NEWS from U.S. Senator Bob Dole

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DOLE CHARGES HEW IS SUPPRESSING LIFESAVING MEDICAL TECHNOLOGY

WASHINGTON -- Sen. Bob Dole today charged that the Department of Health, Education and Welfare (HEW) is suppressing critical lifesaving drugs and medical devices developed under support from the National Institutes of Health.

Dole said that HEW is violating federal regulations in "stonewalling" requests and ignoring petitions from major universities and medical research institutes seeking to collaborate with the private sector for purposes of developing medical inventions for public use.

"While the department continues to 'study' the issue, 29 life-sustaining inventions are languishing on the bureaucratic shelves of HEW," Dole said.

He stated that HEW's refusal to relinquish ownership of inventions developed by university scientists with NIH support "precludes the possibility of these lifesaving drugs and medical devices every reaching the public."

Dole asserted that HEW is destroying the process by which new medical technology is transferred to the public because of the belief that this new technology will increase the cost of medical care.

One of the examples Dole cited was a new method of testing the effectiveness of cancer drugs. With this procedure, the effectiveness of cancer-retarding drugs could be evaluated without having to administer the drug to the patient. The new procedure would eliminate the needless suffering caused by toxic side-effects that usually accompany cancer chemotherapy.

"Patients will not be able to benefit from this revolutionary new approach until the HEW general counsel allows the new cancer test to undergo further development," Dole said. "I wonder just who is being served by such a policy."

Following is the text of Sen. Dole's statement and the list of inventions being held by the HEW general counsel:

During the past year, the delivery to the public of potentially lifesaving drugs and medical devices developed under the auspices of the Department of Health, Education and Welfare has been dealt a crippling blow. In clear violation of federal regulations governing disposition of inventions, HEW has reversed its long-standing policy of permitting universities and medical research institutes to collaborate with the private sector for purposes of developing medical advances for diagnosing and treating such diseases as cancer, arthritis, hepatitis and muscular dystrophy. HEW's decision to effectively suppress these medical breakthroughs is without precedent and is so unconscionable that I feel they are properly designated "horror stories."

HOW HEW CONTROLS MEDICAL TECHNOLOGY

HEW's present position of denying to inventors and their universities ownership rights to inventions they have made under HEW grant and contract support precludes the possibility of these inventions ever reaching the public. Inventions derived from government-supported research almost always exist as a prototype and therefore must undergo very expensive development and clinical evaluations. The government research grant represents only a small fraction of the total cost of bringing a new drug or medical device to the public. Product development and evaluation of medical devices, which often take years to accomplish and require investments of millions of dollars, can only be carried out by the private sector. The government has neither the financial resources nor the expertise to bring a medical innovation to completion. Industry just cannot be expected to underwrite a very risky development process unless it is provided a modicum of protection through granting of patent rights for a limited period of time.

AN ILLUSTRATIVE CASE: A NEW DIAGNOSTIC TEST FOR CANCER

To understand how lifesaving medical technology is made available to the public and how its development is dependent on the whim of HEW bureaucracy, consider the following scenario.

At a prominent medical research institute, a professor was awarded a grant by the National Cancer Institute of the National Institutes of Health (NIH) to investigate Carcino-Embryonic Antigens (CEA) as a diagnostic marker for cancer. Initial evaluation of this new assay has revealed it is superior to existing procedures for detecting cancer of the digestive tract. These cancers are extremely difficult to treat and therefore early detection is absolutely crucial.

The advantages of diagnosing and evaluating cancer with blood samples were felt to be so significant that the professor promptly brought his research findings to the attention of the administration of the medical school as well as to his project manager at NIH. The NIH as well as the university informed the professor that funds for clinical evaluation, running into the millions of dollars, were unavailable and suggested that he seek support from a private firm interested in marketing the device. Several companies were contacted in an effort to establish a collaboration with the university. At least one firm expressed a willingness to commit the necessary capital for development, but pointed out that even if the assay turns out to be as effective as the present evidence indicates, the company has no protection against its competitors copying the technique. Were this to take place, not only would the competitor have saved itself millions of dollars of risk capital, but in light of the limited market the firm could never recoup its investment. It therefore insisted on patent rights for a reasonable period of time as a shield against unscrupulous practices of other firms.

Believing this to be a reasonable request, the professor petitioned HEW for rights to the invention so that patent protection could be extended to the private firm. After going many months without receiving word from HEW, the university requested a status report. It was informed the petition was under study.

