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PREVALENCE OF INDUSTRY SUPPORT AND ITS RELATIONSHIP TO RESEARCH INTEGRITY

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Abstract

Most U.S. clinical trials are funded by industry. Opportunities exist for sponsors to influence research in ways that jeopardize research objectivity. The purpose of this study was to survey U.S. medical school faculty to assess financial arrangements between investigators and industry to learn about investigators' first hand knowledge of the effects of industry sponsorship on research.

Here we show first-hand knowledge that compromises occurred in: research participants' well-being (9%), research initiatives (35%), publication of results (28%), interpretation of research data (25%), and scientific advancement (20%) because of industry support. Financial relationships with industry were prevalent and considered important to conducting respondents' research.

Keywords

financial conflict of interest; industry sponsorship; research integrity

Introduction

Comparison of individual studies and the results of meta-analyses have raised concerns about the undue influence industry funding may have on research integrity (Tereskerz, 2007; Bero and Rennie, 1996; Kjaergard and Als-Nielsen, 2002; Stelfox et al., 1998; Davidson, 1986; Friedberg et al., 1999; and Bekelman et al., 2003). Research demonstrates that financial entanglements between investigators and industry sponsors are associated with an adverse

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affect on assessments of research credibility (Chaudhry et al., 2002; Schroter et al., 2004; and Kim et al., 2004). In spite of these concerns, most clinical trials are financed by pharmaceutical companies (Kaplan and Brownlee, 1999; and Maatz, 1993). Circumstances such as adverse research reports or delays in getting drugs to market can translate into millions in lost revenue (Tereskerz, 2007), producing incentives for sponsors to influence research to advance their interests. They may also produce conflicts of interest (COI's) for investigators that can compromise scientific objectivity (Rochon et al., 1998; Bodenheimer, 2000; and Reed and Camargo, 1999).

A challenge faced by those developing policies/regulations to manage financial COI's is the lack of empirical data on financial arrangements between industry and investigators at academic research institutions (Tereskerz and Moreno, 2005). There have been institution-specific studies describing the nature of university faculty researchers' personal financial relationships with industry sponsors (Tereskerz, 2007). Estimates of such arrangements have also been made by others (Bekelman et al., 2003). Whether these data represent national experience is generally unknown.

The objective of this study was to examine the prevalence of various financial arrangements between industry and investigators at top U.S. research institutions and to investigate researcher practices that relate to research integrity regarding industry-sponsored research. We asked respondents to report question-able research integrity practices in their institutions and departments, about which they had first-hand knowledge. We tested to see if those with greater amounts of industry support, or those employed in departments that have industry support, are more likely to report that they know of such practices. We also examined disclosure practices and assessed the importance of industry support to investigators' careers.

Methods

Sample¹

We purposely targeted the 33 universities in the United States which received the most research funding. Using sample selection methods from similar studies (Blumenthal et al., 1996), we used medical school catalogs and *Peterson's Guide to Graduate Programs in the Biological and Agricultural Science* (Peterson's Guide 1997) to identify all life science departments and graduate programs at the selected institutions. Departments were classified as clinical or nonclinical, depending on whether their names designated a clinical discipline. From each school, we randomly selected one department of medicine (internal medicine or other medicine subspecialties), another clinical department, and two nonclinical departments (N = 132). Faculty in departments of medicine and their subspecialties were thus over-sampled, because they often receive more extramural research funds than other departments. To focus on active researchers, clinical faculty were included in the sample only if they had published at least one article listed in the National Library of Medicine's MEDLINE database during a five year period preceding the study.²

Instrument Design

Study variables were identified from the literature and other sources (Boyd and Bero, 2000; Public Health Service, 2001; 42 CFR; and National Institutes of Health, 2000), and a survey instrument was designed. A definition of industry or commercial sponsorship was created (see Appendix A). Industry support for research and publication was determined by asking about

¹The sampling procedures for the medical school portion of the study are described here. Procedures used to sample nursing school faculty will be described elsewhere.

²An additional screener was included in the questionnaire. Respondents were instructed not to fill it out if they had not published any research in the previous five years.

10 types of support from industry sponsors (Question 7, Appendix A). Overall support included these items, along with receipt of honoraria for serving as a consultant, on an advisory board, or giving a speech, with a separate item to identify those with chaired professorships funded entirely or in part from industry sources.

Instrument pretesting was accomplished in three phases. The first two used focus groups of University of Virginia (UVA) researchers. After debriefings to receive participant feedback, the survey was revised. The third phase involved a sample of 48 researchers, (not included in the final study survey population) drawn at random from the medical faculties of the national sample and offered a modest cash incentive for taking the revised pretest. Sixteen completed the telephone debriefing, and the questionnaire was revised a final time.

