The Systemic Distorting Effects of Industry-Sponsored Research on Food and Health

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Health-related food and nutrition research may be problematic — in ways that have not been fully appreciated — because of existing funding streams and other research incentives. The few scholars exploring the impact of industry-funding on this research have focused on individual financial conflicts of interest, and have drawn attention to evidence suggesting that researchers with such conflicts tend to generate outcomes more favorable to industry sponsors. However, industry-sponsored research on so-called "functional foods" (that is, foods promoted for purported health benefits above and beyond basic nutrition) raises more fundamental systemic concerns, including: (1) that this research tends to investigate only the health *benefits* of certain foods, ingredients or components, and (2) that funding sources for research on functional foods may systemically distort the way research in the field is conceptualized and interpreted. This presentation will explore the extent to which the current regulatory framework for food labeling in the U.S. may be contributing to this state of affairs.

In order to obtain FDA-approval for *health claims*, the category of claims that tie the consumption of a food or ingredient to the reduced risk of a disease or "health-related condition," food companies are not required to explore the potential adverse effects of consuming those foods for their potential health benefits. Companies need only submit evidence to the FDA sufficient to demonstrate "significant scientific agreement" about the purported benefits. The regulatory requirements for *structure-function claims* – the category of claims that address the potential impact of a food or ingredient on a structure or function of the human body – are even less demanding. These claims do not need to be submitted to the FDA for approval, and they are rarely challenged by the FDA. In addition, there are commercial incentives for industry actors to fund studies that *appear* to support either kind of claim – particularly for audiences that do not

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possess relevant scientific expertise. The studies can be used to seed stories in the media about the health benefits of companies' products — whether or not there is any scientific agreement about the practical implications of this research. In contrast to the incentives to explore health benefits, there are clearly no commercial incentives for companies to sponsor research exploring the potential adverse effects of consuming these foods for the potential health benefits — particularly long-term effects.

Drawing on the analytical framework of "institutional corruption," existing funding streams and research incentives may be described as corrupting or distorting the field of functional foods research. Industry funding also affects research sponsored by government agencies and non-profit organizations – not least, because of its impact on the way research in this area is framed. For example, the term "functional foods" is defined solely by reference to benefits, and the scope of some scholarly journals is similarly one-sided. In addition to concerns about the impact on scientific knowledge and practice, there are concerns about the institutional integrity of academic research centers and the potential impact of food research on consumer behavior, public policy, and public health. If we take these concerns seriously, systemic responses – including regulatory reform and the creation of new funding streams – need to be explored. As part of that exploration, the presentation will conclude with a brief analysis of the new regulatory framework for food and nutrition claims in the European Union – in particular, the extent to which this framework (a) does (and does not) address the problems described, and (b) offers (and does not offer) lessons for the U.S., where the First Amendment protections for commercial speech impose regulatory constraints.