Several more months have gone by and it is a year and a half since the initial petition was submitted. The university was recently informed by the private company that it no longer can commit its funds and must rescind its agreement. The professor has essentially given up on HEW and is back in his laboratory working on other projects. Interest in this once promising cancer diagnosis breakthrough has almost totally dissipated, and the assay is little more than an idle curiosity in the professor's laboratory notebook.

There is little more to add to the story except to state that the scenario is not fiction. The professor's name is Dr. Sela, who is president of the world-renowned Weizmann Institute in Israel.

HEW SEEKS TO RESTRAIN NEW INVENTIONS

Recognizing the importance of developing its medical inventions, HEW, for the past 10 years, has been willing to relinquish ownership of inventions to grantees in order to foster commercialization. HEW's decision to actively encourage private-public collaborations was made following an investigation in 1968 by the GAO of the pharmaceutical research programs in NIH. The GAO could not find evidence of a single pharmaceutical developed with NIH support ever having reached the public, and concluded that HEW's retention of all rights to inventions was the primary reason for its pitiful record.

In 1968, in response to the GAO's accusation that hundreds of millions of dollars had been expended on drug research with no measurable return, HEW altered its policy and began awarding patent rights to grantees in nonprofit institutions. In the next 10 years, the introduction of more than 70 inventions attracted hundreds of millions of dollars for capital formation. The benefits to the public measured in terms of jobs and business enterprises created, trade spawned and human lives saved are difficult to calculate. All this at no additional cost to the taxpayers.

How short the institutional memory of HEW! For some inexplicable reason, HEW has now decided to pull the plug on development of government-supported biomedical research and thereby deprive us of the medical innovations we have come to expect in return for the billions of dollars in annual federal expenditures for biomedical research.

HEW HORROR STORIES

My office has documented 29 cases where a university has been joined by the sponsoring institute of NIH (e.g., NCI) in its petition to HEW's general counsel for ownership rights on an invention. The petitioners have not received so much as an acknowledgment.

In the past 10 years, following standard operating procedures of HEW, a petition for invention rights was thoroughly reviewed by the sponsoring institute of NIH. The institute's recommendation for invention rights was then forwarded to the assistant secretary for health, who made the final decision. Thus, prior to August 1977, the HEW general counsel did not undertake a separate review, and therefore additional delays were nonexistent. As can be seen from the enclosed list of petitions, delays caused by the general counsel are, in some cases, now running almost a year.

In response to inquiries from my office, I have been informed that all patent matters are being deferred pending completion of the general counsel's study and that HEW does not have a good estimate as to when the review will be completed.

The decision to "stonewall" esteemed scientists from some of our most prestigious universities is in clear violation of the federal procurement regulations that state that "The Agency (HEW) is obligated to consider, record and notify the party requesting patent rights--and that if the Agency does not wish to grant greater rights, the basis for the final action must be communicated."

Of the 29 cases requesting patent rights, 13 cases have identified a private firm that has offered to commit millions of dollars for development. Included in this list of "horror stories" are potential cures and diagnostic methods for cancer, arthritis, tuberculosis, hepatitis and muscular dystrophy. The magnitude of the problem is made graphic from a consideration of the individual cases. For example:

"Bioassay for Cancer Treatment," University of Arizona (Drs. Salmon and Hamburger). An article in the June 26 edition of Time Magazine describes a new means of testing the effectiveness of drugs in a specific case of cancer, without having to administer them to the patient. In cancer chemotherapy, patients often suffer needlessly from the drug's toxic side-effects even though therapy may not retard the cancer. With this procedure, physicians will be able to plan an individual course of treatment. It can also be used to evaluate new anticancer drugs without endangering the patient.

"Treatment for Several Auto-immune Diseases," University of Texas (Dr. Goldstein). Thymosin is a hormone treatment which is expected to prove effective in treating patients with malfunctioning immune systems, which include several types of cancer, rheumatoid arthritis, muscular dystrophy and possibly schizophrenia. By providing immunities the body cannot produce, it is effective in treating immunodeficiencies in children who suffer from raging infections because of a breakdown in natural immune systems. Immunodeficient patients will be treated with thymosin in the way diabetics are supplied with insulin. In cancer studies, thymosin has been found to be very effective against lung cancer of the dreaded Oat Cell-Lung Cell Type."