Respondents were asked to report their receipt of financial support in various forms from industry. They were also asked directly about industry sponsor pressures to favor the sponsor's interests. To alleviate concerns respondents may have about admitting to practices that compromise research integrity, two questions asked respondents whether they had "first-hand knowledge" of questionable practices within their working environment, rather than to report on their own behavior (see Appendix A). Other survey methodologists have used similar methods to encourage veracity about sensitive topics (California Environmental Protection Agency, 2002). This technique also obviates the risk if respondents' anonymity was breached. By limiting reports to *first-hand knowledge* and events at their own institution or within their own department/research unit, we sought to reduce reports based on suspicions or rumors about questionable practices in other departments or institutions, which would lead to overreporting of questionable practices.

Some questions applied to all respondents, whether or not they were involved in units with industry-sponsored research. Others were asked only of a subset of respondents who reported that people in their current department or research unit received financial support from industry-connected sponsors. These questions were, by design, answered by a smaller number of respondents.

Survey Administration

Questionnaires were sent to a sample of 1,548 clinical researchers, of whom we estimated that 1,156 were qualified for the study.³ To maximize response rates, surveys were mailed by the UVA Center for Survey Research (CSR), following the principles and specific techniques developed by Dillman (Dillman, 2000). The study protocol was approved by the UVA Social and Behavioral Sciences Institutional Review Board.

A prenotice letter was sent to those selected to participate in the survey, followed by a questionnaire and cover letter. Anonymity was afforded to respondents by the use of a separate post-card returned by the respondent to acknowledge response. This allowed for tracking nonrespondents without identifiers on the questionnaires. A second survey was sent to nonresponders; final contact was made by telephone, asking for a response. CSR did not complete questionnaires by phone but mailed/faxed another copy of the questionnaire to any respondents who misplaced theirs.

³The overall sample also included about 500 nursing school researchers; results for the nurse subsample will be reported elsewhere. The estimated eligible respondents exclude those expressly disqualified, the unreachable (those for whom notice was received that the address was faulty), and the estimated number of disqualified and unreachable among the "open status" cases. The latter estimate was reached by first calculating the percentages of nonqualified and unreachable cases among those for which return mail was received, and then applying that percentage to those cases remaining in "open status." We follow the conventional assumption that the percentage of ineligible among cases whose eligibility is unknown is the same as it is among those whose eligibility is determined.

Results

The overall response rate for the medical and nursing school sample (calculated by American Association for Public Opinion Research [AAPOR] Standard Rate RR4) (AAPOR, 2008), was 703/1479 (48%), of whom 528 were medical school researchers. Completed questionnaires were received from respondents in at least 102 medical school departments, representing every institution in the sample. Table 1 gives the demographics of the sample, excluding any who left a demographic question unanswered. Respondents were predominantly male, experienced, senior-ranked researchers with significant authorship activity. Responses were received from all 33 institutions included in the study.

Types of Industry Support

Sixty-six percent of respondents indicated that they have received some form of industry support (Table 2). Sixty-two percent reported receiving research and publication support (Table 3). Notably, 13% of respondents held an endowed chair, of which 14% were funded by industry. Overall, males (77%) and respondents with 11 years or more research experience (79%) were significantly more likely to receive overall support than were females (23%), and respondents with 5 years or less research experience (6%). Similarly, respondents who have worked 11 years or more at their institutions (60%) or had 11 years or more experience in clinical practice (45%) were significantly more likely to receive industry support. In addition, industry support occurred more frequently among investigators who held higher academic ranks and published more frequently. Full professors (51%) and respondents with 11 or more publications in the last two years (28%) were significantly more likely to receive overall industry support than were associate professors (25%), assistant professors (23%), or respondents with one or no publications during the last two years (5%). The same patterns apply when looking specifically at research and publication support (Table 3).

Respondents reported various types of financial arrangements with industry within the last five years. Seven percent (7%) owned an equity interest in a company that supported their research, generally a company doing pharmaceutical research. Of these respondents, half (50%) owned an equity interest in the \$100,000–\$500,000 range.

More than half of the respondents (57%) did not answer the question requesting the proportion of their salary covered by industry during 2003–2004. Of those answering this question, 68% said no part of their salary was covered by industry, with the remaining 32% indicating that some portion of their salary was paid for by industry. In addition, 50% of those responding indicated that some portion of staff salaries were covered by industry, and 56% responded that industry paid for supplies and/or equipment used in their research.

Importance of Industry Support

Overall, respondents indicated that industry support was important to their research and publications (Table 4). Of items with at least 25% of respondents receiving support, the following were most important: research grants or contracts (91% judging these to be extremely important, very important, or somewhat important), support for staff or study coordinators (79%), biomaterials (78%), and support for students or fellows (74%). Although smaller in number, industry support was extremely or very important in the areas of patents and new product/company development.

Disclosure to Human Subjects

Respondents who had received one or more forms of research and publication support from industry were asked a screening question to identify those whose research projects in the last five years involved human subjects. This subset of 139 medical researchers was then asked

about institutional disclosure requirements (mandated disclosure to human subjects) for financial arrangements with industry. They were asked if disclosure of each element was required at their institution, and—if not required—how often they make the disclosure in their own studies. Table 5 presents these results. Interestingly, many institutions do not require disclosure of investigator financial relationships with industry to research subjects. In institutions without such requirements, the data reveal considerable variability in researcher disclosure practices.

