Evaluation of academic scientists’ responses to situations that pose a conflict of interest

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Introduction

It is widely accepted in the scientific and medical community that conflicts of interest pose a major problem for scientific and clinical integrity, and have the potential to erode public trust in academic research.\(^1\,^4\) Conflicts of interest are defined as situations or circumstances in which secondary financial or other interests may either influence or appear to influence professional actions or judgments.\(^5\) A secondary interest may not be improper in and of itself, but it can conflict with a primary interest.\(^6\) An academic scientist or clinician may enter into a conflict of interest when the economic motives of a private funding source or another secondary interest unduly influence his or her primary academic responsibilities.\(^7\,^8\) While non-financial pressures such as promotion or recognition may create a conflict of interest as indicated, for example, by a biased reporting of results, the scientific process and institutional policies tend to manage these types of conflicts of interest.\(^9\) This study considers the non-financial pressures, but primarily focuses on financial conflicts of interest, which are, at present, not adequately governed by institutional policies.

Conflicts of interest exist in academic science, with reports that funding by private industry may include strings such as control of the study design or statistical analysis.\(^10\) Academic scientists face stressful pressures, including but not limited to promotion, recognition by peers, pressure to publish, obtain funding and contribute to the public good by addressing pain and suffering.\(^9\,^11\) These strong forces can create conflicts, but they also serve to incentivize biomedical discovery and new treatments. These same pressures can make academic scientists vulnerable to financial conflicts of interest. Put differently, the need to fund studies to accomplish academic goals may create conflicts when the for-profit motivations of private funding sources place restrictions or pressures on academic scientists to behave in certain ways in return for the funding. For example, a pharmaceutical company may offer to provide funding to an academic scientist on the condition that the company must approve any manuscript prior to submission. This creates a conflict of interest for the academic scientist because the pharmaceutical company’s economic motives to control what is published in the literature impact the scientist’s primary motive to obtain funding for biomedical inquiry and discovery. Ultimately, the strings attached to private funding may hurt the public because experimental results may never be disseminated, the results may be presented in a skewed manner or doubt may be cast upon the results of such studies.\(^12\) In addition, these situations can impact scientific integrity.\(^13\) However, at the time of entering into the agreement with the pharmaceutical company, the scientist may be primarily concerned with funding research and research staff, and may not fully consider the potential impact of allowing the for-profit motives of the pharmaceutical company to control the design of the study or dissemination of the results.

Another example of a financial conflict of interest in academic science concerns the tension between the academic goal of publishing results as quickly as possible and the private sector’s interest...
Vignettes were sorted in protecting results from disclosure for intellectual property protection. For example, a pharmaceutical company may offer to fund research on drug discovery, but require that the academic scientist not publish any results until the company can obtain intellectual property protection. This may mean that the publication of results will be delayed for many years as the private company works through a regulatory approval process. Concerns about funding or promotion may, however, place the scientist in a position to accept the private funding and its attendant strings.

Conflicts of interest exist at the clinical level as well. It has been recognized that even small gifts from pharmaceutical companies can unduly influence decisions by medical students and physicians. Studies have shown that payments per recruitment of each subject in a clinical trial may create conflicts of interest. In addition, financial conflicts of interest may arise if an academic scientist in a clinical trial also stands to gain financially from the outcome of the trial.

Some argue that academic researchers are trained to be objective and therefore should not be influenced by money. While scientists are trained to be objective, and there is the threat of reputational scars for failures of objectivity, it would be naïve to assume that universities do not require appropriate financial conflict of interest policies to address the recent increase of problems associated with receiving funding from private sources or holding equity in companies.

The rise of financial conflicts of interest appears to coincide with the passage of the Bayh-Dole Act in 1980. One outcome of the Bayh-Dole Act is that academic institutions are allowed to patent discoveries developed from research supported by federal funding, giving the institution the ability to license technology to the private sector. This change in intellectual property rights spurred the creation of Technology-Transfer offices at universities. Universities created their own policies regarding financial conflicts of interest; however, the guidelines have variability across institutions.

The National Institutes of Health (NIH) has policies addressing conflicts of interest. Specifically, the NIH requires that grant applicants disclose potential conflicts of interest. Over the past 15 years, the NIH lowered the threshold amount that must be disclosed.

Reports in the scientific and medical literature appear to agree that the myriad policies currently in place at universities and in government are not adequate to address the serious issue of conflicts of interest. Due to the complexity of the problem, universities and the government struggle to properly regulate this area.

