

ONLINE FIRST

From Disclosure to Transparency

The Use of Company Payment Data

Susan Chimonas, PhD; Zachary Frosch, BA; David J. Rothman, PhD

Background: It has become standard practice in medical journals to require authors to disclose their relationships with industry. However, these requirements vary among journals and often lack specificity. As a result, disclosures may not consistently reveal author-industry ties.

Methods: We examined the 2007 physician payment information from 5 orthopedic device companies to evaluate the current journal disclosure system. We compared company payment information for recipients of \$1 million or more with disclosures in the recipients' journal articles. Payment data were obtained from Biomet, DePuy, Smith & Nephew, Stryker, and Zimmer. Disclosures were obtained in the acknowledgments section, conflict of interest statements, and financial disclosures of recipients' published articles. We also assessed variations in disclosure by authorship position, payment-article relatedness, and journal disclosure policies.

Results: Of the 41 individuals who received \$1 million or more in 2007, 32 had published articles relating to orthopedics between January 1, 2008, and January 15, 2009. Disclosures of company payments varied considerably. Prominent authorship position and article-payment relatedness were associated with greater disclosure, although nondisclosure rates remained high (46% among first-, sole-, and senior-authored articles and 50% among articles directly or indirectly related to payments). The accuracy of disclosures did not vary with the strength of journals' disclosure policies.

Conclusions: Current journal disclosure practices do not yield complete or consistent information regarding authors' industry ties. Medical journals, along with other medical institutions, should consider new strategies to facilitate accurate and complete transparency.

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OVER THE PAST 25 YEARS, IT has become standard practice in medical journals to require authors to disclose relationships with industry.¹⁻³ However, the requirements vary across journals and often lack specificity. It is left to authors to determine the appropriate period for disclosure or the relevance of a financial relationship to a submitted article. As a result, disclosures may be inconsistent, with neither reviewers nor readers fully informed of the ties between authors and industry.⁴

We now stand on the brink of an extraordinary change. Pharmaceutical and medical device companies are publicly reporting data on physician payments. Under settlement agreements with the US Department of Justice or in an effort to improve public reputation, 15 companies are releasing information about their payments to physicians and health care orga-

nizations.⁵⁻⁷ Even more notably, the newly enacted health care reform legislation requires commercial health care entities to disclose gifts and payments to physicians.⁸ Beginning in 2013, manufacturers of pharmaceuticals, medical devices, biological products, and medical supplies must report all payments to physicians worth more than \$10. The information will be publicly available and searchable online.

The industry payment data currently available provide a unique opportunity to evaluate the strengths and weaknesses of traditional disclosure mechanisms. Although some company data have been online since 2007, they have not been systematically analyzed. One important exception is a recent study that compared device company payment information with the disclosures (as printed in the program) by presenters and board and committee members at the 2008 annual meeting of the American Academy of Or-

Author Affiliations: Center on Medicine as a Profession, College of Physicians and Surgeons, Columbia University, New York, New York.

thopedic Surgeons.⁹ The authors identified as their “most notable finding . . . the high rate of nondisclosure” (29% [99 of 344]).^{9(p1471)}

Although accurate disclosure of industry relationships is vital to the integrity of professional meetings, full disclosure in medical journal articles is of even greater concern. These articles constitute a permanent scientific record that is used by practicing physicians, guideline committees, purchasers, and patients to evaluate treatment options. Journal editors, reviewers, and readers must be fully informed about authors’ industry relationships to consider the potential for bias.^{1,10,11}

Our analysis compares device company payment information with disclosures of industry ties in published journal articles. We examined the 2007 physician payment information from 5 orthopedic device companies—Biomet, DePuy Orthopedics, Smith & Nephew, Stryker, and Zimmer—to evaluate the transparency provided by the current system.^{5,7} We assessed the completeness and accuracy of the information provided by published disclosures and used the findings to propose more effective means for promoting transparency.

METHODS

We downloaded disclosures of all device company payments to their “consultants” in 2007. “Consultants” included individuals, as well as hospitals, academic medical centers, professional medical associations, foundations, and corporations who received payments for “services relating to hip and knee reconstruction and replacement.”⁵ Companies specified only whether payments were direct or “in-kind” (reimbursements), not what service the direct payment was for (eg, consulting, royalties, honoraria).

