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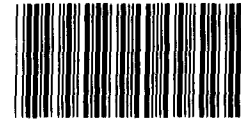
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FEDERALLY FUNDED
RESEARCH

Controlling Inappropriate
Access to Research Results

Statement by Jim Wells, Associate Director, Energy and Science Issues, Resources, Community, and Economic Development Division



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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the findings of our May 1992 report, University Research: Controlling Inappropriate Access to Federally Funded Research Results (GAO/RCED-92-104), and the implications it has for the issues being addressed by this hearing. Our report--which dealt with research grants awarded by the National Institutes of Health (NIH) and the National Science Foundation (NSF)--examined the growing interactions between universities and private industry and discussed the increased potential for conflicts of interest or other relationships that might give a particular company inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research.

This same kind of concern over conflicts of interest and other special relationships would apply equally to major, multimillion-dollar funding agreements entered into by nonprofit research institutions that receive substantial funding from the government, such as the Scripps Research Institute. This hearing is looking into business relationships between recipients of federal research grants and companies intent on commercializing their discoveries and, in particular, a new 10-year, \$300 million agreement between Scripps (a nonprofit biomedical research institute) and Sandoz Pharmaceuticals Corporation (a private drug firm). While we have not seen this agreement, we understand that NIH learned of it only after it was completed and announced by Sandoz in December 1992.

In summary, we believe that, as a general principle, the public interest is better served if the government--and, in this case, NIH--ensures that appropriate controls and safeguards are in place governing who gets access to and ultimately benefits from the results of federally funded research. In this regard, our May 1992 report recommended that NIH and NSF require that their grantees have procedures in place to effectively manage potential conflicts of interest, such as by requiring that investigators and other key personnel disclose any outside interests as part of the grant award process. Similarly, we believe it is important that the government at least be consulted about any major, multimillion-dollar agreement that a university, hospital, or other nonprofit research institution seeks to negotiate with a private company if the institution receives substantial federal funding and rights to commercialize resulting technologies.

PERSPECTIVE

Let me provide some perspective on these issues based on our May 1992 report.

The relationship of federally funded research to technological innovation was transformed dramatically during the 1980s as new linkages were established among the academic community, industry,

and the federal government. One of the primary changes strengthening links between universities, hospitals, and other nonprofit institutions (hereafter referred to as nonprofit organizations) and private industry was enactment of the Patent and Trademark Amendments of 1980 (P.L. 96-517). The act encourages nonprofit organizations and small businesses to commercialize inventions they make in whole or in part with federal funding by allowing them, with few exceptions, to elect to retain rights to such inventions. Nonprofit organizations then can transfer their rights to businesses by granting exclusive (sole) or nonexclusive (generally available) licenses.

Appropriate access to federally funded research can include (1) granting an exclusive license to commercialize resulting technology to a business that co-sponsored a research project, (2) granting an exclusive license to a business that did not fund the research but is considered best able to commercialize the technology, or (3) encouraging the scientist who developed a technology to further develop and commercialize it by working with the licensee. In contrast, inappropriate access can occur if a business that has not sponsored a research project obtains inside information about it or gets favored treatment in obtaining license rights to the resulting technology. Such inappropriate access could result from a financial or personal relationship between the business and a member of the nonprofit organization, or a financial relationship between the business and the nonprofit organization itself--such as through a major, multimillion-dollar research agreement.

UNIVERSITIES LICENSE A SUBSTANTIAL AMOUNT OF FEDERALLY FUNDED TECHNOLOGY

During fiscal years 1989 and 1990, the 35 universities in our study (1) granted 197 exclusive licenses and 339 nonexclusive licenses and (2) earned \$29.3 million from exclusive licenses and \$52.7 million from nonexclusive licenses. Typical licensees given exclusive rights to commercialize the results of federally funded research were small U.S. businesses; and most exclusive licensees were pharmaceutical, biotechnology, or other medical companies.

Most of the surveyed universities substantially expanded their programs to transfer technology to businesses during the 1980s. Twelve universities formed an office to license technology, while many others expanded and/or reorganized their technology licensing activities. For example, Harvard University, which granted its first license in December 1980, granted 39 licenses in fiscal year 1990.