One approach to moving toward an effective policy is to study how academic scientists might behave as they enter into arrangements that may create conflicts of interest. In this way, policymakers can attempt to create policies that incentivize certain behaviors deemed positive and disincentivize behaviors that are deemed negative. An understanding of how scientists respond to situations in which a conflict of interest might arise could be important to develop policies that effectively address conflicts of interest. To this end, the present study surveyed academic scientists and assessed their responses to hypothetical situations posing a potential conflict of interest. The following questions were addressed: (1) whether junior faculty may respond differently than senior faculty to questions raising a potential conflict of interest because junior faculty may be less experienced and may be more susceptible to the increased pressure to be productive; (2) whether faculty with primary research responsibilities may respond differently than faculty with primary clinical duties; and (3) whether responses were related to federal grant money per faculty in respondents’ home departments. The present study is complementary to other studies that analyze the extent of different types of relationships between academia and industry. An improved understanding of how academic scientists respond to situations in which a conflict of interest may arise may identify areas in which appropriate policy incentives can be used to minimize conflicts of interest.

Results

Invitations to complete a conflict-of-interest survey consisting of seven vignettes were sent to 6,357 candidates via e-mail. The invitation included a brief description of the survey and a link to the survey itself (survey available from the first author). Of the 6,357 invitations sent, 464 (7.3%) were either returned as undeliverable or received an “out of office” response, leaving a total of 5,893 potential participants. A total of 603 (10.2%) faculty members responded to the survey. In terms of academic rank, 138 (22.9%) were assistant, 149 (24.7%) associate and 306 (50.7%) full professors. In terms of specialty, 262 (43.4%) reported their home department as medicine, family medicine, pediatrics or emergency; 196 (32.5%) as a medical specialty department (e.g., dermatology, neurology); 62 (10.3%) as psychiatry or psychology; 49 (8.1%) as a physical science department (e.g., biology, biochemistry); 21 (3.5%) as a social science department (e.g., epidemiology); and 13 (2.2%) as pharmacy. In terms of 2009 federal grant money received per department faculty member, the mean was $0.11 million (SD = 0.15, range 0–0.93).

Tobit analyses. Vignettes were sorted into four categories (pharmaceutical, data, profit and promotion) and responses were recoded so that zero was the response that would be least likely to lead to a conflict of interest. We used tobit regression models to separately test whether mean responses

<table>
<thead>
<tr>
<th>Table 1. Mean response by vignette type and academic rank</th>
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<tbody>
<tr>
<td>Vignette type</td>
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<tr>
<td></td>
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<tr>
<td>Pharmaceutical</td>
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<tr>
<td>Profit</td>
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<tr>
<td>Data reporting</td>
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<tr>
<td>Promotion</td>
</tr>
</tbody>
</table>

Note: For all vignette types, scores ranged from 0–9. Across rows (i.e., by academic rank) and down columns (i.e., by vignette type within each rank), cells that share the same superscript were not significantly different, p > 0.05.
to each vignette category differed by academic rank, academic sector (clinical vs. research) and home department federal grant money per faculty. Mean ratings by rank and vignette type are shown in Table 1. The pattern of means suggested that full professors differed from other faculty; consequently, we dichotomized rank into full vs. less than full. Results of the four tobit models are shown in Table 2. We then used the procedure described by Roncek to derive from each coefficient a value reflecting the change in outcomes with a change in the predictor variable for those with responses greater than zero, and a value reflecting the effect of the predictor on the probability of a zero response.27

The tobit coefficients for academic rank were negative and significant in each model, meaning that full professors gave significantly lower (i.e., more appropriate) responses to each vignette type. Full professors were approximately 11% more likely to give a zero response than their more junior colleagues on the pharmaceutical and data vignettes, and 3 and 5% more likely on the profit and promotion vignettes. Of those who gave non-zero responses, full professors gave responses that were 0.20 points lower than other faculty on the pharmaceutical vignettes, 0.22 points lower on the data and profit vignettes and 0.31 points lower on the promotion vignettes.

The effect of departmental grant money per faculty was significant and positive for the pharmaceutical, data and profit vignettes. That is, respondents whose departments received more federal grant money in 2009 tended to give significantly higher (i.e., less appropriate) responses to these hypothetical situations. A one-unit increase in departmental grant money (i.e., an additional $1 million per faculty) was associated with a 0.5 point increase in scores on the pharmaceutical and data vignettes, and a 0.8 point increase on the profit vignettes. The same one-unit increase in departmental grant money was associated with a 26% increase in the probability of non-zero responses for the pharmaceutical vignettes, 24% for the data vignettes and 12% for the profit vignettes. Departmental grant money was not significantly associated with responses to the promotion vignettes.