Industry Support and Research Integrity

Requests by Industry Sponsors—The questionnaire gave different treatment to questionable action by sponsors as opposed to questionable action by researchers themselves. With regard to sponsor requests or pressures, we directly asked respondents who reported having industry support for their research and publication: “Has an industry-connected sponsor ever asked you to do any of the following?” With respect to researchers acceding to improper requests (for example, actually suppressing unfavorable results), we protected our respondents by asking only for “first-hand knowledge” of such events.

Table 6 shows the results for industry requests, based on the reports of the 231 respondents who receive industry support for their research and publication and answered this series of questions.⁴ Only 4% reported that a sponsor had ever asked them to withhold research results from publication, but 13% said they had been asked to delay publication of research results. Nearly 8% have been asked by a sponsor to present research results in a way that favors the sponsor’s drug or product. About 7% have been asked by an industry sponsor to keep the research results secret. Far more common (and of lesser concern) were reports of being asked to give the sponsor prepublication review (61%) and being asked to acknowledge the sponsor in the publication (62%).

To investigate whether receipt of these requests was associated with the importance of industry support for the respondent’s research, we constructed an index of industry support by summing together responses to the ten items listed in Question 7 (Appendix A). The construction of the index, which has a reliability (Cronbach’s alpha) of .88, is detailed in Appendix B. As seen in Table 7, the importance of industry support to a respondent’s research and publication has a significant relationship with the frequency of many sponsor requests. Considering only those who scored high on the index of support, meaning that they received several forms of industry support that they rated as “very important” or “extremely important,” we found that 28% had been asked either to withhold results, delay publication, present results more favorably, or keep the project secret. The frequency of receiving one of these requests is significantly related to higher scores on the support index.

All Respondents’ First-Hand Knowledge of Questionable Practices—All respondents were asked about their first-hand knowledge⁵ of research practices associated with industry-sponsored research at their institution. Table 7 shows responses related to knowledge of compromises in research integrity because of a request or pressure from an industry sponsor. When all respondents are considered, fairly small percentages reported any compromise.

⁴Some respondents who answered “yes” to one or more of the research and publication support items in the Question 7 series skipped the long series of follow-up questions that applied to them. While 275 answered “yes” to one or more of the Question 7 items, only 231 answered the follow-ups. Most of those who skipped the follow-ups had reported little or no support that they considered important in the Question 7 series.

⁵*First hand* is defined as: from the original source or personal experience; direct. Compact Oxford English Dictionary. Available at <http://www.askoxford.com>.

However, when responses were categorized according to the importance of industry support, using the support index, statistically significant increases were seen in the reports of these compromises as the importance of industry support increased (Table 7). For those researchers who assigned the greatest importance to their industry support, the rates of first-hand knowledge were: 25% for delaying publication, 17% for presenting results to favor the sponsor, and 11% for suppression of publication because of pressure from the sponsor.

All respondents were asked whether there are people in their “department or work unit” currently receiving support from industry sources (question 22, Appendix A); 59% said “yes.” Those who said “yes” were more likely to have first-hand knowledge of delaying publication (16% with knowledge compared to 9% without); to know of results presented to favor the sponsor (7% compared to 3%); and, to know of cases in which results were suppressed (6% compared to 2%). Each of these contrasts is statistically significant.

Respondents from Departments with Industry-Sponsored Research—A second set of questions asking for first-hand knowledge was directed only to the subset of respondents reporting (in question 22) that others in their department or research unit receive financial support from industry-connected sponsors ($n = 173$; see Table 8). Fifteen respondents out of 173 (9%) reported first-hand knowledge that the well-being of research participants at their institution was compromised because of industry support of researchers in their department. In 40% of these instances (six cases), the well-being of participants was either seriously or significantly compromised.

Other compromises were noted as well: 28% reported that the publication of research results had been compromised; 25% reported that the interpretation of research data at their institution had been compromised; and, 35% reported that research initiatives had been compromised because individuals in their department or research unit were supported by industry. Twenty percent believed that scientific advancement in their area of research had been compromised by industry support.

Consistent with our other findings, the more important industry support is to respondents’ research and publication, the more likely it is that they have first-hand knowledge of these compromises to research. The pattern of increased reporting with increased importance of industry support to the researcher is evident to some extent for all five types of compromise, and is statistically significant for four of the five items.

Discussion

What new information does this study provide? It represents the first recent attempt to gather data from the leading research institutions on financial arrangements between medical school investigators and industry that explores not only what types of financial relationships exist and with whom but also shows association between industry support and first-hand knowledge of questionable integrity practices. We purposely sampled major research-intensive institutions, assuming that these institutions would yield the greatest number of active researchers receiving industry support.

An important new finding is the report of 9% of respondents with industry-funded colleagues that had first-hand knowledge of compromises to the well-being of research subjects at their institution because researchers in their department/research unit received industry sponsorship. One way to view this finding is that only a small subset of these participants ($n = 15$) reported this, with 9 respondents noting that the compromise was minor. However, the concern is not that compromising the well-being of human research participants happens frequently but that

it happens at all. There should be zero tolerance for compromising the well-being of human research participants in any study, regardless of the source of the study's support.