We analyzed the distribution of company payments and then selected for closer analysis individuals who received \$1 million or more in direct payments from a single manufacturer (including 1 individual who received more than \$1 million from each of 2 companies). We selected that cohort because many journal reviewers and readers would find relevant a \$1 million payment from an orthopedic device manufacturer to an author writing about orthopedics, whether or not the article specifically addressed that company’s products.^{12,13} Our preliminary analysis also indicated that this cohort accounted for the majority of the funds dispersed to individuals.

We obtained recipients’ publications in orthopedic journals or where the title indicated orthopedic content using Publication Harvester software, which uses the PubMed database to locate authors’ publications.¹⁴ This program allowed us to search different versions of an authors’ name to obtain as complete and accurate a list as possible. If we remained uncertain whether an article was written by the recipient in question, the institution listed in the article was matched to the city and state in the company database.

We sampled each individual’s most recent articles over the period January 1, 2008, to January 15, 2009, to ensure that the authors had received the 2007 payment of \$1 million or more by the time the article appeared in print. To obtain an adequate sample of each individual’s publications while avoiding overweighting frequent publishers, we examined all articles over this period for those who published 3 or fewer articles, the 3 most recent articles for those who published 4 or 5 articles, the 4 most recent articles for those who published between 6 and 10 articles, and the 5 most recent articles for those who published 11 or more articles.

We reviewed articles’ acknowledgments, conflict of interest statements, and financial disclosures to determine whether company payments were acknowledged. We examined each article to see whether it disclosed any relationship with the company from which the author received at least \$1 million and whether it provided information regarding the size of the payment. We also determined whether multiple articles by the same author consistently disclosed a company relationship, inconsistently disclosed a relationship, or never disclosed.

We assessed whether greater disclosure was associated with the strength of journals’ disclosure policies (based on the disclosure standards outlined in the Uniform Manuscript Requirements of the International Committee of Medical Journal Editors [ICMJE], in place in 2007). The ICMJE recommends that journals require authors to (1) disclose all financial relationships that might bias the work; (2) disclose all personal relationships that might bias the work; (3) state explicitly whether conflicts exist or not; (4) identify sources of funding; (5) declare what role the study sponsor had in data collection, analysis, or manuscript preparation; and (6) inform study participants of the author’s conflict of interest. We correlated the number of ICMJE policy areas a journal endorsed with the proportion of articles appearing in that journal that disclosed the author’s company relationship.¹⁵ We also conducted journal-level *t* tests to examine associations between the proportion of author-recipient disclosure in each journal and whether that journal endorsed specific ICMJE policy areas.

In addition, we explored differences in disclosure by authorship position and payment-article relatedness. For each article, we recorded the payment recipient’s rank in the list of authors (first/sole, middle, or senior). Payment-article relatedness was assessed using a method similar to that of Okike et al⁹: articles focusing on hip or knee implants were coded as “directly related” to company payments; those involving hip or knee arthroplasty but focusing on topics other than implants (eg, surgical techniques, procedures for measuring alignment or assessing/managing anatomic variations in patients) were categorized as “indirectly related”; and articles were considered “unrelated” if they did not involve hip or knee arthroplasty. Two coders (S.C. and a research assistant) reviewed all 95 articles so that intercoder reliability could be observed. During the coding process, each reviewer was blinded to the authors’ conflict of interest information and the codes of the other reviewer.

RESULTS

DISTRIBUTION OF PAYMENTS

The 5 manufacturers, in aggregate, made 1654 direct payments in 2007, amounting to \$248 million (**Table 1**). The mean payment to all “consultants” was \$150 000, and the median was \$13 850. Individuals received 985 payments totaling \$184 million (81% of total funds); the mean and median were \$187 000 and \$17 500, respectively. Such a disparity between the mean and median values suggests that a few very high-value payments skewed the distribution. In fact, 40 individuals (38 physicians and 2 nonphysician researchers with PhDs) received at least \$1 million from a single manufacturer, and 1 physician received more than \$1 million from each of 2 companies. Payments to these 41 recipients ranged from \$1 042 238 to \$8 862 500, with a mean of \$2 781 866 (median \$2 187 500). This cohort received \$114 million, 62% of the total funds disbursed. In effect, most of the com-

