Testimony by
Dr. James A. Shannon,
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before the
Subcommittee on Patents, Trademarks, and Copyrights
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Mr. Chairman and Members of the Committee:

I appreciate the opportunity afforded by your invitation to appear before this Committee and discuss the relationships of patent policies to NIH programs, especially as it concerns research financed by multiple sources or situations where additional private funds are necessary for the full development of an invention. At the outset, I would emphasize that the NIH, as one of the bureaus of the Public Health Service, is a component of the Department of Health, Education, and Welfare, and functions within the patent regulations set forth by the Department.

I understand that the Department's patent policies and its position on the legislation before this Committee have already been presented. For this reason, I will limit my statements to the two areas of concern mentioned in your invitation.

I would first like to address myself to situations where additional private funds are necessary for the development of an invention made under Federal support, since I believe the policy problems attending these situations are a major public concern.

The NIH supports research activities through grants, contracts, and within its own laboratories which may result in the discovery of

potential therapeutic agents. Before one of these agents can reach the marketplace for public consumption, it must travel a long road, usually measured in years, from discovery to complete development. This road includes the actual discovery of the potential therapeutic agent, the preliminary screening to determine if the agent has possible therapeutic usefulness, different stages of animal testing, preliminary tests in humans and, finally, full-scale clinical testing of the agent. The newly discovered agent may be a completely new chemical entity or an old chemical either of which is shown to be useful as a therapeutic. The developmental process in either case is governed by the Federal food and drug laws which require evidence of careful testing before the agent can be cleared for the market.

In most instances the NIH or its grantees do not participate in the full development of a therapeutic agent up to the point where it is made available commercially. We view our role in the Nation's medical research effort as complementary to the activities of the other elements within our society, both public and private, that also support research and development related to health. It seems to us that the interests of the American people are best served when the various elements of this medical research structure can interact. The most effective interrelationship results when the particular capabilities of the various elements, Federal and nonfederal, can be utilized to the fullest extent.

Generally speaking an NIH scientist or grantee will be involved, if at all, at one of four points in the developmental process:

a. NIH funds may be involved in the organic synthesis of a compound and perhaps in a portion of its screening in biological systems. He may participate in animal and clinical testing but will not usually, except in psychopharmacology and cancer chemotherapy, pursue this to a definitive conclusion.

More generally the chemist, given freedom of action, would approach the pharmaceutical industry which has extensive capability to undertake the entire development and testing process and is able to accumulate all the data from different stages of development necessary for FDA acceptance.

b. NIH funds may also be involved in support of research which involves the probing of biological mechanisms with chemical agents. Out of such investigation may well come new knowledge on novel uses for a compound, but in general such an investigator will rarely have the capability of follow-through as with a wholly new therapeutic agent.

c. NIH funds more recently support broad clinical investigation and such work has a heavy commitment to the assessment of therapeutic activity either in absolute or comparative terms. Out of this type of work in the past has come wholly new therapeutic uses that have had broad impact on clinical medicine. I have in mind in this respect the discovery of tranquilizing properties of reserpine when this drug was in use as a blood pressure lowering agent and the discovery of energizing properties of isoniazide when the drug was being explored as an antitubercular agent.

d. Finally, NIH has, in the past, supported and/or participated in the extensive type of field trial which firmly establishes the net benefit to be derived from a given compound under well-defined clinical conditions, and will no doubt do so in the future.

The first three of these types of studies can be expected to yield patentable discoveries and consequently the rate of evolution to an effective therapeutic agent generally available to the public will be determined by the terms and conditions which facilitate the interplay of the resources of the Federal Government, the university scientists and the pharmaceutical industry.

Although NIH support of an investigator may stop at an early stage of development or cover only a part of the complicated sequence of drug development, our Departmental patent policy requires that his invention be reported to the Surgeon General for his disposition since the invention in most instances is complete within the definition of the U.S. Patent Office. The Surgeon General's disposition generally results in title to the Government in accordance with the provisions of the Department's regulations, the title provisions of the President's Memorandum and the Executive Order governing disposition of employee inventions.

The uncertainties involved in after-the-fact determinations have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application. The industrial firms want some guarantee of

exclusive patent rights as compensation for and protection of their possible investment, which may be considerable before FDA clearance can be obtained. Because, as I understand it, there is some question as to whether we can or should extend such a guarantee, it is often difficult to motivate industry to undertake the perfection and marketing of the NIH-supported inventions.

We, of course, support the basic policy that title to health and welfare inventions generated primarily with Federal support should reside in the Government. It does seem to us as persons responsible for the largest Federal medical research program that there does need to be clarification of the situation with regard to the issuance of licenses to inventions held by the Government. One possible solution might be the granting of short periods of exclusivity in such situations as I have discussed--that is, where it is found to be necessary to develop an invention to the point of practical application and there is no other way to obtain the needed industry cooperation. Compounds which show some promise in early stages of investigation may be of no benefit to the public and may not serve the public interest unless clinical testing is undertaken and the resulting drug is cleared by the FDA and marketed. We also believe that it seems sensible to be able to involve industry in the testing and marketing phases of drug development since these firms already possess capabilities in these areas that would have to be duplicated elsewhere to accomplish these necessary purposes.

The Department is in the process of reviewing its entire patent policy and practices.

Passing on now to the second area on which you wished my comments, I would note that one of the common characteristics of scientific research activities performed in universities is receipt of joint and simultaneous support from Government and nonprofit organizations, and not infrequently from industry. In the biomedical sciences, the Government support is most frequently provided in the form of a grant from the NIH. Funds from these different sources of support are often commingled with the result that a given research project may be financed and dependent upon several different sources of income at the same time. Where the private sources of support impose no conditions upon their grant relating to inventions, the DHEW regulations requirement that the NIH grantees report all their inventions to the Surgeon General for his disposition poses no problem. However, where, as in the case of the American Cancer Society and the American Heart Association, co-sponsors maintain patent policies requiring their grantees to agree to assign all invention rights to them, the grantee who accepts support for the same research activity from both the NIH and such other sponsors has undertaken conflicting obligations he cannot fulfill. It is difficult to solve problems of conflict after the fact on the basis of priority as between the co-sponsors. Neither is it a satisfactory solution to suggest that the grantee be limited to acceptance of support from only a single source which imposes such an obligation.

I believe it is in the public interest to encourage support of research from the private sector of our economy and to discourage exclusive reliance upon Government-financed support. In order to further this objective, it may be necessary to relieve universities and their researchers from the dilemma created by conflicting obligations to assign patent rights.

At the present time, it is my understanding that the patent regulations of our Department do not take into consideration the equities of co-sponsors in making disposition of inventions arising from research financed by multiple sources, and the Surgeon General must make his determination solely on the basis of our support. As I have mentioned, I do understand that these regulations have been under review for some time with this matter being given consideration by the Department.

Thank you very much for this opportunity to appear before you. I would like to emphasize that I am obviously not a patent expert, but I would be glad to answer any questions from my perspective as the director of a large Federal research activity.