Medtronic, Inc.
3055 Old Highway Eight
P.O. Box 1453
Minneapolis, Minnesota 55440
Telephone 612 781-6061
Cable: Medtronic Telex: 29-0598

2 August 1979

Norman J. Latker
HEW GC
NIH
Westwood Building
Bethesda, Maryland 20205

Dear Norm:

I read with great pleasure, this morning, page 476 in the 3 August 1979 issue of SCIENCE. "Whistle Blowers" deserve appreciation and respect; we have too few of them.

Good luck.

Best wishes,

Les

Lester Goodman, Ph.D.
Director, Biomedical Engineering

LG:pag

THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

DEPARTMENT OF INTERNAL MEDICINE
SECTION OF HEMATOLOGY AND ONCOLOGY

(602) 626-6372

August 6, 1979

Mr. Norman J. Latker
HEW Patent Counsel
National Institutes of Health
Westwood Bldg., Room 5A03A
Bethesda, Maryland 20014

Dear Mr. Latker:

I was pleased to read last week's edition of SCIENCE and learn about your reinstatement and of the progress on the patent act. Since last fall, I was quite glum about the events that befell you.

Enclosed you'll find a copy of a letter that I sent to Senator Bayh this past May as well as my testimony related to the patents and procedures act. I thought that you'd like to see them.

With best regards,

Sydney E. Salmon, M. D.
Professor and Chief
Section of Hematology and Oncology
Director
Cancer Center Division

SES/sbm

Enclosures

P.S. I also wanted to thank you for your assistance in relation to our request for release of rights of our invention.

May 8, 1979

The Honorable Birch Bayh
Chairman
Subcommittee on the Constitution
Committee on the Judiciary
United States Senate
Washington, D. C. 20510

Dear Senator Bayh:

I am very disappointed that I will be unable to testify in person at the May 17 Senate Judiciary Committee hearing on S414, the University and Small Business Patent Procedure Act. As you know, I had made plans to attend on April 11, and fully understand why the hearing date had to be changed. Please accept my sincerest condolences.

Unfortunately, a longstanding prior commitment to speak and participate in the annual meeting of the American Society of Clinical Oncology and the American Association for Cancer Research in New Orleans followed by a commitment for invited lectures in England resulted in an impossible schedule conflict for me on May 17.

However, I have revised my testimony to emphasize your important role in the release of stalled inventions last summer and the unfortunate firing of Mr. Latker, whom I considered to be an outstanding civil servant. In my opinion, he had the best interests of government and the public in mind.

If you need additional testimony in June, I would be pleased to come to the hearings and testify in person.

Sincerely,

Sydney E. Salmon, M. D.
Professor of Medicine and Chief
Section of Hematology and Oncology
Director
Cancer Center Division

SES/sbm

Enclosure

Revised 5/8/79

TESTIMONY OF SYDNEY E. SALMON, M. D. OF TUCSON, ARIZONA, FOR SUBMISSION ON THE "Small Business Non-Profit Organization Patent Procedures Act" of Senators Bayh and Dole.

I am Sydney E. Salmon, M. D., Professor of Internal Medicine and Director of the University of Arizona Cancer Center in Tucson. My academic career has been dedicated to clinical and laboratory cancer research, and I have published in excess of 100 original scientific articles. I wish to testify in support of the bill introduced by Senators Bayh and Dole and colleagues as I believe that passage of this bill will clearly facilitate the delivery of important new inventions to the public as well as aid the government in gaining return of its investment in federally supported university and small business programs. Passage of this bill into law will also improve our country's capability to maintain technological leadership and favorably influence our balance of payments in an increasingly competitive environment.

My own personal experience in relation to the problems of a university scientist attempting to patent an invention designed to improve the care of cancer patients should provide useful supportive data indicating the need for your bill. I want to emphasize at the outset that the Department of Health, Education and Welfare eventually did come to my aid and to the University of Arizona so that we were able to submit a patent and eventually gain rights to an invention, however the time delays involved were noteworthy, and need to be reviewed. Additionally, some other unfortunate events relating to the NIH patent counsel warrant careful review by your committee.