Table 1. Distribution of 2007 Company Payments

Company	Total Value of Payments, \$ (%) ^a	Mean/Median Value of Payments, \$ ^a	Total Value of Payments to All Individuals, \$ (%) ^a	Mean/Median Value of Payments to All Individuals, \$ ^a	Total Value of Payments to Recipients Receiving ≥\$1 Million, \$ (%) ^a	Mean/Median/Maximum Value of Payments to Recipients Receiving ≥\$1 Million, \$ ^a
Biomet	27 785 000 (11)	159 000/13 000	19 148 000 (10)	168 000/13 000	7 175 000 (6)	1 794 000/1 825 000/3 463 000
DePuy	63 088 000 (26)	132 000/8000	47 346 000 (26)	187 000/9000	31 663 000 (28)	4 523 000/2 938 000/8 863 000
Smith & Nephew	24 166 000 (10)	103 000/20 000	19 296 000 (11)	146 000/22 000	12 663 000 (11)	2 533 000/2 438 000/3 138 000
Stryker	45 643 000 (18)	183 000/38 000	36 906 000 (20)	238 000/38 000	19 149 000 (17)	2 394 000/2 437 000/4 313 000
Zimmer	87 545 000 (35)	169 000/18 000	61 049 000 (33)	184 000/18 000	43 408 000 (38)	2 412 000/1 895 000/7 027 000
Total	248 226 000	150 000/14 000	183 744 000	187 000/18 000	114 057 000	2 716 000/2 199 000/8 863 000

^aTo nearest \$1000.

Table 2. Number of Publications and Disclosures of Payment of \$1 Million or More per Company

Company	No.	No. (%)	
	Articles in Sample Written By Payment Recipients	Articles in Sample Identifying Company Name	Articles in Sample Disclosing Payment "Exceeds \$10,000"
Biomet	8	6 (75)	1 (13)
DePuy	19	10 (53)	4 (21)
Smith & Nephew	9	3 (33)	0
Stryker	17	12 (71)	0
Zimmer	38	10 (26)	2 (5)
Total	91^a	41 (45)	7 (8)

^aThe 4 articles written by 1 author who received \$1 million or more from each of 2 companies are excluded only from the company-by-company analysis.

pany funds went to a small minority of recipients, and these recipients became the focus for our analysis.

FREQUENCY OF DISCLOSURE

Of the 41 individuals who received \$1 million or more in 2007, 32 published a total of 151 articles relating to orthopedics between January 1, 2008, and January 15, 2009. These authors published an average of 5 articles during the study period, with the most prolific author publishing 11 articles. We examined the 95 articles fitting the inclusion criteria. These articles ranged from clinical studies and literature reviews to meta-analyses and device materials evaluations.

Published disclosures of company payments varied considerably (**Table 2**). Fewer than half of the journal articles (n=44 [46%]) disclosed a financial relationship between the author and the orthopedic device manufacturer from which an author received at least \$1 million. Only 7 of the 95 articles provided any information regarding the amount of money received; they all appeared in a single journal whose guidelines asked authors to disclose whether the company paid the author "in excess of \$10,000."¹⁶ An additional 3 articles in our sample appeared in this same journal, but none of them disclosed the company payment.

CONSISTENCY OF AUTHOR DISCLOSURE

To evaluate consistency among articles published by the same author, we examined the 27 authors who had more than 1 article in the sample. Four authors (15%) consistently mentioned the company name; 14 authors (52%) were inconsistent, with some articles mentioning the company and others not; and 9 authors (33%) never mentioned the company payments.

EFFECT OF JOURNAL POLICY

Articles in journals with more stringent policies were no more likely than others to reveal an author's industry relationship (**Table 3**). We found no correlation between the number of 2007 ICMJE policy recommendations a journal endorsed and the proportion of articles in that journal that disclosed a company relationship. There was no association between a journal's endorsement of specific ICMJE policy recommendations and the proportion of articles in that journal disclosing authors' company payments.

