Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity1–3

The International Life Sciences Institute North America Working Group on Guiding: Sylvia Rowe,4 Nick Alexander,1 Fergus M. Clydesdale,3 Rhona S. Applebaum,6 Stephanie Atkinson,7 Richard M. Black,8 Johanna T. Dwyer,6 Eric Hentges,10* Nancy A. Higley,11 Michael Lefevre,12 Joanne R. Lupton,13 Sanford A. Miller,14 Doris L. Tancredi,13 Connie M. Weaver,16 Catherine E. Woteki,17 and Elaine Wedral10

4SR Strategy LLC, Washington, DC 20036; 5McMaster University, Department of Pediatrics, Hamilton, ON L8N 3Z5, Canada; 6Kraft Foods Global, Inc., Glenview, IL 60025; 7Frances Stern Nutrition Center, New England Medical Center, Boston, MA 02111; 8International Life Sciences Institute North America, Washington, DC 20005-1743; 9PepsiCo, Inc., Scientific and Regulatory Affairs, Valhalla, NY 10595; 10Utah State University, Center for Advanced Nutrition, Logan, UT 84322-4715; 11Texas A&M University, College of Agriculture and Life Sciences, Department of Nutrition and Food Science, College Station, TX 77843; 12University of Maryland Center for Food, Nutrition and Agriculture Policy, College Park, MD 20742; 13Cadbury Adams USA LLC, Science and Technology, Whippany, NJ 07981; 14Purdue University, Department of Foods and Nutrition, West Lafayette, IN 47907-1264; and 15Mars, Inc., McLean, VA 22101

Abstract

There has been substantial public debate about the susceptibility of research to biases of various kinds. The dialogue has extended to the peer-reviewed literature, scientific conferences, the mass media, government advisory bodies, and beyond. While biases can come from myriad sources, the overwhelming focus of the discussion, to date, has been on industry-funded science. Given the critical role that industry has played and will continue to play in the research process, the International Life Sciences Institute North America Working Group on Guiding Principles has, in this paper, set out proposed conflict-of-interest guidelines regarding industry funding for protecting the integrity and credibility of the scientific record, particularly with respect to health, nutrition, and food safety science. Eight principles are enumerated, specifying ground rules for industry-sponsored research. The paper, which issues a challenge to the broader scientific community to address all bias issues, is only a first step; the document is intended to be dynamic, prompting ongoing discussion and refinement. J. Nutr. 139: 1051–1053, 2009.

Guiding principles

In the conduct of public/private research relationships, all relevant parties shall:

1) conduct or sponsor research that is factual, transparent, and designed objectively; according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2) require control of both study design and research itself to remain with scientific investigators;
3) not offer or accept remuneration geared to the outcome of a research project;
4) prior to the commencement of studies, ensure that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;
5) require, in publications and conference presentations, fully signed disclosure of all financial interests;
6) not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;

1 Supported in part by educational grants from Cadbury Adams USA, LLC; the Coca-Cola Company; ConAgro Foods Inc.; General Mills; Kraft Foods; Mars Snackfoods US, LLC; PepsiCo Inc.; Procter & Gamble; Sara Lee, and Tate & Lyle. This paper is the product of a working group on conflict of interest/scientific integrity organized by the North American branch of the International Life Sciences Institute (ILSI North America). ILSI North America is a public, nonprofit, scientific foundation with branches around the world that provides a forum to advance the understanding of scientific issues related to the nutritional quality and safety of the food supply. ILSI North America carries out its mission by sponsoring relevant research programs, professional education programs, and workshops, seminars, and publications, as well as by providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. The programs of ILSI North America are supported primarily by the ILSI North America industry membership. This paper underwent independent scientific review by more than 25 reviewers.


3 This article is published as an excerpt to the full text that appeared in Nutrition Reviews. For the complete article and citations of references 1-43, see Nutrition Reviews 2009; Vol. 67(5):264-272.

4 To whom correspondence should be addressed. E-mail: ehentges@ilsi.org

0022-3166/08 $8.00 © 2009 American Society for Nutrition.


First published online April 29, 2009; doi:10.3945/jn.109.105668.
7) guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers; and
8) require that academic researchers, when they work in contract research organizations or act as contract researchers, make clear statements of their affiliation; require that such researchers publish only under the auspices of the contract research organizations.

Import and implications of the guidelines
Obviously, guidelines are just...guidelines. They are not law, but if the research community embraces them, or even embraces their spirit, we believe there will be a profoundly beneficial effect on the quality and integrity of research, encouraging responsible oversight and stewardship of scientific research by all funding organizations. Following the guidelines will doubtlessly lead to closer and more open communication between funding bodies and researchers, resulting in a new spirit of collaboration. Still, it must be stressed that each organization wishing to adopt these guidelines needs to develop its own quality control mechanism to ensure compliance.

A strong peer review system coupled with open declarations of research sponsorship in all scientific communications is a mandatory prerequisite for these guidelines to be effective. The second prerequisite is that university and industry policies be promulgated to address the issues raised in these guidelines regarding control of the design and conduct of the research and its publication. It is the responsibility of both the funding entity and the researcher(s) being funded to adhere to the guidelines; existing oversight structures are also encouraged to endorse and adhere to them. Furthermore, it should be understood that failure to embrace the guidelines would raise serious questions about any research project so conducted.

It has been suggested that, in the past, industry-funded research may have revealed a bias toward results favored by the food industry (21,43). The authors of one publicized study (4) reaching that conclusion proposed several explanations: 1) that food industry companies may wish to demonstrate the superiority of their products to those of competitors; 2) that investigators are influenced by their funding in formulating their research design and/or hypotheses; 3) that industry sponsors of research may suppress unfavorable results; 4) that authors of scientific reviews may deliberately bias their searches and interpretations to the benefit of their industry funders; and 5) that scientific reviews may disproportionately represent studies "arising from industry-supported scientific symposia." Such criticism overlooks the fact that most university research is basic in nature and that companies frequently enter into research agreements with university faculty at a point at which preliminary experiments (whether conducted in the faculty member's laboratory or the company's laboratory) have established the proof of concept and, therefore, the likelihood that the research will have positive results is enhanced.

Notwithstanding the obvious observation that scientific reviews conducted by nonindustry-supported authors are also subject to many potential biases, the 8 principles articulated in this paper address all of these possible sources of skewed research. Indeed, if these principles are vigorously adopted as the guidelines they are intended to be, there would be virtually no reason to quarrel with a research conclusion except by disputing the science itself.

In fact, the 8 principles articulated here are intended to provide a clear statement of responsibility on all sides, those that are funding activities as well as those being funded, when academic institutions or academicians are recipients of industry funding for research, publication, or presentation. The principles are intended to offer guidance for the food industry and academic researchers who work with industry when industry-funded research projects are involved. They may be thought of as a checklist to help ensure insulation of any research project from the provision of the resources enabling the project.

Finally, the guidelines are offered as only a first step in creating a firewall against bias in research; this paper is intended to be a dynamic document, prompting ongoing discussion and refinement of the guidelines it presents.

Literature Cited