Further, the finding that significant numbers of respondents in units with industry support have noted compromises to research initiatives (35%), publication (28%), interpretation of data (25%), and overall scientific advancement (20%) is of concern.

This concern is compounded when you take into account our results showing that most respondents who received industry support indicated that industry financing of research through grants and contracts is important to their research/publications. This is particularly troubling in light of the finding that the more important the support of industry to respondents, the greater the pressure seen from sponsors and the greater the respondents' first-hand knowledge of compromises to research integrity. Researchers responding to this survey with more and important industry support are significantly more likely to report receiving requests to withhold research results, delay publication, present results in ways that favor the sponsor's product, or keep the project and results secret. Furthermore, the level of first-hand knowledge of such compromises is significantly greater among those for whom industry support is most important. This pattern of results can be understood in terms of Emerson's (Emerson, 1962) classic observation about power relations in a dyad: the power of A over B is the inverse of B's dependence on A for key resources. If an investigator rates industry support as very important, it may indicate a degree of dependence on such support that empowers the sponsor to make improper requests of the investigator.

Our data demonstrate that senior-level investigators who responded to the survey receive a wide variety of industry-sponsored support which is important for their careers, and that industry support of research and researchers is pervasive in the clinical and research departments of top U.S. research institutions.

Indeed, two-thirds (66%) of our sample reported receiving support from industry-connected sources. Full professors and those with large numbers of publications were significantly more likely to receive industry support than were their more junior colleagues. A recent study of practicing physicians (Campbell, Russell et al., 2007) also reported the prevalence of industry sponsorship. Examining a wider variety of support in more categories, our data show higher levels of industry support among our respondents, presumably due to our sampling method.

The data presented here now bring into national focus the quandary that industry sponsorship of research presents. Various financial relationships with industry are both prevalent and considered important by investigators with regard to the conduct of their research. This is not surprising given that industry is the primary financier of clinical research. Clearly, research grants, consulting, and honoraria are the primary means by which industry pays investigators (Tereskerz, 2007). In this study, ownership interests in sponsoring companies occur infrequently. However, when such an equity interest exists, it appears to be substantial. This type of financial entanglement has been implicated in some of the more notorious anecdotal cases of research abuse (Tereskerz, 2007).

That these patterns are seen among those most deeply immersed in industry supported research, and that these individuals are also the most senior and prolific members of their departments, is a disturbing finding. Our data thus lend credence to concerns being raised in the literature (Tereskerz, 2007; Bero and Rennie, 1996; Kjaergard and Als-Nielsen, 2002; Stelfox et al., 1998, Davidson, 1986; Friedberg et al., 1999; and Bekelman et al., 2003).

Our data indicate that researchers' financial arrangements with industry are not always fully disclosed to research subjects. In addition, research institutions do not universally require disclosure of researcher's equity interests in the sponsoring company, joint commercial

ventures with the sponsor, other financial payments, and funding of key personnel and equipment. In situations where such disclosures are not required by the institution, our respondents varied in their disclosure practices.

Taken together, these findings of nondisclosure of industry connections, compromises to research results, publications and scientific advancement, and compromises to human subject well-being provide evidence to suggest that efforts to educate investigators about their moral obligations have not fully succeeded. Even if one were to argue that these compromises are minor, they demonstrate a lack of respect for those who volunteer in good faith as research participants and a lack of attention to scientific objectivity and integrity. Industry sponsors and the scientific community need to review the adequacy of their efforts in light of these findings.

Because industry-supported respondents were significantly more likely to be the most senior and prolific researchers, their leadership and potential influence over the cultures of individual research units are considerable. Our data raise the possibility of research cultures in which abuses of research integrity are known but are not openly discussed or addressed. Recent findings of reluctance on the part of U.S. physicians to report incompetence or serious mistakes of peers (Campbell, Russell et al., 2007) lend credence to these concerns.

Study Limitations

The study's primary limitation is the response rate. Lower response rates are expected when the questions involve sensitive topics. In fact, this study's response rate compares favorably to a recent study reporting national survey results on research misconduct which had a 31% response rate (Pryor et al., 2007). In addition, others have noted increasing difficulty in obtaining physicians' responses to surveys and have reported response rates similar to those reported here (Campbell, Russell et al., 2007). It is well recognized among survey methodologists that physician response rates tend to be lower than those of other individuals (Campbell, Regan et al., 2007; Cummings et al., 2001; and VanGeest et al., 2007). Rates are even lower when no monetary incentive is used to encourage respondents to reply, as was the case in this study (Kasprzyk et al., 2001). We determined that it was inappropriate to use such an incentive in a study that had financial conflict of interest as a focus.

This issue and our purposive sampling approach mean that we cannot generalize from this sample to the U.S. medical school population. Additional research with larger samples is needed and likely will require incentives to increase the percentage of respondents.

