STATEMENT OF SENATOR BIRCH BAYH TO THE NATIONAL INSTITUTES OF HEALTH

MAY 25, 2004

I appreciate NIH's invitation to comment on the intent of Congress when it enacted the Bayh-Dole law. I am accompanied by Joe Allen, currently President of the National Technology Transfer Center, and formerly my primary staff member who worked on this legislation. The focus of my comments will be the contention that Bayh-Dole gives NIH the ability to control the price of a product developed under the law by exercising the march-in rights provided in Section 203 of its provisions.

Before proceeding, I should emphasize that I am not being compensated to appear here today. Also, I should note that I am not familiar with the specifics of the drug which is the basis of the petition before NIH, so I will not comment on the merits of this particular case. However, I do know the intent of this legislation which I was privileged to sponsor with my friend, Senator Bob Dole.

As NIH proceeds with this examination of the petition, it should prove informative to the responsible officials here at NIH and the petitioners as well, to be reminded of the history behind the introduction and passage of Bayh-Dole. Particular attention should be given to the economic environment which existed prior to the introduction of Bayh-Dole.

By the late 70s, America had lost its technological advantage:

- We had lost our number one competitive position in steel and auto production. In a number of industries we weren't even No. 2.
- The number of patents issued each year had declined steadily since 1971.
- Investment in research and development over the previous 10 years was static.
- American productivity was growing at a much slower rate than that of our free world competitors.
- Small businesses, which had compiled a very impressive record in technological innovation, were receiving a smaller percentage of Federal research and development money.
- The number of patentable inventions made under federally supported research had been in a steady decline.

What had happened to American innovation, which had sparked generation after generation of international economic success?

Our investigation at the Patent and Trademark Office disclosed that the U.S. government owned 28,000 patents, only 4 percent of which had been developed as a product for use by the consumer.

Close examination disclosed that most patents procured as a result of government research grants, particularly those developed in university laboratories, resulted from basic research. The ideas patented were in the embryonic stages of development. Often millions of dollars were required to produce the sophisticated products necessary for marketability. Since the government refused to permit ownership of the patents, private industry and business refused to invest the resources necessary to bring the products to consumers. As Thomas Edison said: "Invention is 1% inspiration and 99% perspiration." With regard to publicly funded research, government typically funds the inspiration and industry the perspiration.

The well-intentioned voices, such as Senator Russell Long and Admiral Hyman Rickover, opposed Bayh-Dole on the basis "If the taxpayer funds the research, the taxpayer should own the ideas produced." However, the result of this policy was billions of taxpayer dollars spent on thousands of ideas and patents which were collecting dust at the PTO. The taxpayers were getting no benefit whatsoever.

Changes to Bayh-Dole should be made only after giving careful consideration to what has been accomplished by those who have utilized the provisions of the law. The London "Technology Economist Quarterly" called Bayh-Dole "Possibly the most inspired piece of legislation to be enacted in America over the past half century." (I have attached the full text of the article for your information.)

The Economist estimated that Bayh-Dole created 2,000 new companies, 260,000 new jobs, and now contributes $40 billion annually to the U.S. economy. This assessment was made almost six years ago and more progress has been made since then.

One is entitled to second guess us and say that we should have allowed the government to have a say in the prices of products arising from federal R&D. However, if changes are believed warranted, we have a process for doing so. That is to amend the law. You simply cannot invent new interpretations a quarter of a century later. This is what is being proposed.

When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear, we included the march-in provisions that are the subject of today's meeting.

The clear intent of these provisions is to insure that every effort is made to bring a product to market. If there is evidence that this is not being done, the funding agency can "march-in" and require that other companies be licensed. If the developer cannot satisfy health and safety requirements of the American taxpayer, agencies may march-in.

It was first brought to my attention that attempts were underway to rewrite history when I saw an article in the **Washington Post** on March 27, 2002, entitled *Paying Twice for the Same Drugs.*. The crux of the article was that:

> Bayh-Dole ... states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it is not, then the government can insist that the drug be licensed to more reasonable manufacturers, and if refused, license it to third parties that will make the drug available at a reasonable cost.[1]

This view mistakes how our law works. Bob Dole and I responded in a letter to the editor of the **Washington Post** on April 11, 2002 setting the record straight.[2]

You can imagine my surprise when I see the same arguments were being formally presented in a petition to NIH in an attempt to control drug prices. The quotations in the petition flagrantly misrepresent the legislative history supporting Bayh-Dole. The petition shows complete lack of understanding of how the legislative process works. The current petition says: "The clear language of the Bayh-Dole act requires reasonable pricing of government supported inventions."[3] It later adds: "The legislative history evidences an intent to require that government supported inventions be priced reasonably."[4]

All but one of the citations in the petition used to conclude that march-in rights were intended to control prices actually refer to hearings on bills other than Bayh-Dole. While perhaps interesting, these are not pertinent legislative history. I could find only one citation from the real legislative history. Here is the petition language:

> This consensus was recorded in the Senate's Committee Report on the bill, which explained that march-in rights were intended to insure that no 'windfall profits,' or other "adverse effects result from retention of patent rights by these contractors."[5]

The petition footnote on this section adds "statement of Senator Bayh that the march-in provisions were meant to control the ability of 'the large, wealthy, corporation to take advantage of Government research and thus profit at taxpayers' expense."[6]

Rather than being a statement of fact, my quotation is actually taken from a question I asked the Comptroller General on another topic altogether.

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[1] Peter Arno and Michael Davis, "Paying Twice for the Same Drugs," Washington Post 27 Mar. 2002: A21.

[2] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post 11 Apr. 2002: A28.

