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Senate

UP AMENDMENT NO. 1626

(Purpose: To give the Office of Health Technology certain administrative responsibilities)

The Senator from Kansas (Mr. DOLE) proposes unprinted amendment number 1626 to unprinted amendment numbered 1627 proposed by Mr. KENNEDY:

At the proper place, insert the following:

"SEC. 111. (a) The Assistant Secretary for Health, acting through the Office of Health Technology, shall have the responsibility (1) for developing the policies of the Department of Health, Education and Welfare with respect to the rights to inventions of its employees, grantees and contractors, subject to applicable laws and regulations; (2) for issuing invention and patent administration policies and procedures, (3) for administering the receipt of and processing invention reports by employees, grantees and contractors, of the Department and maintaining records and documents incident to patent and invention administration; (4) for making determinations of rights in inventions and patents involving inventions of employees, grantees and contractors of the Department; and (5) for making determinations with respect to applications for licenses under patent applications and patents owned by the United States, as represented, and for accepting licenses issued to the United States as represented by the Department.

(b) All functions of the Office of General Counsel relating to patent administration and administration of invention reports by employees, contractors and grantees of the Department are transferred to the Office of Health Technology, provided, however, that all legal services and functions, relating to patents inventions by employees, grantees and contractors of the Department shall remain in the Office of General Counsel.

Mr. DOLE. Mr. Presdent, I echo what the distinguished Senators from Pennsylvania and Massachusetts have said with reference to S. 2466. Amended S. 2466 is a marked improvement over the original bill. It goes far in alleviating many of the concerns I raised in my original floor statement on the bill. At that time, you may recall, I objected to the establishment of a new and very substantial bureaucratic entity, under the umbrella of a national institute. Establishment of this public health service agency consisting of two new institutes and a center has now been deleted. The bill's sponsors are now offering a much more modest proposal that authorizes the extension of the National Center for Health Services and the National Center for Health Statistics and Epidemiology, and provides legislative authorization for the Office of Health Technology.

Levels of authorization in the original bill have also been pared down considerably. No longer are we being asked to approve a 100-percent increment over the existing appropriation. Instead a more reasonable increase of about 30 percent is being requested. In light of the importance of the health care issues before the country, these new funds are not very much out of line, at least when measured in terms of the absolute dollars requested.

What caused me the greatest concern in the original bill was the creation of an entirely new center for the evaluation of medical technology. Although the present proposal only authorizes funding for an already established Office of Health Technology in HEW, I am not entirely comfortable with what I understand to be the responsibilities of the new office. There still exist potential problems of overlap [illegible] authorities with the existing [illegible] I would [illegible]

cies are devoting considerable resources, in excess of $120 million for the evlauation of the safety and efficacy of more than 30 important medical technologies. Considering the limited resources of the new office, I would anticipate that every effort would be made to avoid duplication of the ongoing projects of these established agencies.

A second concern raised in my previous statement on S. 2466 was the trepidation that, through its power to set standards, the office would be transformed into another regulatory agency in HEW. I am assured by the committee that no such regulatory authority is being assigned to the office. The stated purpose of the office is to coordinate and evaluate medical technology in collaboration with NIH, FDA, and CDC and other agencies and to transfer this information to the various State and Federal health agencies.

As clearly stated in the committee report on S. 2466, two major issues have been raised in connection with the management of medical technology. The first relates to the too-rapid application of insufficently evaluated technology. The second issue, commonly referred to as the "bench to bedside" problem refers to the inordinate lag in the transfer of knowledge from the laboratory to the patient. Additional attention might well be paid to this problem of transfer of technology.

With this in mind, and in order to strengthen the transfer of technology capability of DHEW, I will reoffer in a moment an amendment that previously had been offered. The amendment would create a focus for technology transfer activities within the Office of Health Technology. This will be accomplished by transferring the administrative responsibilities of the DHEW Patent Counsel, who presently serves as the principal technology transfer agent in DHEW, from the Office of the General Counsel to the Office of Health Technology.

To understand why this amendment is necessary, let me review briefly how biomedical technology developed with HEW funds reaches the public. All biomedical inventions and pharmaceuticals emanating from HEW extramural (that is, at universities) and intramural research programs are reported to the HEW Patent Counsel. These inventions are almost always in an early stage of development, requiring substantial additional development and evaluation before they can be introduced to the public.

The development process is very expensive, many times more expensive than the original research grant, and therefore requires the participation of the private sector. Establishing the necessary collaboration between the HEW-supported scientist at the University and the private sector firm is the responsibility of the HEW Patent Counsel. Through the allocation of patent rights to the university the Patent Counsel seeks to create a working relationship between the two sectors for the purpose of bringing the medical invention to the public.