By asking for first-hand knowledge of compromises to research integrity due to industry sponsorship, we chose to accept some risk that participants would respond from incomplete knowledge or low opinion of colleagues rather than based on their direct experience. Certainly our strict guarantees of anonymity were designed to mitigate this possibility, but we cannot assess whether responses were skewed based on these factors. Given the proportionally large number of respondents at selected institutions, there is a possibility that one incident was noted by multiple participants. To minimize this possibility, one of the two first-hand knowledge questions asked specifically about "people in your department or research unit" who were supported by industry-connected sponsors. To address the potential concern that a single case at one institution may be over represented, we examined the record of questionnaire returns by institution and department, based on those whose affiliation was known because they returned a separate postcard (N = 410) confirming participation. We cannot directly verify how many departments reported any specific practice. However, the broad pattern of response achieved across 102 departments from every institution sampled makes it unlikely that respondents' reports of questionable practices represent only one or two departments or institutions. In addition, we measured first-hand knowledge rather than specific incidents. While obtaining the latter information would be difficult, even with assurance of anonymity,

further study of the number of incidents and actual harms resulting from compromises to research integrity is needed.

Nonresponse bias might affect the survey results in either a positive or negative direction, or not at all, depending on whether or not response tendencies correlate with the variables measured in the survey. Since the survey deals with sensitive topics (industry sponsorship and research integrity) and asks specifically about prohibited or stigmatized practices, the most likely pattern of nonresponse would be that those with the most industry support and those with greatest knowledge of questionable practices would be less likely to return their questionnaires. Such a pattern would lead to underreporting of the questionable practices. A less likely scenario, but one of potentially greater concern for this study, would be the possibility that questionable practices are overreported. This would occur if those who knew of questionable practices (by their colleagues) were eager to report them and were more likely to respond to the survey than those who knew of no such practices.

Given our guarantees of anonymity to participants, no information is available on nonresponders that would allow direct test of these possibilities. However, we compared the data for early and late responders, as it is probable that late responders have more in common with nonresponders than do those who responded immediately to the survey request. This analysis compares the characteristics and responses of the 350 respondents who returned the questionnaire received in the first packet to the 159 who responded to the second packet or telephone reminder. Early and late responders did not differ significantly in their seniority, as measured by their years involved in research, years in clinical practice, years at institution, or number of publications. While 60% of the first-packet responders had received industry support, 69% of the second-packet responders had received such support, a statistically significant difference ($p = .05$) suggestive of modest underreporting of industry support. Of the three questionable practices reported in Table 7, two did not differ significantly: delay of publication and suppression of research results from sponsor pressure. However, later responders were more likely to report first-hand knowledge of results having been presented to favor the sponsor (10% of late responders as compared with 5% of early responders, $p = .045$). This result again suggests selective underreporting rather than overreporting in the survey results.

There was no difference between early and late responders in the percentage who had departmental colleagues receiving industry support. For the questions posed to this group reported in Table 8, there were no significant differences between early and late respondents in the percentages reporting any of the five questionable practices. These indirect comparisons of response bias demonstrate that early and late responders do not differ very much, and when they did differ, it was in the direction of underreporting. While indirect, this analysis lends support to the survey's findings.

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Appendix A: Selected Survey Questions

Definition of Industry-Connected Support

We are interested in learning more about the support that university medical researchers receive from *industry-connected sources*. These sources include commercial and industrial firms that make or market drugs, medical devices, or other medical products. Also included are private foundations that are closely linked or associated with any such firm. We distinguish these industry-connected sources from other sources of funding, such as federal grants and contracts, funding from state and local government, quasi-governmental or public organizations, health-oriented nonprofits, or any other entity not closely linked to the medical industry itself.

Definition: Industry-connected sources of research funding are for-profit firms that make or market medical products (including drugs and devices), and any private foundations or nonprofit organizations closely linked to them.

Wording of Specific Questions

Note: Questions 7 and 8 were used to define those with and without industry support and to construct the index of industry support. Question 17 is used in Table 6. Question 21 is used in Table 7. Question 23 is used in Table 8. Question 22 is used in the analysis.

7. We list ten types of support that researchers may receive from industry connected sources. How important was each of the following received *from industry-connected sources* in support of your research or publication?

If you have not received a particular type of support from an industry-connected source in the past five years, please indicate this by circling the number 8 in the last column.

Industry-connected support	Extremely important	Very important	Somewhat important	Not at all important	Not received in past 5 years
a. Research contract or grant	1	2	3	4	8
b. Equipment	1	2	3	4	8
c. Biomaterials (reagents, clones, antibodies, tissues, cell lines, etc.)	1	2	3	4	8

Industry-connected support		Extremely important	Very important	Somewhat important	Not at all important	Not received in past 5 years
d.	Discretionary funds or gifts to your institution	1	2	3	4	8
e.	Support for students or fellows	1	2	3	4	8
f.	Trips to professional meetings	1	2	3	4	8
g.	Honoraria	1	2	3	4	8
h.	Gifts (worth more than \$100) made to you as an individual	1	2	3	4	8
i.	Support for staff or study coordinators	1	2	3	4	8
j.	Funds for publication costs	1	2	3	4	8

Please summarize your responses above by answering this question:

8. In the past five years . . .

1. I have **NOT** received any research and publication support from industry-connected sources —▶ **SKIP TO PAGE 9**

2. I **HAVE** received such support —▶ **GO TO THE NEXT PAGE**

If you answered “Not Received” to all ten items in Question 7 above, then you have not had any *industry-sponsored* research in the past five years and you should **SKIP TO QUESTION 20 ON PAGE 9**. If you were able to rate any item in Question 7, please continue to Question 9 on the next page.