"Blood Test for Detecting Cancer," Columbia University (Dr. Spiegelman). This invention is a method for detecting the presence and evaluating the status of cancer by assaying blood plasma for tumor-related viral proteins. The blood test would be ideal for initial mass screening programs for early detection of the disease. The procedure would also be useful in evaluating the outcome of surgical, chemotherapeutic and radiation therapies and for determining whether there has been a recurrence of the disease.

"Treatment of Hypertension," University of Vermont (Dr. Kuehne). A naturally occuring alkaloid, vincadifformine, has been widely used in several countries in Europe to treat cerebral vascular diseases and hypertension. For the elderly, who are high-risk candidates for stroke, this drug is believed to be of special importance. Because of unstable political conditions in the country where the substance is found, it is anticipated that sufficient quantities of the drug will not be available for FDA clearance in the United States. Thus the total synthesis of the drug is a major breakthrough for all patients suffering from arterial disease.

SACRIFICE OF LIVES TO GOVERNMENT OVER-MANAGEMENT

The above cases and the 25 other inventions represent the cream of the NIH biomedical research program. Yet they are being held back from development. Why? Who is served by HEW's policy? Certainly not the taxpayers who have paid for this research. Certainly not the scientists and physicians who have devoted so much of their energies to conquer these dreaded diseases. And certainly not those of us unfortunate enough to need these technologies to sustain life.

Rarely have we witnessed a more hideous example of over-management by the bureaucracy. In the anticipation of a presently nonexistent abuse, HEW is apparently willing to intervene in the development of lifesaving technology.

The extent to which HEW is willing to go in its control of biomedical research findings obtained by NIH-supported university scientists is illustrated in the following passage from an internal memorandum of the HEW general counsel:

> "Historically, the objectives of our patent policies have been to make inventions developed with government funding available to the public as rapidly and as cheaply as possible, goals which are sometimes incompatible.
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> While these objectives are basically sound, recent experience with the high cost of proliferating health care technology suggests that there may be circumstances in which the Department would wish to restrain or regulate the availability and cost of inventions made with HEW support, sometimes encouraging rapid, low cost availability, at other times restraining or regulating availability."

What I believe we are witnessing in HEW is an ill-considered "lashing out" at medical science out of a sense of frustration about the cost of health care. It seems clear to me that HEW's change in policy is in fundamental conflict with its mandated mission of bringing beneficial medical technology to the taxpayer. I am shocked to learn that HEW has in effect destroyed the process by which the inventions I have identified are transferred to the public, presumably on the basis that the new technology may increase the cost of medical care.

As the ranking member of the health subcommittee of the Senate Finance Committee, and having devoted so much of my time this session to a consideration of the rising costs of health care, I have more than a passing interest in this problem. The senator from Kansas, however, fails to understand how HEW's policy of cutting off the scientific process at its very inception can ever result in lower health care costs, not to mention the disastrous consequences of such a policy for maintaining the health of our citizens.

It is my position that the technology must be developed sufficiently before judgments about benefits to the public can judiciously be made. Let me illustrate this point. I am advised that HEW is now aiding in development of a drug that will, at the cost of less than a dollar a day, dissolve gallstones. This treatment would obviate the need for costly surgical treatment and the $200-a-day charge for hospitalization. Can anyone maintain that NIH should not develop this drug to the point where its cost to the user can be evaluated? But, as I have demonstrated, this is precisely the position that HEW has adopted.

HEW'S DISTRUST OF THE PRIVATE SECTOR

The unfortunate state of HEW's technology delivery system, I feel, is symptomatic of government reluctance to involve the private sector in efforts to solve the problems besetting this country. We must face the reality that the creative energies in the private sector must be utilized in tackling the societal challenges of health, energy and urban decay. President Carter stated in his 1978 State of the Union Address that "Government cannot solve our problems. Government cannot eliminate poverty, or provide a bountiful economy, or reduce inflation, or save our cities, or cure illiteracy, or provide energy."

It is time we stop paying "lip-service" to the contributions of the private sector and demonstrate good faith with decisive action. 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 a willingness to work together on common problems.

ACTION TAKEN BY SENATOR DOLE

Today, I am calling on the secretary of HEW to justify his department's policy, and tell the American public why it is in the public interest to be deprived of the benefits of the world's finest biomedical research program. I am also requesting that the GAO immediately undertake for the Congress a full-scale investigation of the medical technology transfer program in HEW and its relationship to federal patent policy. Finally, together with other members of the Senate, I shall be introducing a bill establishing a federal patent policy that will give universities and small businesses the oppurtunity to develop inventions funded with government support.