

NEWS from
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REMARKS OF SENATOR BOB DOLE

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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 [illegible]

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.

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FOR RELEASE

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WASHINGTON, D.C., SEPTEMBER 13 --A wealth of scientific talent at American colleges and universities--talent responsible for the development of numerous innovative scientific breakthroughs each year--is going to waste as a result of bureaucratic red tape and illogical governmental regulations, Senator Birch Bayh (D.-Ind.) said today.

Bayh said regulations covering procedures that govern the issuance of patents for inventions resulting from government-financed research by universities and small businesses have kept new and potentially beneficial ideas from being marketed.

To rectify this problem, Bayh and Senator Bob Dole (R.-Kan.) announced today they are introducing the University and Small Business Patent Procedures Act. The two Senators were joined at a Capitol Hill news conference by several representatives of academic and scientific research institutions.

"Our nation has become a leader in the world of technology, in part, because we have not been afraid to move on bold, new concepts," Bayh said. "Often, government-backed research programs provide the starting point for medical innovations that ultimately save thousands of lives, or starts the ball rolling on projects that in the end result in new sources of energy."

The Hoosier Democrat pointed out, however, that America seems to be falling behind in the development of new technology. "This trend," he said, "strikes at the heart of our traditional American economic strength--our inventiveness and ability to adapt to a changing world."

Bayh explained current federal regulations have prohibited universities and small businesses from obtaining patent rights on inventions if any of the research leading to the invention was supported by federal money.

"The problem, very simply, is the present policy followed by most government agencies of retaining patent rights on inventions," Bayh said. He noted government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public.

"It is not the government's responsibility--or indeed, the right of government--to assume the commercialization function," Bayh pointed out. "Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle."

Bayh noted that approximately 28,000 patents are now sitting on government shelves. Untold thousands of other developments have not been patented by the government, but rather have gone unused or underutilized simply because no exclusive rights could be obtained during the critical developmental period, the Senator added.

"Although my first involvement in this issue arose with respect to energy research," Bayh said, "the most dramatic examples of this failed government policy can be found in the area of health research. Numerous developments, including cancer-related drugs and procedures, remain at a very early stage of development and unavailable to the public because the government has not granted the necessary patent rights for industry to expend the sums of money needed for further development, leading to public availability."

Bayh referred to problems that have plagued the development of a new source of alcohol fuels by Dr. George Tsao at Purdue University. The Tsao process--a new method for converting cellulose and cellulostic wastes into alcohol for use as a fuel--has been funded by grants from the U.S. Department of Energy. Yet, without exclusive rights that

would arise from patent protection, no commercial enterprise has been willing to risk commercialization of the Tsao process. Bayh said that although this specific problem after long delay appears now to be solved by a waiver from DOE, the underlying problem remains a very real fact of life with respect to many other research projects.

"The bill Senator Dole and I are introducing will allow universities, non-profit organizations and small businesses to obtain limited patent protection on discoveries they have made under government-supported research, if they spend additional private resources necessary to bring their discoveries to the public," Bayh said. "Our universities and small businesses have a proven capacity to develop the sort of bold, new inventions that our country needs to maintain its leadership in the world economic community. This bill provides a careful balancing of the rights of the federal government to use for itself and the public inventions arising out of research that it helps to support, and the equally important rights of the inventor and the people to see that the inventions attain their full potential.

Bayh said an important provision of the bill will allow the government to recoup its investment in research projects. Under this "pay-back" provision, the federal government would be reimbursed for its research expenditures out of royalties or income in excess of a fixed figure.

"At a time when we want to be careful about how we utilize our hard-earned tax dollars, it seems to me that it makes good sense to have the federal government's investments in research projects pay off," Bayh said. He said too many research dollars now go down the drain because a complex welter of government regulations keep innovative developments from realizing their full potential in the marketplace.

Bayh cited a number of statistics which he said clearly demonstrate the patent problem. The number of patents issued to American inventors has declined year by year since 1971, he noted, adding that during the same time, the number of United States patents granted to persons other than Americans has increased. He went on to say that invention disclosures and patents resulting from federally-funded research and development have also decreased steadily since 1970.

"I have no doubt that one major reason for this decline is the fact that patents have been very difficult to obtain under our existing federal policy," Bayh said. "The incentive for disclosure of inventions is reduced if the inventors conclude the commercialization of the invention will be impossible because no patent will be issued."

The Bayh-Dole bill is expected to be referred to the Senate Judiciary Committee. A copy of the bill, as well as other briefing materials are included in a press packet available at this morning's news conference or upon request.

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