Direct Questions for Respondents with Industry Support

17. Has an industry-connected sponsor ever asked you to do any of the following?		No	Yes
a.	Withhold research results from publication	N	Y
b.	Delay publication of research results	N	Y
c.	Present results in a way which reflects more favorably on the sponsor’s drug or product	N	Y
d.	Acknowledge the sponsor in the publication	N	Y
e.	Grant the sponsor prepublication review of any resulting manuscripts	N	Y

17. Has an industry-connected sponsor ever asked you to do any of the following?		No	Yes
f.	Keep the research project and results secret	N	Y
g.	Convey all resulting patents to the sponsor	N	Y
h.	Participate in research that involves proprietary information	N	Y

First-Hand Knowledge Questions for All Respondents

The following questions refer to any research conducted at your current institution, whether or not you were involved in the research.

21.	Do you have first-hand knowledge of any research conducted at your institution where any of the following occurred because of a request or pressure from an industry-connected sponsor?	No	Yes
a.	Research results were suppressed or withheld from publication	N	Y
b.	Publication of research results was delayed	N	Y
c.	Results were presented in a way that reflects more favorably on the sponsor's drug or product	N	Y

22. Are there other people in your current department or research unit who receive financial support from industry-connected sponsors?

1 No → **Go on to Question 25**

2 Yes →

8 *Don't know (go on to Question 25)* ↓

23. Based on your first-hand knowledge, to what extent have any of the following ever been compromised because people in your department or research unit were supported by industry-connected sponsors?

		<i>Seriously</i>	<i>Significantly</i>	<i>Only in minor ways</i>	<i>No compromise occurred</i>	<i>Don't know</i>
a.	Research initiatives	1	2	3	8	9
b.	Interpretation of data	1	2	3	8	9
c.	Publication of results	1	2	3	8	9
d.	The well-being of research subjects	1	2	3	8	9
e.	Scientific advancement in your area of research	1	2	3	8	9

Appendix B: The Index of Industry Support

Question 7 lists ten sources of industry support for research and publication. Respondents rated each item on a 1 to 4 scale, with 1 indicating “extremely important” and 4 indicating “not at all important.” They could also indicate if they had not received this form of support in the past five years. To create the support index, these responses were first recoded so that a 0 indicated no such support, a 1 indicated that the support was “not at all important,” and so on up to a 4 to indicate extreme importance. A reliability check on the items when so recoded yielded a Cronbach’s alpha score of .884, indicated strong inter-item correlations. Accordingly, the items were summed to yield an index that could range from 0 to 40. In this survey, actual scores on the index ranged from 0 to 36, with a median score of 3 and mean score of 5. For analysis purposes, this index was grouped into four categories: respondents with “no support,” as shown by a score of 0 (39% of the sample); those with “little support,” shown by a score of 1 to 4 (21%); those with “some support,” shown by a score of 5–12 (21%); and those with “important support,” with scores of 13 or more on the index (19%). In Table 6, the first two categories are grouped together and labeled as “unimportant support,” since the questions reported in that table were not supposed to be answered by those who had no support.

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TABLE 1

Respondents' Demographic Characteristics

Label	Category	Overall	
		n	%
Gender (A42)	Male	360	71.1
	Female	146	28.9
Years involved in research (A37)	0-5	39	7.6
	6-10	94	18.3
	11+	382	74.2
Years involved in clinical practice (A38)	0-5	271	54.2
	6-10	43	8.6
	11+	186	37.2
Years worked at institution (A39)	0-5	124	23.9
	6-10	108	20.8
	11+	286	55.2
Number of publications in last 2 years (A40)	0-1	35	6.8
	2-3	123	24.0
	4-5	117	22.9
	6-10	123	24.0
	11+	114	22.3
Academic rank (A41)	Full Professor	231	44.7
	Associate Professor	121	23.4
	Assistant Professor	144	27.9
	Other	21	4.1

