Jesse E. Lasken
3 Echo Court
Rockville, Md. 20854
October 18, 1979

Mr. H. Patrick Swygert
Office of Special Counsel
Merit Systems Protection Board
Rm. 215
1717 H. St., N.W.
Washington, D.C. 20419

Dear Mr. Swygert:

As a Federal employee concerned that the integrity of the career civil service is upheld and that the goals of the Civil Service Reform Act are met, I wish to bring to your attention a matter that I believe warrants your attention.

I believe that persons within the Department of Health, Education, and Welfare (HEW) may have engaged or be engaged in a prohibited personnel practice against Mr. Norman Latker, formerly Chief of the NIH Patent Branch. In particular, the actions taken against Mr. Latker may violate 5 U.S.C. §2302(b)(8). The charges that appear to have been brought against Mr. Latker clearly are in reprisal for the criticism leveled against the Department by various university officers and, more importantly, various members of Congress for recent changes in HEW patent practices. I am aware of the nature of several of the changes that have taken place in HEW patent policy in recent years, and there should be no question in anyone's mind that these changes, if allowed to continue, would represent as "substantial and specific" a "danger to public health" as is likely to ever come before the Merit Systems Protection Board. It is my understanding that the Civil Service Reform Act has as one of its purposes the protection of employees who refuse to stand idly by while their superiors are engaged in anti-social behavior.

Before substantiating my statement about the "public health," let me summarize my credentials for addressing this area. I am an attorney with the National Science Foundation.[1] Although my current duties do no encompass patent matters, from 1972-74 I was responsible for day-to-day patent matters at NSF. During this period I drafted NSF's current policies and regulations. For a number of years I served as NSF representative on the Executive Subcommittee of the interagency FCST Committee on Government Patent Policy and on the University Patent Policy Subcommittee of the same committee. I was one

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[1]This letter, however, is my personal letter and has not been discussed or cleared with anyone else at NSF and is not be construed as representing an NSF position.

of the principal drafters of the 1975 Report on University Patent Policy which was adopted unanimously by the FCST Committee on Government Patent Policy[2], and I was the principal draftsman of the 1978 amendments to the Federal Procurement Regulations which implemented the recommendations in the Report referred to above. Prior to working for NSF, I had staff responsibility at the Commission on Government Procurement for the section of its report dealing with patent policy. In 1966-67 I held a fellowship in Government Procurement Law at The George Washington University School of Law and co-authored a monograph on Patents and Technical Data. I believe, therefore, I am well qualified to provide an opinion on the issue at question.

NIH supports extensive university medical and biological research. Out of some of this basic research sometimes come new ideas and inventions (such as new compounds) that a researcher believes may have potential applications as medical cures, diagnostic tools, and the like. In other words, while basic research is primarily aimed at expanding the base of knowledge, there emerge from time to time inventions with potentially more immediate application. However, the process of transforming such inventions into commercially available medicines, medical procedures, or medical instrumentation requires substantial additional time, effort, and financial investment from the private sector. For example, a university researcher may synthesize a new compound in his laboratory as part of his research effort, but it requires the efforts of private chemical or pharmaceutical companies to test the compound for potential efficacy, to scale-up production of the compound, to test it, to achieve FDA clearance, and to market it. Unless these steps are completed the public will simply never receive the potential benefits of the compound developed during an NIH supported project.

That NIH patent policies have a direct effect on whether these steps are taken has been well documented. The 1968 Harbridge House, Inc. "Government Patent Policy Study" commissioned by the Federal Council for Science and Technology contains a detailed analysis showing that a shift in NIH policies in the early 1960s to Government retention of title to inventions made by its grantees and contractors led to a breakdown in industry development of NIH supported inventions.[3] In 1968 the General Accounting Office reached the same conclusions and recommended that NIH use Institutional Patent

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[2]This report recommended that agencies adopt university patent policies modeled after those of HEW.

[3]See, in particular, Volume II, Part II, of the study.

Agreements and expedite review of waiver petitions.[4] In past testimony before Congressional committees, Mr. Latker has documented the difference in industrial investment in NIH supported inventions pre and post 1968.[5]

One fundamental change at NIH in 1968 was the adoption of a policy giving qualified institutions an "Institutional Patent Agreement" which allowed them to elect to retain ownership to inventions subjects to certain limitations and safeguards. NSF adopted essentially the same policy in 1973, and as noted previously it was recommended for Government-wide use in 1975 by the Committee on Government Patent Policy. In 1968 NIH also began expediting the handling of waiver requests in cases when an IPA was not involved.

From the foregoing it should be apparent that there is well documented and understood evidence of how different HEW/NIH patent poliicies affect the utilization and commercialization of NIH supported inventions. We have real life case histories of the effects of two different policies. Anyone with any concern for the public health must surely favor policies that bring the benefits of the billions of dollars of NIH funded research to the public and would oppose the adoption of policies known to stifle the development of new medicines and medical procedures.

However, at NIH, beginning in 1977, it appears that persons above Mr. Latker in the DHEW Office of General Counsel choose to ignore past history. What was underway was a reversion to the very same pre-1968 policies that the GAO and others have so correctly found wanting. Mr. Latker has been made the scapegoat by persons above him for the entirely predictable, adverse reaction to their efforts to turn the clock back ten years.

Senator Dole's staff and others have documented the fact that from the summer of 1977 until late 1978 (when Senators Dole, Bayh, and others began to complain) that numerous petitions that would have previously been acted on were sitting in the DHEW Office of General Counsel.

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[4]GAO Report B-164031(2), Aug. 12, 1968, Problem Areas Affecting Usefulness of Results of Government Sponsored Research in Medicinal Chemistry.

[5]Hearings on Science Policy Implications of DNA Recombinant Molecule Research before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 95th Cong., 1st Sess (No. 24), p. 965.

my knowledge is incomplete on events since then, but one has the distinct impression that only Congressional pressure has prevented a continued "stonewalling" of petitions for patent rights by inventing organizations.

At around the same time a draft report was prepared by the DHEW Office of General Counsel recommending possible changes in Department patent policy. This draft suggested as a viable option the discontinuance of Institutional Patent Agreements. One ground cited for this suggestion reflects the incomprehensible mentality that was prevailing:

> "It is also possible that inventions might be made that could be harmful to the public welfare. We might wish to suppress such an invention or to carefully regulate its use." (Underlining added)

Apparently the author believed it possible for Government employees to predict the tranformation of an invention (idea) into an "evil" product. (One wonders what they might have done if fire or the wheel was invented under an NIH grant.) Apparently, also the author finds fault with the rather extensive procedural requirements of the Food and Drug Administration for pre-market clearance of drugs and medical instrumentation.

I submit that anyone with any understanding of how university research in the health areas is translated into useful products would have found the developments taking place at DHEW in 1977 and 1978 and to the present to be a "substantial and specific danger to the public health." While I personally believe that it was the universities whose petitions were going unanswered, more than Mr. Latker, who, so to speak, blew the whistle, it is Mr. Latker who is being harassed for not being a loyal bureaucrat and enthusiastically supporting the unconsionable policies that were being proposed and implemented.

I urge your office to take action to put a stop to further action against Mr. Latker. Hopefully, you might influence the new HEW Secretary and General Counsel to reevaluate what has been happening in the DHEW Office of General Counsel.

Sincerely yours,

Jesse E. Lasken

cc: Norman Latker