EFFECT OF AUTHORSHIP POSITION

Recipients of \$1 million or more appeared as first or sole authors in 25 articles (26%), as middle authors in 34 (36%), and as senior authors in 36 (38%). Differences in disclosure rates among these 3 authorship categories were not statistically significant. However, when we combined the first/sole and senior categories into a single measure of "authorship prominence," significant variations emerged: the rate of disclosure was 54% when the payment recipient was the first, sole, or senior author, compared with 32% for middle authors (P=.03) (**Table 4**).

EFFECT OF ARTICLE-PAYMENT RELATEDNESS

Agreement between reviewers in assessing payment-article relatedness was excellent (intraclass correlation coefficient, 0.92 [88 of 95 {93%}]). In the majority of articles (n=52 [55%]), the topic was directly related to company payments. Thirty-four articles (36%) were indirectly related, and another 9 (10%) were unrelated to the payments in question. Again, differences in disclosure among these 3 categories were not statistically significant.

Table 3. Number of Articles, Disclosures, and ICMJE Policy Endorsement Per Journal

Journal	No.			No. (%)	
	ICMJE Policy Areas Endorsed by Journal	Authors Publishing in Journal	Articles in Sample Appearing in Journal	Articles in Sample Mentioning Company That Paid Author $\geq$ \$1 Million	Articles in Sample Acknowledging Payment of $>$ \$10 000
<i>Acta Orthop</i>	3	2	2	0	0
<i>J Am Acad Orthop Surg</i>	2	2	2	2 (100)	0
<i>Am J Orthop</i>	3	2	2	0	0
<i>Am J Sports Med</i>	1	1	1	0	0
<i>Ann Surg</i>	3	1	1	1 (100)	0
<i>J Arthroplasty</i>	1	21	24	7 (29)	0
<i>J Biomech</i>	4	2	4	1 (25)	0
<i>J Bone Joint Surg</i>	5	8	10	7 (70)	7 (70)
<i>J Cell Physiol</i>	2	1	1	0	0
<i>Clin Orthop Relat Res</i>	1	15	18	14 (78)	0
<i>Eur Radiol</i>	3	1	1	0	0
<i>Expert Rev Med Devices</i>	4	1	1	1 (100)	0
<i>Hand Surg</i>	1	2	2	0	0
<i>J Hand Ther</i>	1	1	1	0	0
<i>Health Care Manage Rev</i>	1	1	1	0	0
<i>Hip Int</i>	1	1	1	0	0
<i>Instr Course Lect</i>	No policy available	1	1	0	0
<i>Int Orthop</i>	2	2	2	0	0
<i>J Biomed Mater Res</i>	0	2	3	2 (67)	0
<i>Knee</i>	4	2	2	1 (50)	0
<i>Magn Reson Imaging</i>	2	1	1	0	0
<i>J Nutr Health Aging</i>	No policy available	1	1	0	0
<i>J Orthop Res</i>	2	2	2	0	0
<i>Orthopedics</i>	1	9	9	8 (9)	0
<i>Rheumatology</i>	3	1	1	0	0
<i>J Surg Orthop Adv</i>	1	1	1	0	0
Total for 26 journals			95	44 (46)	7 (7)

Abbreviation: ICMJE, International Committee of Medical Journal Editors.

Table 4. Number of Publications and Disclosure Rates by Authorship Position of the Payment Recipient and by Article-Payment Relatedness

Variable	No. (%)	
	Articles in Sample	Articles in Sample Mentioning Company That Paid Author $\geq$ \$1 Million
Authorship rank		
First/sole	25 (26)	15 (60)
Middle	34 (36)	11 (32)
Senior	36 (38)	18 (50)
Article-payment relatedness		
Directly related	52 (55)	26 (50)
Indirectly related	34 (36)	17 (50)
Unrelated	9 (9)	1 (11)
Total	95 (100)	44 (46)

cant, but combining the direct and indirect categories into a single measure of “relatedness” yielded significant results: the rate of disclosure was 50% among articles related (directly or indirectly) to company payments, compared with 11% among unrelated articles ($P=.04$). This finding is only suggestive or tentative, however, given the small number of unrelated cases (Table 4).

