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Points to Consider Regarding Conflicts of Interest in Medical Research

Although observers have been arguing for many years that conflicts of interest in medical research hurt patient care and diminish research integrity, the issue has lately become particularly salient to policy makers, researchers, institutions, and other stakeholders. The result is an environment with increased suspicion about the relationships between industry, research institutions, and physicians and greater regulation of these relationships.

The Bioethics Committee of the Board of Directors of the Biotechnology Industry Organization (BIO) has developed the following Points to Consider to provide a decision-making framework for BIO policy committees and to articulate general principles regarding conflict of interest issues.

I. Financial relationships between industry and academia have had a beneficial impact on research and patient care.

Although conflicts and potential conflicts should be addressed, close relationships between industry and researchers have had a beneficial impact on research and patient care. Many of the conflicts or potential conflicts that trouble industry watchdogs have proven enormously valuable. Financial relationships between academia and industry help bring new drugs to the market for patients and fuel economic development in states or regions. They also increase research budgets, supplementing funds obtained elsewhere.

The federal government recognized these potential benefits almost 30 years ago, with the enactment of the Bayh-Dole Act. The Act permitted universities and small businesses to own inventions made as a result of federal funding through patenting and authorized licensing to industry. The policy objective was to encourage the licensing of inventions developed in universities to industry, which would commercialize them into products for patients.

The Act has been enormously successful. The incentives it enabled have spurred research, led to the creation of new jobs, and facilitated the development of important public health products, including a Hepatitis B vaccine, human growth hormones, and synthetic penicillin.

Thus, we must consider the benefits, along with the dangers, of allowing industry funding for academic research. When addressing financial conflicts of interest, private and government policymakers must develop policies to achieve several goals—ensuring patients receive high quality care, maintaining research integrity, and promoting important and beneficial collaborations.

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II. Potential conflicts exist in many different contexts. Tools to manage these conflicts should be tailored for each situation with the objective of improving patient care and protecting research integrity.

Disclosure and outright prohibitions are the tools used most often to address conflicts or potential conflicts. Prohibitions usually take the form of banning relationships with individuals that have a designated financial stake in the research or in the commercial entity sponsoring the research. Disclosure policies take many forms but typically require the researcher or clinician to reveal his or her sources of financial support.

However, potential conflicts arise in many different contexts. For example, serving on an FDA Advisory Committee, attending a conference sponsored by a drug manufacturer, acting as an investigator for a company in which one has a large financial stake, and recruiting patients for a study with which one has no other connections, are all distinct situations. A one-size-fits-all model of addressing conflicts is not appropriate. Rather, each situation should be analyzed for the potential conflicts that could harm patient care or affect research integrity and solutions should be developed based on that analysis. In each case, though, entities, agencies, or individuals developing conflict of interest rules and policies must take care to protect beneficial collaborations.

In certain contexts, parties should strive to eliminate conflicts or prohibit collaborations if the researcher has certain financial interests at stake. In other situations though, eliminating conflicts may not be possible or may be counterproductive to good patient care. An example would be when FDA recruits members of its Advisory Committees. In some of these situations, such as when the agency is reviewing the data surrounding new drugs for very rare diseases, there may be few experts available to provide the agency with scientific advice; these experts may also have a relationship with commercial sponsors.

Thus, conflict policies must also be sufficiently flexible to not prohibit the agency from access to necessary expertise because that will not benefit patients. In these situations, disclosure might be the best method to manage a conflict.

By using techniques to manage conflicts based on the facts of each situation, stakeholders will be better able to balance the competing concerns of preserving the integrity of research while also protecting beneficial collaborations.

III. Other, non-financial conflicts that could hurt patient care or research integrity should be addressed.

Many other conflicts and potential conflicts exist throughout the research system. Examples of non-financial conflicts researchers may confront include: the desire for faculty advancement and having good relations with peers and supervisors, competing successfully for research grants, receiving the prestige that comes from publications, and

alleviating pain and suffering. Very little published research has analyzed the impact of these non-financial conflicts and few policies have been developed to help stakeholders identify and manage these conflicts.

IV. More research is needed to determine whether financial conflicts affect research quality or patient care.

Most conflict of interest policies focus exclusively on financial conflicts and potential conflicts. Yet, there is insufficient empirical data about the impact of financial conflicts on research quality or patient care.

In fact, recent studies demonstrate that many assumptions about financial conflicts of interest are not true (e.g., "Knowing Doctor's Financial Interests Doesn't Deter Clinical Trial Participants", *Science Daily*, April 2, 2008). Some published analyses of university financial disclosure policies cast doubt on not only disclosure as a technique to manage conflicts but also on whether many financial relationships actually affect patient decisions regarding whether to participate in a research project (e.g., Weinfurt, KP, Dinan, MA, et al, "Policies of Academic Medical Centers for Disclosing Financial Conflicts of Interest to Potential Research Participants", *Acad Med.* 2006 February; 81(2): 113–118).

Moreover, while agencies and institutions typically identify a conflict based on a financial relationship between the researcher and a commercial entity, there is little data to suggest that a specific dollar threshold would influence a researcher's behavior and if it did, what that amount would be. Perhaps reflecting this lack of consensus, the amount deemed to be a conflict varies by institution and by regulatory agency.

Conclusion

BIO remains ready to work with stakeholders including researchers, research institutions, and regulators to develop policy solutions that protect patient care and research integrity as well as promote productive relationships between industry and researchers.

- *Approved by the Biotechnology Industry Organization's Board Standing Committee on Bioethics, June 19, 2009.*