Academic sector did not predict responses to the pharmaceutical, data or promotion vignettes. There was a significant effect on the profit vignettes, such that non-zero responses from clinicians were about 0.3 points lower than non-zero responses from researchers. Additionally, clinicians were about 4% less likely to give non-zero responses compared to researchers.

### Discussion

This study investigated the responses of medical school faculty to vignettes where conflicts of interest may arise. For all four vignette types, we found that full professors were significantly more likely than assistant and associate professors to respond in a way that would minimize the possibility of a conflict of interest. In addition, with the exception of promotion-related vignettes, we found that respondents whose home departments received more federal grant money per faculty were more likely to respond in ways that would increase the probability of a conflict of interest.

Interestingly, participants’ mean responses varied depending on the type of vignette. For example, the mean response to vignettes concerning promotion was higher (i.e., less appropriate) than to the vignettes concerning pharmaceuticals (Table 1). The vignettes used to analyze these two categories were not overlapping. This opens the possibilities to a number of explanations: (1) conflicts concerning pharmaceuticals are more obvious to faculty; (2) institutional policies address non-financial conflicts of interest better than financial conflicts of interest or (3) the vignette itself did not present as obvious a conclusion. In any event, the difference in the mean response may be useful in crafting an effective pre-intervention policy that governs conflicts of interest.

The difference in responses may provide important insight into the need for consistent and effective conflict of interest policies. That is, the differences in responses suggest that new or revised policies may be needed. Current approaches to addressing conflicts of interest may not account for differences in faculty rank, position or responsibilities.28 Further, many financial conflict of interest policies focus on

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Table 2. Tobit regression models of vignette responses

<table>
<thead>
<tr>
<th>Vignette type</th>
<th>Predictor</th>
<th>Coefficient</th>
<th>Std. Err.</th>
<th>t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>Rank</td>
<td>-0.55</td>
<td>0.08</td>
<td>-7.14**</td>
</tr>
<tr>
<td></td>
<td>Department grants</td>
<td>1.37</td>
<td>0.45</td>
<td>3.05**</td>
</tr>
<tr>
<td>Data</td>
<td>Sector</td>
<td>-0.26</td>
<td>0.21</td>
<td>-1.24</td>
</tr>
<tr>
<td></td>
<td>Department grants</td>
<td>0.97</td>
<td>0.42</td>
<td>2.31*</td>
</tr>
<tr>
<td>Profit</td>
<td>Rank</td>
<td>-0.42</td>
<td>0.7</td>
<td>5.60**</td>
</tr>
<tr>
<td></td>
<td>Department grants</td>
<td>1.13</td>
<td>0.43</td>
<td>2.64**</td>
</tr>
<tr>
<td>Promotion</td>
<td>Rank</td>
<td>-0.49</td>
<td>0.12</td>
<td>3.97**</td>
</tr>
<tr>
<td></td>
<td>Department grants</td>
<td>-0.07</td>
<td>0.65</td>
<td>-0.11</td>
</tr>
</tbody>
</table>

*p < 0.05; **p<0.01
disclosure after a conflict comes into existence (e.g., that a gene therapy has been patented by a private company with which the academic scientist is involved).\textsuperscript{13,21} The purpose for the disclosure requirement appears to be that an independent body may then be appointed or consulted to determine whether steps can be taken to manage the academic scientist’s conflict of interest.\textsuperscript{1,29} The disclosure approach may be inadequate because of the difficulties associated with evaluating each scenario from an ex ante perspective to determine if a financial conflict of interest should be addressed such that no harm could ever occur. Given that issues with conflicts of interest continue to arise in academic medicine and lead to reported harms, the current policies appear ineffective or inadequate.