Relationships between licensees and universities are becoming increasingly complex. The 35 universities reported that (1) scientists who developed the technologies for the 61 exclusive licenses consulted for, owned a substantial amount of stock in, or

had other relationships with the licensees and (2) members of industrial liaison programs were granted exclusive licenses in four cases. In 12 additional cases, companies that had long-term agreements with universities to fund general research received exclusive licenses for technology they did not directly co-sponsor. None of these relationships are necessarily inappropriate; in fact, in many cases, they are necessary for commercializing the technology. However, the potential exists that exclusive rights to federally funded technology could be inappropriately granted because of undisclosed conflicts of interest or other relationships.

NIH AND NSF LACK STRONG CONTROLS OVER INAPPROPRIATE ACCESS TO RESEARCH RESULTS

NIH and NSF, which spent \$5.8 billion for university research in fiscal year 1990, have general guidelines that rely on funding recipients to establish policies and procedures to resolve and report any potential conflicts of interest or other relationships. Neither agency requires funding recipients to submit their policies and procedures for review to ensure that they adequately address conflict-of-interest issues.

The 35 universities surveyed have established various policies and procedures to prevent inappropriate access to research results by businesses. Fourteen universities generally relied upon faculty and other members of their university community to voluntarily disclose a potential conflict of interest.

In contrast, 21 universities required that faculty and/or technology licensing personnel disclose outside interests or certify whether potential conflicts of interest exist at specified points. In particular, of the 21 universities, (1) 16 required faculty who are principal investigators to certify in writing whether any potential conflicts of interest exist as part of the approval process for sponsored research projects, (2) 9 required that some or all of their faculty annually disclose outside interests, and (3) 14 required that technology licensing office personnel annually disclose outside interests or certify whether a potential conflict of interest exists. These procedures increase the likelihood that potential conflicts of interest will be disclosed, allowing the universities then to decide how best to resolve and/or monitor any such relationships.

In response to the growing involvement of businesses in university research, both NIH and NSF are considering alternatives to strengthen their guidelines for universities and other funding recipients to better, and more uniformly, control potential conflicts of interest in the conduct of research. In December 1989, after an early attempt, NIH withdrew proposed guidelines that would have restricted interactions between grant investigators and businesses in response to many commenters' strong concerns about

their effect on university-industry relationships. NIH is again planning to promulgate a regulation by publishing a Notice of Proposed Rulemaking in the Federal Register for public comment. NIH's Associate Director for Extramural Affairs indicated that the proposed rule is likely to retain the requirement that all investigators and other key personnel involved in NIH-funded research disclose certain types of outside interests before an award is made and annually thereafter. In addition, NIH is considering whether to prohibit investigators and other key personnel for clinical drug trials from having any financial relationship with a business whose product is being tested.

On July 16, 1992, NSF issued a notice of proposed changes in the Federal Register that would require faculty members, investigators, and professional employees at grantee institutions who are involved in NSF-funded research and educational activities to disclose certain types of outside interests before an award is made.

CONCLUSIONS

Growing interactions between universities or nonprofit research institutions and private companies increase the potential for conflicts of interest or other relationships that might give a particular company inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research. Requiring that investigators and other key personnel disclose certain types of outside interests as part of the grant award process is an essential first step for improving a grantee's management controls over potential conflicts of interest. Accordingly, our May 1992 report recommended that both NIH and NSF require their grantees to have procedures in place to effectively manage potential conflicts of interest and that both agencies review their grantees' policies and procedures to ensure that grantees adequately address conflicts of interest. Both NIH and NSF have initiated steps to address these issues through the regulatory process.

With respect to the specific issues being addressed in the hearing today, we believe it is equally important that a recipient of substantial federal research funding--whether a university or a nonprofit research institution--notify and consult with NIH or other federal agencies before entering into any such major agreement that may give rights to commercialize resulting technologies to a particular company if substantial federal funds are involved. In this way, the government can become aware of who gets access to and ultimately benefits from the results of federally funded research and take any appropriate actions to help ensure that the public's interest is protected.

Mr. Chairman, this concludes my statement. I would be happy to respond to any questions you or members of the Subcommittee may have.

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