The Scripps Research Institute Testifies before Congress

Washington, D.C., March 11, 1993 -- Dr. Ernest Beutler testified today before Congress on behalf of The Scripps Research Institute. The Subcommittee on Regulation, Business Opportunities and Technology of the House Small Business Committee was studying the details of private research agreements fostered by federal technology transfer laws. In the last 15 years several amendments and statutes have been passed by Congress to foster such cooperative agreements.

In an attack on a common form of corporate sponsorship of basic scientific research at academic research institutions, NIH Director Bernadine Healy questioned the details of a proposed $300 million, 10-year research agreement between Scripps and Sandoz Pharmaceutical Company. Healy claimed that the proposed agreement presented "major concerns with compliance with the policy objectives" of federal law.

In addition to addressing her specific concerns, Dr. Beutler, a member of the National Academy of Sciences and Chairman of the Department of Molecular and

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Experimental Medicine at the La Jolla, California-based research organization, responded generally to Healy's testimony and to comments of the Subcommittee Chairman, Congressman Ron Wyden (D-OR), by pointing out the substantial benefits to the taxpayer that result from private funding for institutions such as Scripps. He said that funding from outside sources enhances the ability of research institutions to carry out basic research supported by taxpayers, thereby adding value to federally funded research.

"It is unfortunate that the NIH has attempted to draw conclusions from their first, cursory reading of the Scripps/Sandoz agreement without expressing their concerns to anyone at Scripps," Beutler said. "We have offered to work closely with NIH officials to review the agreement in detail and answer any questions they may have. We hope that they will study the agreement more carefully, in the context of other similar agreements that they are now collecting, and we are confident that, on a more thorough reading, NIH will discover that the agreement is fully within the letter and spirit of current federal law."

In addressing the specific points raised by Healy, Dr. Beutler expressed extreme disappointment and shock at what he described as Healy's mischaracterizations of the agreement in a number of important respects. "Fortunately," he stated, "her description of the arrangement is simply inaccurate. Were it not, I would not choose to conduct my research and professional career at Scripps."

Among other things, Healy claimed that the Scripps/Sandoz agreement creates a
Joint Scientific Council through which Sandoz would oversee and set the agenda for all research activities at Scripps. She said that this arrangement would stifle free enterprise, the free exchange of ideas, and the development of small business. Dr. Beutler disputed Healy's characterization and read from the proposed agreement the provision which specifically states that Scripps "is an independent research institute which is controlled and directed by its Board of Trustees and management, and that the Joint Scientific Council may not control or direct (Scripps') research and related affairs." Dr. Beutler further pointed out that clinical research at Scripps must be approved by an independent Institutional Review Board, which is not part of The Scripps Research Institute, but rather is part of Scripps Clinic, which receives no funding from Sandoz.

Healy also alleged that the agreement was "an aberration," even though she acknowledged that she had not yet read other similar agreements requested from roughly 100 other universities and research institutions. Dr. Beutler pointed out to the Subcommittee that the Scripps/Sandoz agreement was essentially the same as an existing agreement between Scripps and Johnson & Johnson that has been in effect for more than 10 years, and not different in principle from many other existing agreements at research institutions nationwide.

Healy further claimed that, under the Scripps/Sandoz agreement, NIH and Sandoz funds are being "co-mingled." Dr. Beutler again pointed out the statement's inaccuracy, explaining that Scripps has not yet received funding from Sandoz, but when it does, it
will handle the funding as it does in other similar transactions. Funds from various sponsors are always accounted for separately, even when specific research projects are funded by more than one source.

Dr. Beutler cited examples of how such agreements have helped foster the development of medical products from the laboratory to the marketplace, and explained his personal involvement in bringing the drug 2-CdA (trade name, LEUSTATIN™) to FDA approval just two weeks ago. Cited as one of the most promising chemotherapeutic agents developed in the last decade, LEUSTATIN™ is unique for its high rate of treatment effectiveness after only a single, seven-day course of therapy for a rare and often fatal malignancy of the white blood cells, hairy cell leukemia.

"If we had not had access to an industrial partner (Johnson & Johnson) to undertake the expensive, time-consuming and admittedly risky task of licensing LEUSTATIN™ it would still be a scientific curiosity; an experimental treatment available only at a few research centers," he stated. "LEUSTATIN™ may be a cure for this disease. It is certainly the best treatment available. It is also very effective in the treatment of certain other leukemias. And now it can be used by patients everywhere in treating serious diseases," Dr. Beutler added.

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