In April, 1975, I recruited Dr. Anne Hamburger to work with me on a new project. I proposed that we develop a bioassay to permit growth of human tumor stem cells. Tumor stem cells which comprise less than one percent of the cells in a cancer are the key cells which are responsible for a cancer's ability to undergo continued growth and spread through the body in a process called metastasis. Studies in experimental animals suggested that the response of tumor stem cells to

treatment could be predictive of the response of the animal to cancer treatment. Dr. Hamburger joined my laboratory in August, 1975. In less than 1 year we devised a technique which permitted colony formation by human tumor stem cells permitting us to accurately measure the effects of anticancer drugs on biopsy samples. At first we tried the test on multiple myeloma and ovarian cancer, but have subsequently found it useful also in a wide variety of cancers, and predictive of the patient's response to treatment. The initial work was supported largely by donated funds, but federal funds did support Dr. Hamburger's salary as a beginning research associate in my laboratory. Because of our continued success with this research and the obvious potential of our discovery to improve the management of cancer patients and facilitate the development of new anticancer drugs, we disclosed our invention to the University. A decision was reached that the discovery should be patented. Inasmuch as some limited HEW funds had been used in support of our work, the University was obligated to request permission to gain and administer rights to this invention in relation to the patent process. The petition was submitted on July 5, 1977, and filed by the NIH patent attorney, Mr. Latker, on July 20, 1977. Our first scientific article on the bioassay was published in the journal, SCIENCE, on July 29, 1977.

In view of our publication of our findings, a statute of limitations of one year was automatically applied from that date with respect to filing a patent. The University was understandably reluctant to file a patent without receiving greater rights determination from HEW, as without these rights it would have no way of regaining its investment in filing the patent. No action had been taken on our petition as the filing deadline approached, until late spring 1978 at which time HEW decided that it would underwrite the cost of filing a patent on our invention. Accordingly, a patent application was filed at HEW's expense on July 7, 1978. We appreciated this action because if it had not been taken, the statute of limitations would have run out. I do not know how often HEW takes such action in support of its greater rights petitioners.

Also relevant to development of our test were results which we published in THE NEW ENGLAND JOURNAL OF MEDICINE on June 15, 1978. In that article we demonstrated

that our test was predictive of the response of cancer patients to a variety of anticancer drugs. As a result of this article, the editorials and other publicity which was generated caused several private companies to express interest in investing the venture capital necessary to bring this invention to the market as a convenient, dependable diagnostic drug testing procedure. However, when they learned that the University did not have the approval to administer rights to this invention, they quickly lost interest in its development, and it therefore has remained a laboratory research effort up until the present time. It is my opinion that the press conference you held last summer on the problems of non-release of rights to various inventions was one of the major factors that resulted in the rapid release by HEW of a number of pending requests for rights determination. Unfortunately, our patent was one of those that was still held back by HEW. Mr. Norman Latker, who was then the NIH patent counsel, labored diligently to facilitate review of our invention. I thought he acted in a fashion which was exemplary for a U. S. civil servant. My last correspondence with him was on October 3, 1978. I was shocked to learn that he was subsequently relieved of his position with the federal government. Every dealing I had with him was honorable and I had no reason to question his judgment. It was my opinion that he had a true sense of the public interest and as a responsible government employee had major dedication to seeing the fruits of scientific progress made available for the general good of society.

After substantial further delay following my letter to Mr. Latker, the Assistant Secretary of Health (Julius B. Richmond, M.D.) determined (on March 23, 1979) that the University of Arizona could retain rights to the invention. This recent decision will clearly help our invention to be developed and applied for the good of the public. However, a period of large scale testing and clinical trial will still be required. It is important to point out that a decision on our rights determination petition took a total of 20 months to be granted and faced many obstacles. In my opinion, this slow process of gaining approval from HEW had to delay the availability of our invention to the public by at least one year.

At our present stage of knowledge, I believe that application of this invention to the public will spare cancer patients from receiving toxic drugs which we can predict would be of no benefit. We believe that once this invention is systematically applied by the National Cancer Institute, by our nation's cancer centers and by research laboratories and the pharmaceutical industry, new and effective anticancer drugs will be discovered and developed more rapidly than ever before, and lead to the cure of many types of cancer which still remain incurable.

Please accept my testimony in evidence as supporting your plan to facilitate the process of rights determination in relation to other new inventions. I hope that future inventors will not have to endure the same frustrations which we experienced in attempting to gain rights for their universities. I believe that your bill represents a major step in the general interest of the public, industry, universities, and the government itself. I hope it is quickly passed by Congress and signed into law.

Thank you.