

PRESS RELEASE

How Do Financial Conflicts of Interest Affect Voting in FDA Advisory Committees?

New York, New York, September 8—With the implementation of the Sunshine Act this fall, information about gifts and payments to physicians and hospitals from pharmaceutical and medical device companies will be available in a federal database. This spotlight on physician-industry relationships inevitably raises questions about conflicts of interest and their impact on physician decision making.

A new study in the September issue of *The Milbank Quarterly*, examining the potential for financial conflicts of interest to influence advisory committee members of the Food and Drug Administration (FDA) during the drug approval process, found that there seems to be a voting bias when experts have exclusive financial ties to firms but, surprisingly, not when they have multiple ties.

The study, “Revisiting Financial Conflicts of Interest in FDA Advisory Committees,” looks at 15 years of meetings and almost 16,000 votes from about 380 meetings of FDA Center for Drug Evaluation and Research (CDER) advisory committee members. The purpose of the study was to “reevaluate the association between the financial interests of... CDER advisory committee members and their voting behavior,” writes study author Genevieve Pham-Kanter, PhD, assistant professor of health management and policy at the Drexel University School of Public Health. Using a “vastly expanded data set of... member votes and financial interests” enabled the researchers “to detect relationships that had previously been missed.”

Academic experts regularly serve on advisory committees of the FDA, helping to interpret scientific evidence. The financial ties of these experts have long been a concern. In 1991, the FDA commissioned a study on its use of advisory committees and identified members’ financial ties as an area of concern; in 2009, the FDA commissioned a more detailed study of the relationship between committee members’ financial ties and their voting. In the 2009 study and in a previous smaller study, researchers found no statistically significant relationship between the two despite anecdotal evidence of the industry ties of committee members participating in decisions on products that later had safety problems.

“The stringency of FDA regulation of the financial interests of advisory committee members has waxed and waned,” writes Pham-Kanter. Recently relaxed conflict-of-interest rules for committee members have raised concerns about the impact of their financial relationships on the FDA’s drug approval process.

A Look at Financial Interest and Votes

In contrast to earlier studies, this study found that:

- Individuals with financial interests solely in the sponsoring firm are more likely to vote in favor of the sponsor than are members who have no financial ties.
- Individuals with ties to both the sponsor and its competitors did not seem to vote differently than those with no ties.

Similar patterns emerged based on specific types of financial relationships:

- Having an ownership interest in, being a member of an advisory board or a steering committee for, and being a paid speaker for solely the sponsoring firm are associated with greater odds of voting in favor of the sponsor relative to having no financial ties.
- Receiving honoraria from both the sponsoring firm and its competitors is associated with lower odds of voting in favor of the sponsor relative to having no financial ties.

The level of financial conflicts of interest varied. Across all committees, the median level of meeting “conflictedness” (percentage of people with a reported conflict of interest was about 13%). Committees reported that, on average, half of their meetings were attended by at least one person with a financial conflict.

The most reported conflicts of interest were:

- Consulting (34% of conflicts)
- Ownership interest (25% of conflicts)
- Paid speaker (19% of conflicts)
- Employer grant or contract (13% of conflicts)
- Research investigator of grant /contract recipient (9% of conflicts)
- Blinded endpoint reviewer or member of data safety monitoring board (7% conflicts).

How the Study Can Help Policymakers

This study suggests that, in terms of voting and financial interests, “there appears to be a pattern of exclusive ties to the sponsor being associated with a pro-sponsor voting bias, particularly in relation to advisory boards, but there is no detectable bias among individuals with ties to competitors or ties to both sponsors and competitors,” writes Pham-Kanter. If the objective of the FDA or any other organization concerned about conflicts of interest is to reduce bias, then this study can be used to inform the FDA and the public about the policy effectiveness of various conflict of interest rules.

David Rothman, PhD, professor of social medicine at Columbia University College of Physicians & Surgeons, provides a commentary, “Here Comes the Sun,” on the harmful

effects that conflicts of interest can have on medical professionalism. Conflicts of interest, writes Rothman, have been a “major concern for health care professionals and their organizations” —however, “policies governing conflicts of interest are not as rigorous as they might or should be.” One change that might come as a result of the Sunshine Act, predicts Rothman, is that physicians might be less willing to accept industry payments. Whatever happens, “we are entering an era of unparalleled transparency,” he writes. It would be “surprising if physicians did not behave differently when watched.”

About *The Milbank Quarterly*

Continuously published since 1923, *The Milbank Quarterly* features peer-reviewed original research, policy review, and analysis from academics, clinicians, and policymakers. The *Quarterly*'s multidisciplinary approach and commitment to applying the best empirical research to practical policymaking offer in-depth assessments of the social, economic, historical, legal, and ethical dimensions of health and health care policy. *The Milbank Quarterly* is published in March, June, September, and December on behalf of the Milbank Memorial Fund by John Wiley & Sons.

Contact:

Judith Zimmer
Communications Director
Milbank Memorial Fund
212-355-8400
jzimmer@milbank.org