U.S. DEPARTMENT OF COMMERCE

STATEMENT BY DR. BETSY ANCKER-JOHNSON, ASSISTANT SECRETARY OF COMMERCE FOR SCIENCE AND TECHNOLOGY, BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

March 16, 1977

Mr. Chairman and Members of the Committee:

In October of 1940 a policeman was admitted into the Radcliffe Infirmary, Oxford. Early in September the constable had noticed a small sore at the corner of his mouth, and by October 12th he was obliged to go into the hospital suffering from generalized blood poisoning, caused by a mixed infection of Staphylococcus aureus and Streptococcus pyogenes.

The physicians treated him for a week with sulphapyridine until he developed a rash arising from the drug, but his condition did not improve. They operated on the abscesses to let out the pus in the hope that this would turn the scale, but their hopes were vain. They operated on his eyes, they gave him a blood transfusion, but he grew steadily worse and lost more and more weight. The infection spread to his lungs. He was a dying man, coughing up myriads of germs that were killing him. All that medical science could do, all that care and attention and expert nursing could do, was done for him, without avail.

Upon this hopeless case it was decided to expend all the penicillin in existence. He would now become the first human subject.[1/]

Before continuing with this story I should like to direct your attention still farther backward in time to the year 1929. It is June, just four months before the stockmarket crash. In Great Britain a publication known as the Journal of Experimental Pathology is being readied for distribution to a modest subscription list. One of the articles in this edition has been authored by Alexander Fleming. His subject: penicillin.

At least three effects will flow from the publication of this article. Note that I am here addressing the effects of publication, rather than the effects of Dr. Fleming's discoveries themselves.

The first, most obvious, and, indeed, the intended effect of publication will be to alert the scientific community to a series of important breakthroughs, thereby enabling scientists throughout the world to exploit the advances which have occurred.

A second effect of publication will be to foreclose any assertion of patent rights by Dr. Fleming in Great Britain, as well as in most industrialized countries of the world. In the United States it will begin the running

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[1/] This account of the first human subject to receive penicillin is adapted from Miracle Drug, the History of Penicillin, by David Masters, published by Eyre & Spottis Woode, London (1946)

of a one-year period within which a patent application might be filed, and in Canada a two-year period. Dr. Fleming could avoid the loss of patent rights in Great Britain by filing a patent application immediately, i.e., prior to publication. He chooses not to do so, preferring instead to make a gift to humanity of his fundamental discoveries. It is a decision he will come to look upon with regret.[2/]

The third effect of publication will be to forestall indefinitely the investment of private risk capital in the commercial development of penicillin. Henceforward the funds necessary for this effort must be sought from university, governmental and philanthropic sources.

Let us return now to the story of our first human subject.

On February 12, 1941, the physician in charge of the constable's case administered 200 mg. of penicillin into a vein so that it might enter the blood stream and circulate all over the body. Then every three hours they injected another 100 mg.

By the end of twenty-four hours the transformation was amazing. The wounds on the patient's head ceased to discharge; even the right eye ceased to run. There was every evidence that the constable had taken a turn

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2/ The Law of Chemical, Metallurgical, and Pharmaceutical Patents, Howard I. Forman, Editor, Published by Central Book Co., New York (1967)

towards recovery. On the second day he received injections every four hours of 100 mg. of penicillin. On the third day he was given a blood transfusion and penicillin was administered every two hours through the same drip tube, a total of one gram being given during the twenty-four hours.

By now they were getting woefully short of penicillin. Some of the drug, however, was excreted in the urine which was treated to recover the penicillin it contained. This penicillin was quite unchanged by its passage through the body; no chemical reaction had occurred in it; it was as active as the original dose. The recovered penicillin was used a second time on February 15th.

It was now fairly plain that sufficient penicillin would probably save the constable's life; it was equally plain that in a few hours all the penicillin would be used up. It was a tragic position. In five days they had given the patient nearly 4 1/2 grams of penicillin. The patient felt better, he was getting better, his fever was gone, the sores were healing. The deadly germs were being vanquished.

Unhappily he could not maintain the improvement without the penicillin. For about 10 days he held the balance, then the germs began to get the upper hand and on March 15th he died.

More than eleven years had now passed since Fleming's publication. And all the penicillin that the world had produced in this time was gone. Seven of the eleven years had been utterly wasted. Absent that delay, our tragic constable would not have been the first human subject, but the x^{th} millionth, and he and they would have lived.

