### REMARKS OF SENATOR BOB DOLE

September 13, 1978

# SMALL BUSINESS, NONPROFIT ORGANIZATION PATENT PROCEDURES ACT

Today Senator Birch Bayh and I are introducing the "Small Business, Nonprofit Organization Patent Procedures Act." This bill will not only remove an unfortunate bottleneck in the flow of technology to the public, it will also underscore the need for the public and private sectors to work in partnership on the many problems facing this nation.

## FEDERAL PATENT POLICY BOTTLES UP INNOVATIONS

Inventions developed with government support at this country's major universities and research institutes are wasting away on the shelves of bureaucracies all across government. The present government policy mandates the government take title to all inventions it has had a hand in funding. The policy discourages participation by the private sector, with the end result being that the innovation will never be brought to the marketplace for use by the public. Inventions that could make the difference for this nation's most pressing problems of jobs, inflation, energy, and health are being relegated to the scrap heap.

Why is the government willing to bottle up much of this country's most important technological innovations? Rather than acknowledging the need for the public and private sectors to work in partnership on the many problems facing this nation, we maintain policies that foster an adversary relationship between government and private industry. I can assure you that this attitude will not encourage start-ups of new small businesses, nor will it enhance economic growth, nor increase employment, nor trade competitiveness, nor solve our energy shortage.

It is time we stop paying lip service to the contributions of the private sector. Although patents may be but a small factor in establishing meaningful private-public collaborations, it does provide an opportunity for the government and private sectors to display mutual trust and willingness to work together on common problems.

To this end, Sen. Birch Bayh and I are introducing today the "Small Business, Nonprofit Organization Patent Procedures Act." The bill provides to universities, non-profit organizations and small businesses patent rights to inventions they have made with government grant and contract support. The intent of the bill is to provide the incentives necessary to unleash the creative energies of the private sector in tackling the societal challenges of health, energy and urban decay.

#### SUPPRESSION OF TECHNOLOGY IN HEW

Nowhere are the problems raised by government patent policy more catastrophic than in the biomedical research programs of the Department of Health, Education and Welfare. At this moment, people are being condemned to needless suffering because of the refusal of HEW to release the rights to medical devices and pharmaceuticals developed with government support.

For more than a year now, potentially lifesaving medical technology from the world's most renowned medical research laboratories supported by the National Institutes of Health has been shut down. HEW has decided to pull the plug on development of biomedical research, and withhold from the American public potential cures and revolutionary new diagnostic techniques for treating such diseases as cancer, arthritis, hepatitis and emphysema.

In August when I raised this issue on the floor of the Senate, I was informed by the general counsel of HEW, Mr. Peter Lebassi, that the delay in the release of the more than 30 cases was only a matter of paperwork. But now another month has gone by and still nothing has been released by HEW. We are not witnessing in HEW "an unavoidable bureaucratic delay", but a calculated policy of "search and destroy" aimed at innovations from this country's scientific research programs.

2

### THE DEMISE OF A LIFESAVING INVENTION

Let me illustrate the attitude of some of the zealous bureaucrats in HEW who are now determining the policies for this country. Yesterday, I was informed by the legal counsel of the Weissman Institute of Israel, one of the world's most prominent medical research centers, that the petition for ownership rights submitted by its president, Professor Sella, who is a renowned scientist in cancer research, had been denied. Under a contract from NCI for an investigation of carcino-embryonic antigens (CEA) as a diagnostic marker for cancer, Dr. Sella invented a revolutionary new blood test for detecting cancer of the breast, disgestive tract and pancreas. From all indications it appears to be superior to all presently available procedures, and is especially important for post-operative follow-up diagnosis and prognosis of these dreaded cancers. Clinical trials of this marvelous new discovery that were to take place in collaboration with a private pharmaceutical firm have been cancelled in light of the decision by HEW. I fear we will never know how many lives this invention would have saved.

What possibly could have prompted the HEW general counsel to reach the decision to deny to Dr. Sella the rights to his own invention? I can only wonder who is served by HEW's policy? Certainly not the taxpayers who pay for this country's medical research. Certainly not Dr. Sella who has devoted so much of his life to conquering cancer. And certainly not the hundreds of thousands of us unfortunate enough to be stricken with cancer who need this technology to sustain life.

Rarely have I witnessed a more unfortunate example of over-management by the bureaucracy. In the anticipation of a presently nonexistent abuse, or perhaps out of a preoccupation with the rising cost of health care, HEW is willing to shut down the innovative process.

We must not allow this unfortunate state of affairs to be repeated. Legislation of a government-wide patent policy is needed, and it is needed now.

# INTRODUCTION OF PROMINENT INVENTORS

Later we will hear from several prominent educators and scientists who know first-hand about the problems of government-sponsored research. President Hansen from Purdue and Vice-President Jones of MIT administer two of the most prestigious research programs in America. Doctors DeLuca, Fox, London, Millman, Walser and Goldstein represent this nation's medical research programs and know how it is to be cut down by the HEW bureaucracy. Finally, George Claypoole, representing a small R & D energy firm, can speak to the problems of energy research.