

# CONFLICTS OF INTEREST AMONG SCIENTIFIC ADVISORS: A THREAT TO SOUND SCIENTIFIC ADVICE

## INTRODUCTION AND BACKGROUND

Both for-profit and non-profit organizations look to external scientific advice to help guide, oversee, and evaluate their research and development efforts. To be useful, such advice must be objective and candid, free from biases caused by conflicts between the advisor's obligation to the firm or organization he or she is advising and: (i) financial self interest; (ii) loyalty to another organization; (iii) competing personal or professional agendas; or (iv) personal or professional relationships.

Today, conflicts of interest among scientific advisors are a given. There are few external advisors who don't have institutional, financial, professional, or personal conflicts that represent real or perceived threats to the organization to which he/she is providing advice. *It is not whether conflicts will arise, but how organizations will handle them when they do.* This document is intended to: (i) increase awareness of, and knowledge about, conflicts of interest and the ways in which they can undermine the integrity of scientific advice; and (ii) provide context for a suggested policy for how for-profit firms and non-profit organizations can handle such conflicts, and for a sample disclosure form.

### A. FOR-PROFIT COMPANIES

For-profit companies depend on external scientific advice to help: (i) assure that their products are consistent with the latest scientific knowledge and technological advances; (ii) guide, monitor, and evaluate internal company R and D efforts, including the testing of potential new products; (iii) review and evaluate proposals for support of external R and D; (iv) develop and curate evidence-based databases and literature reviews intended to represent the state of the art; and (v) serve as a company's eyes and ears on the state of science and technology and on science and technology policies. For this reason, it is critical that this advice be free from the biases introduced by an advisor's concern for his/her financial self interests, personal or professional standing or relationships, or loyalty to, or affiliation with, another organization. Profit-making entities are concerned primarily with potential conflicts arising out of situations in which an advisor benefits *financially* from his/her relationship with another company.

An Internet search turned up an excellent document relevant to the issue of advice to for-profit companies. Thomson Micromedex provides evidence-based information to clinicians and other health care providers. The company developed its conflict of interest policy to *"help ensure individuals involved in literature evaluation and content development for Micromedex databases and products are free from financial conflicts of interest."* It goes on to say that: *"Micromedex is committed to providing unbiased evidence-based information on drug uses in accordance with the available medical and scientific literature. The policies and procedures outlined herein identify and resolve potential conflicts of interest for Micromedex external advisors involved in the content development process."*

Micromedex is concerned primarily with the relationships between its advisors or close relatives (especially a spouse) and drug companies, particularly conflicts having to do with the relationship with a pharmaceutical firm whose drug use is being documented. These relationships include:

- *Employment or Leadership Positions* – Includes serving as an employee, director, or partner in the subject pharmaceutical company;
- *Equity or Stock Ownership* – Stock or equity ownership in a company where the advisor or spouse has direct control over the disposition of the ownership interest, and the value of the stock or equity ownership exceeds a specified amount;
- *Fees and Payments* – Money received as fees or payments from a pharmaceutical company for consultation, advice, lecture fees, honoraria, and other services;
- *Research Funding* – Receipt of funding from the pharmaceutical company for research on which the advisor or his/her spouse is the principal investigator; and
- *Intellectual Property* – Including: (i) where the advisor owns the patent, other IP, or royalty rights in a drug that is the subject of a Micromedex review; and (ii) where the advisor holds IP or royalty rights in an unrelated product and receives payments from a pharmaceutical firm.

Conflicts of interest are documented and publicly available on the Micromedex Web site.<sup>1</sup>

## **B. NON-PROFIT ORGANIZATIONS**

Objective scientific advice is equally important for non-profit organizations, including foundations, a wide range of charitable organizations, research universities, and government agencies. Non-profit organizations depend on objective scientific advice to help: (i) guide and oversee service delivery programs that depend on sound evidence of safety and effectiveness; (ii) guide, oversee, and evaluate their internal research and research funding programs; (iii) review research proposals submitted to funding agencies for support; and (iv) assess compliance with regulations intended to protect public health and safety.

Perhaps the most widely used and referred to conflict of interest (COI) policy is that of the National Institutes of Health (NIH) which covers thousands of scientists reviewing thousands of research proposals. NIH perceives COI in scientific peer review to exist “*when a reviewer has an interest in a grant or cooperative agreement application or an R and D proposal that*

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<sup>1</sup> [http://www.micromedex.com/about\\_us/editorial/ed\\_ConflictofInterest.pdf](http://www.micromedex.com/about_us/editorial/ed_ConflictofInterest.pdf).

*is likely to bias his or her evaluation of it.”* NIH identifies the following kinds of situations that might represent conflicts of interest that meet this definition:

- *Financial Gain* – Where the reviewer or a close relative or professional associate would derive a financial benefit from the applicant institution were an application under review to be funded. This benefit could derive from: (i) full or part-time employment; (ii) honoraria; (iii) consulting fees; or (iv) equity or stock ownership.
- *Membership on a Standing Review Group* – *“When a scientific review group meets regularly, a relationship among the individual members exists; therefore, the group as a whole may not be objective about evaluating the work of one of its members. In such cases, a member’s application or proposal will be reviewed by another qualified review group to be sure that a competent and objective review is obtained.”*
- *Longstanding Disagreements* – *“A conflict of interest may exist where a potential reviewer has had longstanding scientific or personal differences with an applicant.”*
- *Applications in Response to a Solicitation* – Individuals serving as a PI or key personnel on an application submitted in response to a solicitation is considered to have a conflict of interest with *all* of the applications received in response to that solicitation, and should not be part of the review process.

These last three are interesting in that they go beyond the usual financial considerations, recognizing the human frailties that may get in the way of a fair and objective assessment of scientific projects.