[3] Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir. Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Essential Inventions, Inc., 2004) 9.

[4] Ibid., 10

[5] Petition to use Authority Under Bayh-Dole Act to Promote Access to Ritonavir. Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220 (Washington: Essential Inventions, Inc., 2004) 10.

[6] Ibid.

The petition language taken from the Committee report mixes up references to two different sections of the law so that the original meaning is unrecognizable.

Let's see what happens when the petition quotes are placed in their proper context. I highlighted the following language referred to in the petition as it actually appears in the legislative history.

With regard to the petition's footnote, during his testimony I asked Elmer Staats, then the Comptroller General of the United States, a question regarding concerns expressed about the Bayh-Dole bill. Here it is:

Mr. Bayh: "The other criticism comes from those that feel that this bill is a front to allow ***the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense.*** We thought we had drafted this bill in such a way that this was not possible. Would you care to comment on this scenario as a valid criticism?"

Mr. Staats: "Of course, this is the key question. There is no doubt about that. In my opinion, the bill does have adequate safeguards..."

The petition also mixes up Senate Judiciary Committee report language describing two unrelated parts of Bayh-Dole. Here's how the report actually reads with the petition extract highlighted:

> The agencies will have the power to exercise march-in rights to insure that no **adverse effects result from the retention of patent rights by these contractors.**[7]

That was the language on section 203, the march-in rights provision. The report continues:

> The existence of section 204 of the bill, the Government pay back provision, will guarantee that the inventions which are successful in the marketplace reimburse the Federal agencies for the help which led to their discovery. Although there is no evidence of ***"windfallprofits"*** having been made from any inventions that arose from federally-sponsored programs, the existence of the pay back provision reassures the public that their support in developing new products and technologies is taken into consideration when these patentable discoveries are successfully commercialized."[8]

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[7] United States. Congress. Senate. Committee on the Judiciary, University and Small Business Patent Procedures Act: Report of the Committee on the Judiciary. United States Senate, on S.414 (Washington: U.S. Government Printing Office, 1979) 30.

[8] Ibid.

Thus, it is only by inappropriately combining language describing an entirely different section of the law that the words **"windfall profits"** can be made to refer to march-in rights. They clearly do not. Such a representation is highly misleading.

When read in context, the real meaning could not be clearer. Rather than controlling product prices, the language actually provided that the Government should be able to recoup a percentage of its investment when an invention from its extramural funding hits a home run in the market.

In fact, this payback provision of Section 204 was later dropped from the bill altogether because the agencies said that the administrative costs of tracking university royalties would far outweigh any monetary benefits from the one-in-a-million breakthrough invention.

NIH itself has found that price controls are not contemplated by Bayh-Dole. Under pressure in 1989, NIH placed a provision in its intramural collaborations with industry that resulting inventions must demonstrate "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public."[9]

When industry collaborations began evaporating, and NIH explored the reasons and found:

> Both NIH and its industry counterparts came to the realization that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the Bayh-Dole Act.[10]

If NIH found that price controls on its intramural research are "contrary to the Bayh-Dole Act," how can the same provisions be applied to extramural research?

If Congress does decide to amend Bayh-Dole someone must clearly define what is a "reasonable price." Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that "bet the farm" on one or two patents. Copycat companies are always waiting until an entrepreneur has shown the path ahead. They can always make things cheaper since they have no significant development costs to recover.

What will happen to the start-up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over their heads? What evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened to NIH.

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[9] National Institute of Health, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (Washington: U.S. Government Printing Office, 2001) 9.

[16] Ibid., 8.

NIH wisely realized that the greater good is to allow American taxpayers to have access to important new products and processes, along with the new jobs and taxes they create than to try and regulate prices.

Bob Dole and I made the same choice in 1980. I still believe that we were correct.

I empathize with the countless individuals in the U.S. and around the world who are suffering from AIDS. If it can be shown that the health and safety of our citizens is threatened by practices of a government contractor, then Bayh-Dole permits march-in rights, not to set prices, but to ensure competition and to meet the needs of our citizens. However, such a procedure must be supported by hard evidence that the need exists. Speculative claims and misrepresentation of the legislative history supporting Bayh-Dole will not suffice.

Let me urge the wisdom of approaching such a decision which great caution. The success of Bayh-Dole goes far beyond the efforts of Bob Dole and Birch Bayh. This legislation combined the ingenuity and innovation from our university laboratories with the entrepreneurial skills of America's small businesses. Most importantly, this combination created the incentive necessary for private investment to invest in bringing new ideas to the marketplace. The delicate balance of ingenuity, entrepreneurship, and incentive upon which the success of Bayh-Dole has depended must not be disrupted.

A few of the products which have been produced in the last six years are:

- Taxol, the most important cancer drug in 15 years, according to the National Cancer Institution.
- DNA sequencer, the basis of the entire Human Genome Project.
- StormVision™, which airport traffic and safety managers use to predict the motion of storms.
- Prostate-specific antigen test, now a routine component of cancer screening.
- V-Chip, which allows families to control access to television programming.

It would be the ultimate folly to march in and alleviate the problem addressed by the petition, availability of a drug to treat AIDS today, and in so doing dampen the ingenuity, entrepreneurial skills and incentive necessary to develop a permanent cure for AIDS, or for that matter the cure for other diseases that plague all too many American mothers, fathers, children and seniors today.

As you search for a solution to the problem before us today, be aware of unintended consequences tomorrow. Insuring the health of our citizens requires the wisdom and determination for a long journey. The procedures of Bayh-Dole have saved countless lives and pain and suffering. It provides an incentive for further progress in the future.

Thank you

Works Cited

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