It is truly ironic that the great chemical houses of Great Britain were discouraged from entering upon the production of penicillin, even after its therapeutic effects were confirmed, because of their fears of chemical synthesis. Consider this explanation:

> "Chemists who studied the technique and saw how far Chain and Abraham had succeeded were likely to believe that penicillin would soon be obtained in a pure form, and it would not be long before its exact chemical constitution was determined and it could be made synthetically in the laboratory.
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> There was the risk. They might spend an immense fortune on plant to obtain penicillin from the mould in the natural way and directly their apparatus was complete they might be faced with the fact that penicillin had been synthesized. At one stroke all their money might be lost, the plant on which they had spent a fortune might be obsolete, and they might be able to make penicillin from certain chemicals in the laboratory at a tenth of the cost of growing the mould. The mere possibility of being able to make penicillin synthetically was bound to have a hampering effect." 3/

In typical British fashion "hampering effect" is a gross understatement.

3/Masters, op.cit., pp. 104-105

There were perhaps several dozen individuals in the world who might -- with their personal fortunes -- have underwritten the risks of the British chemical houses. Had Fleming patented his discoveries and obtained product claims on penicillin he could have given equally persuasive assurances to manufacturers, without risking a shilling. But that opportunity had long ago been forfeited.

What lessons can we abstract from history and apply to the problems before us today?

One lesson we must learn from this experience is that the existence of a protected property interest exerts a powerful influence in determining whether a major health innovation will or will not be available to those who need it, when they need it.

This lesson was drawn for us again in 1968 by the General Accounting Office's report entitled "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry" (GAO Report #B-164031-2). This report indicates that from 1962-1968 the drug-related leads generated by NIH research had virtually no impact on commercial development. The point so forcefully made is simply this: where commercialization necessitates the investment of substantial risk capital (as in the drug industry), there is an identified likelihood that transfer will not occur unless the entrepreneur is offered some property protection in the innovation offered for development.

Last year the attention of your parent committee was directed to yet another hazard threatening the delivery of health-care innovations to the public. In its report of June 30, 1976, entitled "Disclosure of Research Information," the President's Biomedical Research Panel expressed its concerns as follows:

> "The Panel is seriously concerned that the unpredictability of government protection for intellectual property rights, owing to the uncontrolled and unconditioned disclosure of research information under current court interpretation of the Freedom of Information Act, is likely, in the Panel's view, to stifle industry interest in developing potentially important research innovations. Without industry involvement, the transfer of research findings to clinical practice will be impeded. In the judgment of the Panel, there are strong reasons to conclude that the interface between research and health care delivery, an area of vital national interest, is likely to be impaired unless adequate protection is provided for intellectual property rights of biomedical and behavioral researchers whose research is conducted with federal financial support."

The problem identified by the Biomedical Research Panel is not confined solely to "biomedical and behavioral" research. It extends to virtually all Federally-funded research. My concern today is that your committee may inadvertently compound this difficulty by extending it for the first time to the private sector.

I am not unaware of the controversy or the fears associated with the advent of recombinant-DNA technology. Neither am I unaware of the hopes. While most scientists

with whom I have spoken have been decidedly more hopeful fearful, all of them agree on the impossibility of proving that there exists no hazard whatsoever. We must begin, therefore, by assuming the existence of some hazard, however large or however small. The important question is how large or how small. I recognize that I do not possess the competence in microbiology which would enable me to assist your committee in answering this question. Accordingly, I will not attempt to do so. There are others within the Administration who are working on this issue and I am sure they will cooperate fully with your committee.

Let me therefore address the next question with which you must deal. This question presumes that you have already assessed risks, have perceived a clear need for safety procedures, and have satisfied yourselves as to what those safety procedures should be.

The question is this: Given the fact that some residual risk must remain (since it is impossible to legislate away all risk), how can you be assured that the public benefits whose anticipation has led you to endure this risk will themselves be realized?

In my judgment there are only two ways by which we can ensure the realization of public benefits. We must either preserve proprietary rights in the innovations which flow from the research, or we must insist that the

Government itself undertake to do what private industry now does -- bring these innovations all the way to the marketplace.

Unless we are prepared to do the one or the other, we ought seriously to consider the illogic of our taking any risk in the first place.