another potential explanation for the observed rates of nondisclosure is confusion regarding disclosure requirements, which was also identified by survey respondents as a contributing factor. The policies regarding conflict of interest and its disclosure are constantly in flux, and it is possible that additional education regarding disclosure requirements may be needed.

Our study has several limitations. First, we assessed payment relatedness by comparing the topic of presentation at the annual meeting with the specialty of the companies in question (total hip and knee replacement); this method of determining payment relatedness could have underestimated the number of unrelated payments and, consequently, the overall rate of disclosure. However, the proportion of undisclosed payments that we found to be unrelated (33.7%; 30 of 89) was similar to the proportion of survey recipients who reported that nondisclosure was due to the lack of relatedness between the payment and the topic of presentation (38.9%; 14 of 36). Second, conflict-of-interest disclosures were obtained from the final program of the annual meeting, and the use of this source could have led to an underestimation of the disclosure rate, given that 11.1% of survey recipients reported disclosing conflicts that were not printed in the program. Although disclosures made by individual physicians at the time of their actual presentations may have provided better information, we consider disclosures made in the final program to be the most relevant, since this document represents a permanent record of the conference and is often used for research purposes. Third, payment recipients were matched to annual-meeting participants on the basis of name, which could have led to mismatches in the case of participants who shared

Table 3. Factors Associated with Disclosure of Payments.*					
Factor	Rate of Disclosure  <i>no. of payments/ total no. (%)</i>	Univariate Analysis		Multivariate Analysis	
		Relative Risk for Disclosure (95% CI)	P Value	Relative Risk for Disclosure (95% CI)	P Value
Company					
Biomet	29/40 (72.5)	1.00	—	NA	NA
DePuy	59/81 (72.8)	1.01 (0.74–1.19)	0.97	NA	NA
Smith and Nephew	30/49 (61.2)	0.85 (0.54–1.09)	0.27	NA	NA
Stryker	42/54 (77.8)	1.07 (0.80–1.24)	0.56	NA	NA
Zimmer	85/120 (70.8)	0.98 (0.73–1.16)	0.84	NA	NA
Payment amount					
<\$10,000	27/63 (42.9)	1.00	—	1.00	—
\$10,000–\$100,000	87/135 (64.4)	1.50 (1.16–1.79)	0.005	1.79 (1.42–2.03)	<0.001
>\$100,000	131/146 (89.7)	2.09 (1.88–2.20)	<0.001	2.06 (1.76–2.18)	<0.001
Payment made to an individual physician					
No	34/74 (45.9)	1.00	—	1.00	—
Yes	211/270 (78.1)	1.70 (1.47–1.87)	<0.001	1.41 (1.02–1.72)	0.04
Payment included an in-kind component					
No	38/82 (46.3)	1.00	—	1.00	—
Yes	207/262 (79.0)	1.71 (1.49–1.88)	<0.001	1.57 (1.22–1.82)	0.002
Role of payment recipient at annual meeting					
Author of podium presentation					
No	104/147 (70.7)	1.00	—	NA	NA
Yes	141/197 (71.6)	1.01 (0.86–1.13)	0.87	NA	NA
Author of poster presentation					
No	124/181 (68.5)	1.00	—	NA	NA
Yes	121/163 (74.2)	1.08 (0.94–1.20)	0.24	NA	NA
Symposium presenter or instructional-course lecturer					
No	111/190 (58.4)	1.00	—	1.00	—
Yes	134/154 (87.0)	1.50 (1.36–1.59)	<0.001	1.49 (1.30–1.61)	<0.001
Multimedia-education or scientific-exhibit presenter					
No	191/268 (71.3)	1.00	—	NA	NA
Yes	54/76 (71.1)	1.00 (0.81–1.14)	0.97	NA	NA
Member of board of directors or annual-meeting committee or subcommittee					
No	208/301 (69.1)	1.00	—	1.00	—
Yes	37/43 (86.0)	1.25 (1.04–1.36)	0.008	1.32 (1.11–1.40)	0.009
Relationship between company payment and topic of recipient's presentation†					
Unrelated	29/59 (49.2)	1.00	—	1.00	—
Indirectly related	16/32 (50.0)	1.02 (0.61–1.43)	0.94	0.74 (0.34–1.25)	0.32
Directly related	165/208 (79.3)	1.62 (1.38–1.79)	<0.001	1.49 (1.14–1.74)	0.008

\* Only factors that were found to be significant in the univariate analysis were retained in the multivariate model. NA denotes not applicable.

† A total of 45 payments for which presentation abstracts were unavailable and relatedness was classified as unknown are not included.

the same name. However, this is unlikely to have occurred very often within the relatively small community of American orthopedic surgeons. Fourth, our study is limited by the fact that company payment reports were accessed in December 2007, whereas conflict-of-interest disclosures were required to be submitted by October 2007. However, the effect of this discrepancy is unlikely to have been substantial, given that all 120 annual-meeting participants identified on the Zimmer disclosure list as of December 2007<sup>38</sup> were already on the list as of October 2007.<sup>42</sup> In addition, none of the physicians surveyed indicated that receipt of payments after the disclosure deadline may have been a factor in nondisclosure of payment. Finally, our study is limited by the fact that our survey on reasons for nondisclosure had a relatively low response rate.

Currently, disclosures by physicians are largely self-reported, but there is reason to suspect that this may change in the near future. Legislation requiring all drug and device manufacturers to publicly disclose payments to physicians is currently pending in the U.S. Congress<sup>32</sup> and has been met with widespread support. On the basis of the results of our study, one might expect the adoption of such policies to allow the identification of conflicts of interest that were previously undisclosed.

Dr. Kocher reports receiving grant support from ConMed Linvatec and serving as a consultant for ConMed Linvatec, Covidien, EBI (a subsidiary of Biomet), and Smith and Nephew;

**Table 4. Results of the Survey Regarding Nondisclosure of Payments.**

Reason for Nondisclosure	Physicians Who Responded (N = 36)*
	no. (%)
Payment unrelated to topic of presentation at annual meeting	14 (39)
Disclosure requirements misunderstood	5 (14)
Payment disclosed but mistakenly omitted from annual-meeting program	4 (11)
Disclosure process handled by coauthor who did not communicate disclosure requirements	3 (8)
Payment unintentionally omitted from disclosure statement	2 (6)
Payment not large enough to be disclosed	1 (3)
Payment unknown at the time of disclosure	0
Payment received after disclosure deadline	0
Payment intentionally omitted from disclosure statement	0
Other reason given	2 (6)
No reason given	8 (2)

\* Some physicians gave multiple reasons for nondisclosure of payment.

Dr. Mehlman, receiving grant support from Abbott Spine (now part of Zimmer), DePuy Spine, Globus Medical, Medtronic, and Synthes; and Dr. Bhandari, receiving grant support from DePuy, Smith and Nephew, Stryker, and Zimmer and serving as a consultant for Amgen, Osteogenix, Pfizer, and Zelos Therapeutics. No other potential conflict of interest relevant to this article was reported.

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