TABLE 2

Overall Support by Demographic Variables

Label	Category	Overall		P value	Industry support		No support		N
		n	%		n	%	n	%	
Gender (A42)	Male	360	71.1	.001	261	77.2	99	58.9	506
	Female	146	28.9		77	22.8	69	41.1	
Years involved in research (A37)	0-5	39	7.6	.001	22	6.4	17	9.9	515
	6-10	94	18.3		50	14.5	44	25.7	
	11+	382	74.2		272	79.1	110	64.3	
Years involved in clinical practice (A38)	0-5	271	54.2	<.001	157	47.1	114	68.3	500
	6-10	43	8.6		27	8.1	16	9.6	
	11+	186	37.2		149	44.7	37	22.2	
Years at worked at institution (A39)	0-5	124	23.9	.011	71	20.5	53	30.8	518
	6-10	108	20.8		69	19.9	39	22.7	
	11+	286	55.2		206	59.5	80	46.5	
Number of publications in last 2 years (A40)	0-1	35	6.8	<.001	18	5.2	17	10.1	512
	2-3	123	24.0		75	21.9	48	28.4	
	4-5	117	22.9		72	21.0	45	26.6	
	6-10	123	24.0		82	23.9	41	24.3	
	11+	114	22.3		96	28.0	18	10.7	
Academic rank (A41)	Full Professor	231	44.7	<.001	176	50.9	55	32.2	517
	Associate Professor	121	23.4		87	25.1	34	19.9	
	Assistant Professor	144	27.9		79	22.8	65	38.0	
	Other	21	4.1		4	1.2	17	9.9	

TABLE 3
Research and Publication Support by Demographic Variables

Label	Category	Overall			p value	Industry support for Res&Pub			No support		
		n	%			n	%	n	%	n	%
Gender (A42)	Male	348	71.5		<.001	235	78.3	113	60.4	487	
	Female	139	28.5			65	21.7	74	39.6		
Years involved in research (A37)	0-5	34	6.9		<.001	20	6.6	14	7.3	496	
	6-10	92	18.5			40	13.2	52	27.1		
	11+	370	74.6			244	80.3	126	65.6		
Years involved in clinical practice (A38)	0-5	262	54.2		<.001	139	47.0	123	65.8	483	
	6-10	40	8.3			24	8.1	16	8.6		
	11+	181	37.5			133	44.9	48	25.7		
Years worked at institution (A39)	0-5	120	24.0		.024	62	20.3	58	30.1	499	
	6-10	102	20.4			61	19.9	41	21.2		
	11+	277	55.5			183	59.8	94	48.7		
Number of publications in last 2 years (A40)	0-1	34	6.9		<.001	15	5.0	19	10.0	493	
	2-3	118	23.9			58	19.1	60	31.6		
	4-5	108	21.9			66	21.8	42	22.1		
	6-10	119	24.1			75	24.8	44	23.2		
	11+	114	23.1			89	29.4	25	13.2		
Academic rank (A41)	Full Professor	226	45.4		<.001	161	52.6	65	33.9	498	
	Associate Professor	117	23.5			70	22.9	47	24.5		
	Assistant Professor	137	27.5			72	23.5	65	33.9		
	Other	18	3.6			3	1.0	15	7.8		

TABLE 4
Outcomes of Research over Past Five Years and Importance of Industry Support to Research and Outcomes

Label	Received support (%)		n	Importance (%)					n
	Yes	No		Extremely important	Very important	Somewhat important	not at all important		
a. Research contract or grant	40.8	59.2	502	29.3	30.7	30.7	9.3	205	
b. Equipment	24.7	75.3	498	15.4	25.2	27.6	31.7	123	
c. Biomaterials (reagents, clones, antibodies, tissues, cell lines, etc.)	32.6	67.4	500	20.9	23.3	33.7	22.1	163	
d. Discretionary funds or gifts to your institution	25.0	75.0	500	10.4	14.4	38.4	36.8	125	
e. Support for students or fellows	25.9	74.1	498	14.7	25.6	34.1	25.6	129	
f. Trips to professional meetings	27.1	72.9	499	5.9	17.8	42.2	34.1	135	
g. Honoraria	38.5	61.5	499	2.1	8.3	24.5	65.1	192	
h. Gifts (worth more than \$100) made to you as an individual	16.0	84.0	499	2.5	6.3	15.0	76.3	80	
i. Support for staff or study coordinators	26.5	73.5	502	24.1	28.6	26.3	21.1	133	
j. Funds for publication costs	21.0	79.0	501	3.8	16.2	37.1	42.9	105	
k. Patent applications	18.6	81.4	221	25.0	45.0	15.0	15.0	40	
l. Patents, trademarks, or license fees	12.3	87.7	220	30.8	34.6	26.9	7.7	26	
m. Development of a new product that is currently on the market or is market development	19.6	80.4	219	45.2	35.7	14.3	4.8	42	
n. Development of a new company or commercial enterprise	5.0	95.0	219	30.0	30.0	30.0	10.0	10	
o. Trade secrets	9.2	90.8	218	15.8	47.4	26.3	10.5	19	
p. Royalty agreements	8.6	91.4	220	27.8	16.7	33.3	22.2	18	
q. Consulting arrangements	31.7	68.3	221	15.9	23.2	37.7	23.2	69	
r. Discussion of employment with the sponsor	4.6	95.4	218	.0	33.3	22.2	44.4	9	
s. Joint commercial venture	1.8	98.2	219	.0	.0	.0	100.0	3	

TABLE 5
 Rate of Disclosure of Financial Relationships with Industry to Human Research Subjects