This study may prove helpful in drafting new conflict of interest policies. Policy shapes human behavior and can be directed towards incentivizing academic scientists to respond in a particular way when faced with a potential conflict of interest. The present study may be helpful in the following ways. First, it is of great interest that junior faculty (i.e., associate or assistant professors) responded differently to situations concerning a conflict of interest hypothetical than senior faculty (i.e., full professors). While both junior and senior faculty should be governed by the same high level conflict of interest policies; junior faculty, who are less experienced and may face different pressures, may need targeted education programs or other types of oversight in order to assist them in recognizing when a conflict of interest may be present and in dealing effectively with potential conflicts. The design of an education or training program could be based on other studies that analyze ethics training and decision-making, and follow-up studies that analyze the effectiveness of training programs should be performed.\textsuperscript{30}

Second, our survey results suggest that faculty in departments with larger amounts of grant money may respond differently than faculty with smaller amounts of department grant money, suggesting that the amount of grant money in a department may contribute to a culture of attitudes towards conflicts of interest. That is, faculty who are heavily dependent on grant money may have different pressures on them than faculty that are not as dependent on large amounts of grant money.

Third, although the study was not explicitly designed to address differences between researchers and clinicians, the data indicated that these groups may differ, and may therefore require different policies to address the conflicts they may face. A previous study by Campbell and colleagues found that clinical departments have more relationships with industry compared to nonclinical departments.\textsuperscript{35} This suggests that both the amount and type of private funding may be important factors for consideration when crafting conflict of interest policies. Overall, this study exemplifies that work must be done in the area of conflicts of interest because not all faculty respond the same way when faced with a situation in which a conflict may arise.

Our study is not without limitations. First, we used a small number of vignettes in an attempt to understand a much larger topic that has many facets. The rationale for using seven vignettes was to create a less burdensome survey in an effort to obtain a larger number of responses. An onerous survey that is more time consuming may provide comprehensive results, but it also comes with its own limitations (e.g., fewer respondents). Second, it is possible that some respondents did not answer honestly, potentially biasing the findings. However, the relatively large sample and anonymous nature of the survey likely minimized this possibility. Third, the brief survey did not assess a number of other factors that are likely to influence responses, including the extent to which participants have received public and private funding, clinical vs. research duties and experience with conflicts of interest. Finally, although respondents were from five different medical schools, all five are part of the same state university system and may have similar policies and training requirements, potentially reducing generalizability outside of this system.

Importantly, an understanding of how academic scientists respond to situations in which a conflict of interest might arise may assist in the creation of new and effective policies to address conflicts of interest. The law—which effectively shapes human behavior—can be utilized to create incentives for positive behavior and create disincentives for negative behavior in order to craft an effective policy that addresses faculty behavior before a conflict of interest arises.\textsuperscript{24}

Materials and Methods

Study design and sample. Participants were recruited in August and September 2010 from five medical schools at state universities in the southwestern United States. All five are members of the same state university system. Potential participants were identified from medical school faculty listings on publicly available university websites. Due to participants’ anonymity, this study was certified as exempt from IRB review by IRBs at participants’ institutions.

Survey instrument. After reporting their institution, home department, rank and academic track and primary sector (research or clinical), participants read seven vignettes describing situations in which a conflict of interest could arise in academic research. The vignettes reflected potential conflicts with pharmaceutical study sponsors, private investors and university administration. Participants rated their most likely response to each situation on a scale from 0–9.

Data analysis. We hypothesized that mean vignette responses would differ by academic rank and academic sector. We also expected response differences based on 2009 federal grant money per faculty member of respondents’ home departments (retrieved from www.report.nih.gov/funded_organizations/index.aspx). We sorted the vignettes into four non-mutually-exclusive categories: conflicts with pharmaceutical companies (vignettes 1 and 4), reporting of data (vignettes 1, 3, 4 and 5), scientific vs. profit motive (vignettes 2, 5 and 6) and promotion (vignettes 3 and 7). Vignettes falling into each category were averaged to create category scores that were used as outcome variables, and the effects of rank, sector and departmental grant money were tested separately for
each category. The three predictor variables were tested simultaneously in each model. All responses were recoded so that higher scores reflected less appropriate responses. All analyses used an alpha level of .05 and were conducted with Intercooled Stata 11.0.

The distributions of each outcome variable were positively skewed, and in each case zero was the modal score; that is, there was a floor effect such that the data were left-censored at zero. Consequently, we used tobit regression to model these outcomes. The tobit procedure models the effect of predictor variables on underlying latent variables (here, responses to the vignette categories), addressing the presence of floor or ceiling effects. We then decomposed the tobit coefficients into two effects: (1) the expected effect of a predictor (e.g., academic rank) on vignette responses for respondents with non-zero values; and (2) the effect of the predictor on the probability of a non-zero response.

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References

28. US Department of Health and Human Services Office of Research Integrity. Responsibility of applicants for promoting objectivity in research for which PHS funding is sought 2010.