Dr. Elias A. Zerhouni
Director, National Institutes of Health
31 Center Drive
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Dear Dr. Zerhouni:

One of the most successful policy changes in recent years was the enactment of the Bayh-Dole Act (35 U.S.C. 200-212) allowing non-profit organizations and small businesses conducting federally supported research to own and manage resulting inventions while allowing the government to use them royalty free. A major concern at the time of enactment was that important discoveries created under NIH extramural research were not being developed so they could benefit the taxpaying public.

You should feel justly proud that since enactment the greatest successes of the law have come from NIH funding of the life sciences. It has been estimated since passage of the law in 1980 that at least 107 new drugs, vaccines and in vivo diagnostics now available originated in public sector institutions. Interestingly, 55% of the licenses to turn these patents into products went to small companies, many of which were start-ups organized for this purpose. A preference for licensing to small businesses is one of the central tents of the Act. Indeed, NIH extramural funding was a critical component in the creation of the U.S. biotechnology industry itself. Obviously, the Bayh-Dole Act is benefiting public health as well as our economic security as intended.

Considering this record of success, it is very troubling that informal reports indicate that there might be some erosion in the implementation of the Bayh-Dole Act at NIH. I am writing to seek your help in determining whether or not this is the case.

Unless we translate research into products our citizens can use, we have not been completely successful stewards of the public trust. This is particularly difficult in the life sciences area where the investment of time and money needed to produce a new product can run into hundreds of millions of dollars and take more than a decade of effort. Even so, this is at best a high-risk endeavor. That was the reason the Congress enacted the Bayh-Dole Act. It creates vital incentives for inventing universities and their industrial partners to undertake this arduous endeavor.

This makes it all the more surprising that some believe that NIH exempts programs from the requirements of the Bayh-Dole Act more than any other agency. The purpose of this letter is to ask your assistance in helping me document whether or not this is indeed the case.

One component of the Bayh-Dole Act is the use of "exceptional circumstances" found in Section 202 of the law. This provision allows an agency to exempt research programs from the provisions of invention ownership by a non-profit organization or small company in rare cases. Other than situations pertaining to intelligence or classified military research, it was the intent of Congress that this authority be used in those instances when the government itself would fund the development of an invention.

The Senate Judiciary Committee described how this provision of the law was to be used in its unanimous report on the bill:

> It is expected that the "exceptional circumstances" exception will be used sparingly. An example of a situation in which it might be used is when the funding agreement calls for a specific product that will be required to be used by regulation. In such a case, it is presumed that patent incentives will not be required to bring the product to the market.
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> Similarly, if the funding agreement calls for development work on a product, or process that the agency plans to fully fund and promote to the market place, then use of this exception might be justified. In such cases, however, it would be within the spirit of the Act for the agency to either define specific fields of use to which it will obtain rights in any inventions at the time of contracting or to carefully structure any deferred determinations so that the agency does not destroy the incentives for further development of any inventions in fields of use not of interest to the agency.
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> *Report of the Senate Judiciary Committee on S. 414, the University and Small Business Patent Procedures Act, December 12, 1979. Report number 96-480, p. 32.*

Congress felt so strongly that this power be "used sparingly" that it requires any agency seeking to use this provision to notify the Secretary of Commerce (and the Small Business Administration in cases affecting small companies) before they do so. The Secretary of Commerce is empowered with recommending corrective actions when an agency is misusing this authority. Other provisions of the law require the Comptroller General to report on how agencies are applying the statue to insure that the intent of Congress is being uniformly applied. Finally, the statute requires that any university or small company that feels agencies are misusing this provision has the right to a formal appeal as specified in Section 203(2) of the Act.

Thus, the intent of Congress reflected in the legislative history and the law itself that exceptional circumstances were not be invoked lightly seems abundantly clear. Therefore, I seek your assistance in documenting how NIH is employing the exceptional circumstances provisions of the Bayh-Dole Act.

I would appreciate your prompt attention in responding to the following questions:

1. How often has NIH utilized the exceptional circumstances provisions of the Bayh-Dole Act in the last seven years?
2. What were the specific circumstances that NIH believed justified employing this provision?
3. Are these decisions to invoke exceptional circumstances made by the individual institutes or the Director of NIH?
4. Were all instances of NIH utilizing exceptional circumstances reported to the Secretary of Commerce?
5. Were affected non-profit organizations given the chance to appeal these decisions? as required by the Act.
6. Has NIH utilized the exceptional circumstances provisions to deny patent ownership in fields of research simply because the research was felt to be early stage, pre-competitive or of a similarly described nature? If so, upon what legal authority was this determination based?
7. Where NIH policy discourages patent protection, as in the area of genomic inventions, were the exceptional circumstances procedures followed in making these determinations? If not, why not and how does NIH view this policy as consistent with the uniform federal patent policy that was a key goal of the Bayh-Dole Act?
8. Are programs where NIH is restricting patent rights of universities or mandating licensing terms under industry/NIH partnerships (such as testing investigational agents supplied by pharmaceutical companies for possible use in clinical trials) following the procedures for declaring exceptional circumstances required by the Bayh-Dole Act?

As the U.S. enters a new era of increased international competition, it is essential that our taxpayers receive both the scientific and the economic rewards of their hard earned investments in publicly funded research. This is particularly true of the life science area where NIH funding is essential for creating the products needed to protect the public health. Because early stage research is likely to create the industries of the future, it is important that the solid framework of the Bayh-Dole Act not be weakened when we need it the most.

Thank you for your assistance.