Over the past 10 years the development of substantially all of the HEW inventions has been due to the transfer of technology activities of the Patent Counsel. This has been accomplished through the establishment by the Patent Counsel of a network of over 70 technology coordinators at many of the country's major [illegible]

Counsel has not received very much publicity, it has been able to transfer to the public more than 75 lifesaving inventions and pharmaceuticals.

Notwithstanding the above accomplishments, HEW's efforts to transfer medical technology have not achieved all that might be expected on the basis of the $2 billion annual investment in biomedical research. In the main, this lack of performance is due to the underemphasis of transfer of technology within the DHEW. It is in an effort to correct this situation that the Senator from Kansas is introducing an amendment to the bill under consideration.

In addition, I point out that we are working on legislation that I will be introducing at a later time that will modify the present Federal patent policy. But the present amendment does not address policy.

This neglect of an absolutely crucial aspect of HEW's biomedical research programs is manifest in the low visibility and lack of resources assigned to the Office of the Patent Counsel. For example, in spite of the accomplishments of the Patent Counsel, HEW has permitted the staffing of the Office to be reduced from 16 to 7.

HEW's decision to deny to scientists at universities ownership rights to many of the inventions made with HEW support precludes the possibility of these potentially life-saving breakthroughs ever reaching the public.

I have been advised that there are now 29 cases where a university has been joined by the sponsoring institute of NIH in its petition to HEW's General Counsel for permission to develop the invention for introduction to the public. HEW's response has been to ignore the petition—in an effort to "stonewall" the university—to "stonewall" its own department.

Who is served by a policy that holds back from development 29 life-sustaining inventions? Potential cures for cancer, hepatitis, muscular dystrophy. Methods for early diagnosis of cancer are being denied to the American public, because of the actions taken by the HEW General Counsel. The Senator from Kansas just does not understand these attitudes that now prevail in HEW.

Perhaps the major reason for the low visibility of the HEW Patent Counsel is it placement in HEW. The HEW Patent Counsel resides in the Office of the HEW General Counsel. Because the General Counsel has not viewed technology transfer as a primary mission he has consistently downgraded this function. In the last year, the situation has eroded still further through the introduction of an additional review by the General Counsel of all petitions submitted by universities for allocation of patent rights. In the last year, the failure of the General Counsel to even respond to any of these petitions, despite the positive recommendation by NIH, has done much to destroy the existing technology transfer programs at HEW.

The General Counsel's decision to intervene in the transfer of technology program is in clear violation of DHEW's regulations. According to chapter 1-501 of the DHEW organizational manual, "the Assistant Secretary for Health is responsible for evaluation and development of current patent policy and shall [illegible]

It is abundantly clear that the Assistant Secretary for Health, who also serves as the chairman of HEW's patent board, is delegated the administrative authority for patent matters. The General Counsel's assumption of this delegated authority, which effectively undercuts the Assistant Secretary for Health, is totally contrary to DHEW regulations.

The natural home for the focus for transferring medical technology is clearly the Public Health Service where both the knowledge and development agencies, NIH, CDC, FDA, and the health action agencies are located. Coordination of the delivery of medical technology is generally acknowledged to be the responsibility of the Assistant Secretary for Health. I therefore recommend that the administrative responsibilities of the DHEW patent counsel be transferred to the proposed Office of Health Technology. Since this office will be placed under the auspices of the Assistant Secretary for Health and will have the mandated responsibility for encouraging the use of efficacious and cost-effective technologies, it is the obvious place to put the unit responsible for transferring medical technology. Consideration of S. 2466 presents an appropriate opportunity to make an organizational change that will, I feel, go far in improving the expeditious delivery of medical technology to the public.

The Senartor from Kansas is now supporting the bill, based on what I thought were some rather significant changes having been made. It is my hope that we come back from the conference not with the bill we had earlier this year, but something pretty much like the one which may pass today.

Second, it is the hope of the Senator from Kansas that we create an Office of Medical Technology that will serve technology, not suppress it. I do not share the view indicated by the Senator from Massachusetts on the cost of technology. It seems to me our concern should be whether or not we are making progress and what the technology is.

On that basis and on the basis of the amendment I am am offering, I am prepared to yield back the remainder of my time.

The PRESIDING OFFICER. All time having been yielded back, the question is on agreeing to the amendment of the Senator from Kansas to the amendment of the Senator from Massachusetts to the committee substitute.

The amendment was agreed to.