Background Paper to Proposed Amendment

As clearly stated in the Committee Report for 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 insufficiently 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.

The purpose of the proposed amendment is to strengthen the transfer of technology capability of DHEW by creating a focus for these activities within the Office of Evaluation of Medical Technology. This shall be accomplished by transferring the Hew Patent Counsel, who presently serves as the princip technology transfer agent in DHEW, from the Office of the General Counsel to the Office of Evaluation of Medical Technology.

Mechanism for Transfer of Technology

All biomedical inventions and pharmaceuticals emanating from HEW extramural (i.e., 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 responsibili 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 ten 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 university and medical research centers. Although the Office of the HEW Patent Counsel has not received very much publicity, it has been able to transfer to the public more than 75 life-saving inventions and pharmaceuticals.

Inadequate Transfer in DHEW

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 under emphasis of transfer of technology within the DHEW. 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.

Perhaps the major reason for the low visibility of the HEW Patent Counsel is its placement in HEW. Due to some unknown historical precedent, 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 of all petitions submitted by universi for allocation of patient rights. In the last year, the failure of the General Counsel to even respond to any of these petitions, despite the positive recommendations by NIH, has not much to destroy the

existing technology transfer programs at HEW.

Recommendation

The natural home for the focus for transferring medical technology is clearly the Public Health Services where both the knowledge 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 HEW Patent Counsel be transferred to the proposed Office of Evaluation of Medical 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.