Label	Required (%)			If no, Disclosure (%)					n
	Yes	No	n	Always	Sometimes	Never	Not applicable		
In industry-sponsored research, does your institution require you to disclose:									
a.	69.8	30.2	139	29.4	8.8	14.7	47.1	34	
	equity interest in the sponsoring company?								
b.	63.8	36.2	138	28.9	15.6	17.8	37.8	45	
	that key personnel have served as consultant or board member?								
c.	54.5	45.5	134	22.6	14.5	24.2	38.7	62	
	if key personnel are paid as industry speaker?								
d.	57.8	42.2	135	28.6	14.3	24.5	32.7	49	
	if salary for key personnel is paid for by industry sponsor?								
e.	48.8	51.2	127	10.8	3.1	15.4	70.8	65	
	if equipment is donated by industry sponsor?								
f.	55.7	44.3	131	21.6	7.8	11.8	58.8	51	
	if personnel received monetary gifts or honoraria from industry sponsor?								
g.	41.3	58.7	126	11.6	5.8	36.2	46.4	32	
	if industry sponsor paid travel of personnel?								
h.	60.4	39.6	134	18.6	2.3	9.3	69.8	30	
	royalty agreement with industry sponsor?								
j.	60.3	39.7	136	20.0	.0	11.1	68.9	31	
	if personnel have joint commercial venture with industry sponsor?								

TABLE 6
 Respondents with Industry Support: Receipt of Requests from Industry Sponsors*

Industry sponsor requested	All respondents with industry support	Respondents with unimportant industry support	Respondents with some industry support	Respondents with important industry support	p-value of chi-square test
Withhold research results from publication	9/231 (4%)	2/66 (3%)	2/81 (3%)	4/80 (5%)	.662
Delay publication of research results	30/230 (13%)	7/66 (11%)	9/80 (11%)	14/80 (18%)	.380
Present results in a way which reflects more favorably on the sponsor's drug or product	18/231 (8%)	3/66 (5%)	2/81 (3%)	12/80 (15%)	.006
Keep the research project and results secret	15/230 (7%)	2/66 (3%)	4/81 (5%)	8/79 (10%)	.177
(One or more of the above four requests)	44/231 (19%)	9/66 (14%)	11/81 (14%)	22/80 (28%)	.036
Acknowledge the sponsor in the publication	143/231 (62%)	27/66 (41%)	58/81 (72%)	56/80 (70%)	.000
Grant the sponsor prepublication review of manuscripts	140/231 (61%)	29/66 (44%)	48/81 (59%)	61/80 (76%)	.000
Convey all resulting patents to the sponsor	34/225 (15%)	8/66 (12%)	12/80 (15%)	14/75 (19%)	.557
Participate in research that involves proprietary information	91/229 (40%)	14/66 (21%)	30/81 (37%)	46/78 (59%)	.000

* Denominators vary because some questions were relevant to or only answered by a subset of respondents, or there were missing data.

TABLE 7
 All Respondents: Industry Support and Knowledge of Compromising Research Integrity*

First-hand knowledge	All respondents	Respondents with no industry support	Respondents with unimportant industry support	Respondents with some industry support	Respondents with important industry support	P-value of chi-square test
Results were presented to favor sponsor's product because of pressure from sponsor	31/499 (6%)	6/194 (3%)	3/106 (3%)	6/106 (6%)	16/93 (17%)	.000
Publication of research results was delayed because of pressure from sponsor	64/500 (13%)	18/194 (9%)	10/106 (9%)	13/106 (12%)	23/94 (25%)	.002
Research results were suppressed because of pressure from sponsor	21/500 (4%)	5/194 (3%)	5/106 (5%)	1/106 (1%)	10/94 (11%)	.003

* Denominators vary because some questions were relevant to or only answered by a subset of respondents, or there were missing data.

TABLE 8
Industry Support and Compromising Research Integrity: Respondents with Individuals in their Department or Research unit who Receive Industry Support*

First-hand knowledge	All respondents with others in unit who get industry support	Respondents with no industry support	Respondents with unimportant industry support	Respondents with some industry support	Respondents with important industry support	P-value of chi-square test
Well-being of research participant compromised	15/173 (9%)	2/36 (6%)	2/27 (7%)	2/50 (4%)	9/60 (15%)	.179
Publication of results compromised	47/168 (28%)	9/35 (26%)	4/26 (15.4%)	8/47 (17%)	26/60 (43%)	.008
Interpretation of research data compromised	41/162 (25%)	7/33 (21%)	4/27 (15%)	8/46 (17%)	22/56 (39%)	.027
Research initiatives compromised because individuals were supported by industry	56/167 (35%)	10/34 (29%)	5/28 (18%)	9/46 (20%)	32/59 (54%)	.000
Scientific advancement compromised by industry support	35/172 (20%)	5/40 (13%)	5/26 (19%)	6/47 (13%)	19/59 (32%)	.040

* Denominators vary because some questions were relevant to or only answered by a subset of respondents, or there were missing data.