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FEDERAL REGULATION

NO TO NIH CONFLICTS PROPOSALS

WASHINGTON, D.C.—Health and Human Services (HHS) Secretary Louis W. Sullivan directed National Institutes of Health (NIH, Bethesda, MD) officials late in December to scrap their proposed conflict-of-interest guidelines and to develop a new set of "options." The proposals, published last September, provoked a massive response. Although some members of Congress, public interest groups, and academics praised them, most comments were highly critical of the proposals—asserting they are "misguided," a "return to old attitudes," and would "cost enormously."

For instance, the proposals call for "full disclosure of all financial interests and outside professional activities" for researchers, as well as for "their spouses, dependent children, and other dependents." The proposals also specify several "prohibited situations" for researchers, including owning stock in "any company that would be affected by...the research," providing a company "with which a conflict exists" data or products unless or until they also are made available publicly, and receiving fees or honoraria from a private source if evaluating any product from that source.

These proposed restrictions generated a great deal of criticism—and some praise. The National Coalition for Universities in the Public Interest (Washington, DC), a Ralph Nader affiliate, calls the guidelines "an important step forward" and urges NIH to strengthen them. Charles Moertel of the Mayo Clinic (Rochester, MN) admonishes NIH to "stick to your guns on this issue," particularly in insisting that researchers make full financial disclosures. Margaret Mellon, director of the National Policy Center for Biotechnology at the National Wildlife Federation (Washington, DC), calls the guidelines "a good first step...."

Nonetheless, most of the comments are highly critical of the proposals. The list of critics includes more than 400 academic researchers and administrators, representatives from biotechnology and pharmaceutical companies, several industrial trade groups and professional scientific organizations, and officials at NIH.

The Industrial Biotechnology Association (IBA, Washington, DC) says the guidelines "could have a chilling effect upon communication between the academic and industrial sectors." Moreover, it claims that if the guidelines were in place a decade ago, "it is not likely that the biotechnology industry...would exist." IBA calls the draft guidelines "onerous and extravagant....If implemented, [they] will ... interfere with the transfer of technology to the marketplace." In a similar vein, the Association of Biotechnology Companies (Washington, DC) calls the proposals "overly broad" and a "Draconian remedy...[that] is much worse than the disease."

David Korn, Dean of the School of Medicine at Stanford University (Stanford, CA) calls the proposals "futile." Trying to rely on rules rather than individual integrity will "accomplish little else than to stifle research creativity," he asserts. A nine-page critique from officials at the Fred Hutchinson Cancer Center (Seattle, WA) points out that, among other burdens, the paperwork from researchers obliged to make financial disclosures would require at least 4.3 feet per year of storage space. And Bruce Chabner, director of the Division of Cancer Treatment at the National Cancer Institute at NIH, says the guidelines "would have a devastating effect on biotechnology in this country."

Concern for the harmful impact on commercial biotechnology reverberates in the comments sent to NIH. Warren Stern, CEO of Pharmatec (Alachua, FL), whose company was "founded on results of NIH-funded work," calls the guidelines "misguided." David Lucan, vice president of Protein Technology (Petaluma, CA) objects to "both the perspective and content of the guidelines," calling them "inconsistent with reality." And James Vincent, CEO of Biogen (Cambridge, MA) says that NIH overreacted to an "isolated problem," and the proposals "threaten healthy cooperative working relationships between entrepreneurs, academics, and the federal government."

Evidently, the message got through to Secretary Sullivan. He says that the revised proposals will be subject to formal procedures for federal rule making, which entail a lengthy process of public review and revision. Sullivan also insists that "the research process [remain] free of unnecessary burdens and disincentives." And, looking ahead to the future of U.S. commercial biotechnology, Sullivan says that "it is important that we not unnecessarily jeopardize the international leadership position we have built up through years of cooperative government and private investment."

—**Jeffrey L. Fox**

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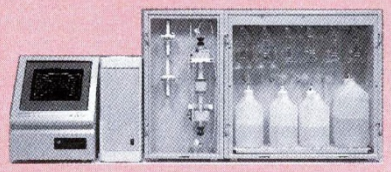

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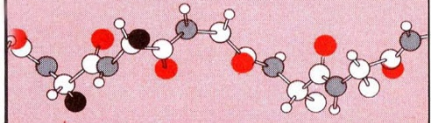

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