Financial Conflicts of Interest in the Research Setting: A Matter of Interpretation?

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On January 21, 2010, the Houston Chronicle reported that the National Institutes of Health (NIH), a division of the U.S. Department of Health and Human Services (HHS), is carrying out an investigation regarding Baylor College of Medicine’s (BCM) alleged lack of compliance with federal regulations governing financial conflicts of interest.¹ The NIH aver that BCM’s corporate conflict-of-interest policies do not comply with current regulations and that BCM failed to report potential conflicts of interest involving its medical staff while conducting research funded by the NIH.² The alleged conflict of interest arises out of the financial relationships that some BCM physicians have, or have had, with drug companies to promote or market some of their drugs³ (for example, drug “A”), while such physicians are actively conducting research seeking future approval of such companies’ drug “B”. Consequently, BCM will face tougher reporting standards until such time it is able to demonstrate compliance, to NIH’s satisfaction,⁴ or successfully defeats the allegations against it.

Regulatory Considerations

Financial relationships between drug companies and physicians have been the subject of scrutiny by the federal government for many years. Between 1988 and 1994, the Office of the Inspector General (OIG) published five Special Fraud Alerts “addressing specific trends of health care fraud and certain practices of an industry-wide character.”⁵ In its 1994 Notice, the OIG specifically identified certain prescription drug marketing schemes⁶ as potential violations of the federal Anti-kickback Statute.⁷ None of the schemes identified in the 1994 Notice fit perfectly with the type of recent conduct allegedly committed by BCM,⁸ However, the 1994 Notice identified as suspect any marketing scheme seeking to induce the provision of a prescription drug item reimbursable by Medicaid.⁹

The OIG’s continuous efforts to deter health care fraud have prompted the federal government to issue guidelines to regulate arrangements previously left to the discretion

² Id.
³ Id.
⁴ Id.
⁶ Id.
⁷ 42 U.S.C. § 1320a-7b(b).
⁸ The three schemes identified by the OIG as “aggressive drug marketing” are “product conversion”, “frequent flier” campaign and “research grant.” Rebecca D. Roberts, Physician Financial Relationships in the New Regulatory Environment, 20:11 PHYS. EXEC. 50 (1994).
⁹ Id.
of physicians and the pharmaceutical industries. Last year, the U.S. Department of Justice (DOJ) and HHS announced they intended to increase efforts to deter health care fraud by targeting physicians and “scrutinizing their financial arrangements with drug and device manufacturers.” Federal prosecutors planned to aggressively examine the conduct of physicians receiving compensation from pharmaceutical companies, including consulting fees, and would apply the anti-kickback statute if the receipt of such compensation is in any way linked to a condition by the company that the physicians prescribe its products.

The NIH has also regulated the financial relationship between physicians and drug companies dating back to 1995, when the PHS published its “Objectivity in Research” guidelines. The purpose of these guidelines was to establish “standards and procedures to be followed by institutions that apply for research funding from the PHS to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research.” Under the current guidelines, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought,” institutions conducting research funded by the NIH must report the existence of any conflicting financial interest and assure that the interest has been managed, reduced or eliminated, before the institution spends any funds under the award. The institution does not have to report the nature of the interest or other details found. However, if the institution discovers any conflicting interest identified subsequent to the institution’s initial report, it must report it within 60 days of that identification. Beginning July 1, 2009, the NIH required “all Financial Conflict of Interest (FCOI) reports for grants and cooperative agreements to be submitted using the new electronic Research Administration (eRA) Commons FCOI Module.”

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12 Id.
14 Id.
15 42 C.F.R. Pt. 50, Sub. F.
16 42 C.F.R. Pt 50.604(g)(2).
17 Id.
18 Id.
The NIH is not responsible for identifying or managing any conflicting financial interest of an investigator. This responsibility has been delegated by the NIH to the researching institution. The NIH’s primary responsibility, as the grantor agency, is to oversee the institution’s compliance with these requirements.

The delegation of this responsibility may be the reason behind the NIH recurring concern on the accuracy of reporting and BCM’s compliance with its internal policies. The alleged lack of compliance may be the result of a difference in the interpretation of the NIH’s regulations. We must bear in mind that the reporting requirements apply to a conflicting financial interest, as determined by BCM upon its delegated authority, instead of to a “potential conflict of interest.” The latter is broader and therefore would require BCM to report any potential conflict, thereby removing the burden on BCM to arrive at a clear determination of conflict that could, despite its good faith efforts, be noncompliant in the eyes of the NIH.