COMMENT

Device company data demonstrate in compelling and unprecedented fashion the inadequate transparency produced by current disclosure practices. Our findings indicate that current journal disclosure policies do not yield complete or consistent information regarding industry payments. More than half of the articles in our sample failed to acknowledge an authors’ relationship to a company. In no article could readers know how substantial the company payment to an author was. More stringent journal policies were not associated with greater transparency. Although prominent authorship position and article-payment relatedness were associated with increased disclosure, nondisclosure rates remained high: even when the recipient of company funds was the first, sole, or senior author, only 54% of the articles mentioned the company tie. Similarly, even among articles directly or indirectly related to payments, the disclosure rate was only 50%.

There are many possible explanations for this lack of full and consistent disclosure. Journals may not solicit—or may not publish—complete financial disclosures.¹⁷ Authors may believe that payments from orthopedic device manufacturers are not relevant to research reports in orthopedics that do not specifically evaluate

the company's products. It is likely that both journals and authors contribute to the lack of full transparency in published articles. Determining their relative roles is a critical question that requires further study. It is evident, however, that whatever the reasons, the current system does not fully inform readers of substantial payments to authors from industry.

This analysis examined a limited sample of articles authored by recipients of more than \$1 million from 5 orthopedic device manufacturers in a single year. Determining whether these findings are representative of other groups of recipients, articles, journals, and specialties requires further research. So too, the variations in disclosure by authorship position warrant additional study. However, the lack of transparency we identified across journals and authors demonstrates the insufficiency of current practices.

Looking forward, medical journals should consider several strategies to facilitate accurate and complete transparency. The growing body of company payment data provides the opportunity to ensure that readers and reviewers are fully alerted to researchers' financial ties to industry. To take full advantage of this opportunity, journals should consider pursuing several strategies.

Journals should collect comprehensive information about authors' commercial relationships. In this spirit, the ICMJE has recently adopted a new common disclosure standard.^{18,19} The new form requires authors to respond to questions about 13 areas in which they might have conflicts (eg, consultancy, honoraria, royalties) and includes an "other" category in which authors are asked to "err on the side of full disclosure." The ICMJE form also sets a specific time frame (3 years) and requires that authors disclose "interactions with ANY entity that could be considered broadly relevant to the work."¹⁹ All journals should consider adopting the new ICMJE disclosure standards. Gathering more information on any relationship within the field of research will likely reduce the inconsistencies produced by different interpretations of disclosure requirements and, therefore, provide for fuller disclosure.

Although the ICMJE form asks for the name of company providing the funds and the type of relationship involved, it does not request information on the size of payments authors receive. To promote transparency, journals should consider obtaining this information as well. Journals should share this information with reviewers and readers and not withhold, in whole or in part, what authors have disclosed. Journal editors should also examine industry data in addition to authors' disclosures and inquire into any discrepancies prior to sending the manuscript for review.

Journals may now find this effort labor intensive because it requires accessing the databases of multiple companies. Recently enacted health care reform legislation, however, is likely to streamline the disclosure process. Beginning in 2013, the Patient Protection and Affordable Care Act requires pharmaceutical and device companies to disclose payments to physicians, which will be housed in a national online database.⁸ The database will include the name, address, and specialty of the recipient and the value and date of, reason for, and product related to the payment. Journals should consider ways to

link and publish the information contained in the national database with articles.

It occurred to us that other medical organizations might also take advantage of company disclosure data. Academic medical centers might use company-supplied data to supplement faculty's conflict of interest statements. Pharmacy and therapeutics committees, as well as other purchasing bodies, might use these data in reviewing members' disclosures. So too, professional medical associations might also refer to company data to examine disclosures by officers, directors, and members who help develop educational activities or formulate clinical guidelines.²⁰ Finally, governmental bodies might compare these data with the disclosure statements of advisory committee members, study group members, and intramural and extramural researchers.

In conclusion, the availability of company data provides an unprecedented opportunity for the medical profession to move to a system of full, verifiable transparency. Medical journals, as gatekeepers of scientific knowledge, should be among the first to use company data, setting the standard for others to follow.

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Correspondence: David J. Rothman, PhD, Center on Medicine as a Profession, Columbia College of Physicians and Surgeons, Columbia University, 630 W 168th St, P&S Box 11, New York, NY 10032 (djr5@columbia.edu).

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