Differing Views on Corporate Conflicts of Interest

BCM’s alleged actions, as explained above, could be interpreted to be contrary to the PHS’s regulations or the result of its interpretation of such regulations. The truth of the matter is that BCM is not alone in its interpretation of the regulations. Institutions like the Harvard Medical School and Weill College of Medicine, when confronted by similar sets of circumstances, concluded that there was no conflict of interest and therefore, no need to report to the NIH the financial relationships between some of their physicians and the drug companies. These institutions appear to have relied on their delegated authority to interpret, identify and manage any possible conflict of interest as the basis for their actions and on the language of 42 CFR Part 50.604(c)(1). Apparently, they have interpreted a conflict of interest to arise only in circumstances in which such financial interest is directly related to the outcome of the physician’s research under an NIH grant.

However to some, like Senator Charles Ernest (Chuck) Grassley, the “top ranking Republican on the U.S. Senate Finance Committee,” the existence of a conflict of interest seems clear. Senator Grassley was in fact the person who asked NIH director, Francis S. Collins, to inquire into BCM’s compliance with federal regulations following a

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21 Id.
22 Id.
24 Institutions must require their investigators to submit a listing of their known Significant Financial Interests (and those of their spouses and dependent children), that could reasonably appear to be affected by the research for which PHS funding is sought and in entities whose financial interests would reasonably appear to be affected by the research.
25 Id.
26 Id.
newspaper article “on universities not reporting employee’s acceptance of drug company money.” Senator Grassley has conducted extensive congressional supervision of the financial ties amongst physicians involved in clinical research funded by the NIH and the pharmaceutical companies. He asked 23 other medical schools for information about their policies addressing the relationship between their faculty members and the drug industry and has worked since 2007 to pass the Physician Payments Sunshine Act, which would require drug, device and biologic manufacturers to report quarterly to the HHS and make public, their payments to physicians. Therefore, the existence of a potential conflict would be easily verifiable.

But Senator Grassley’s efforts at transparency are not free from controversy. His endeavors have been catalogued as a war against the pharmaceutical companies, a campaign to restrict the amount of information about drugs available to physicians and patients, and an unsubstantiated and biased assumption that these marketing practices have had an adverse effect on the welfare of the patients. Others have argued that the corporate conflict-of-interest accusations, in general, have often been used as tactics to “silence scientists who ended up being correct” and that it is “naïve to caricature scientific disputes as battles between ‘industry’ and the ‘public interest’ as if bureaucrats and activists didn’t have their own selfish interests.” In fact, an unintended consequence of this amplified interest on corporate conflict of interest may have been causing “some of the best medical researchers to shun drug company money altogether — not because they think it leads to bad research, but because they are tired of that fact being highlighted every time they are identified in a news story, as if that were the most important thing to know about their work.”

Conclusion

The NIH’s regulations should be enforced to insure that research is conducted free from external influences that may compromise its outcome, in detriment of the general population. But, in order for the guidelines to be just, they must specifically identify the conduct that will require reporting. Delegating to the medical institutions the responsibility of identifying their investigator’s financial conflicts of interest based on a
reasonable appearance of conflict, not only opens the door to a variety of reasonable interpretations, but also subjects the institutions to allegations of noncompliance and possible actions by the OIG, regardless of their best efforts to observe NIH policies. Requiring reporting of a potential conflict of interest would better serve the interests of the NIH.

Notwithstanding the above stated, the NIH and the OIG should acknowledge that physicians in academic settings “have expertise in clinical care, research, and teaching that may appropriately be provided in exchange for reasonable fees.” They should understand that stretching the requirements of 42 CFR Part 50, Subpart F to include any possible financial relationship between physicians and the pharmaceutical industries would denigrate the image of the medical profession because it would assume that, under all circumstances, physician researchers will renounce impartiality and professional judgment in exchange for financial gain. Considering how many different products, any given pharmaceutical company may have available in the market for physicians to select for treatment, where would the conflict end?

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