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STATEMENT

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BEFORE THE

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

WEDNESDAY, JULY 20, 1977

Mr. Chairman and Members of the Subcommittee:

I welcome the opportunity to appear before you to discuss what I think we all recognize to be one of the most complex and, in a very real sense, urgent problems facing the health care enterprise of this country. In a shorthand way, we refer to this problem as "technology transfer," But like most labels, this one falls short of characterizing the issue to which it is applied.

We are concerned not merely with a kind of linear movement that carries an idea from the mind of a scientist-inventor to the patient under a physician's care. Far more critical, from my perspective, are the factors that influence that transfer, or at any rate should influence it. Because it is these factors -- economic, ethical, and social -- that govern the ultimate benefit of health care technology. And it is

our ability and determination to assess health care technology -- and to be guided by such assessments -- that commands the attention of the health care enterprise and the people it serves.

There are, of course, informal mechanisms for the assessment of the health care technology. And it is probably true that such informal approaches served us reasonably well in the past. But for a variety of reasons, we can no longer rely on such informality. As the capacity for technological innovation has expanded, as public and professional expectations have burgeoned, and as the cost of health care has soared -- it is essential that we take a much more critical view of health care technology, that we make a reasonable effort to anticipate the benefits of new technology in relation to their economic and social cost as well as their ethical consequences. These considerations, are not the traditional concerns of biomedical science. Nor are they considerations that can easily be addressed for through informal approaches to technology assessment.

President John F. Kennedy expressed a hope and a conviction that all of us share when he said: "The accumulation of knowledge is of little avail if it is not brought within the reach of those who can use it. Faster and more complete communication from scientist to scientist is needed so that their research efforts reinforce and complement each other; from researcher to practicing physician, so that new knowledge can save lives as swiftly as possible; and from the health profession to the public, so that people may act to protect their own health."[1] But to that I would add, we must also have the means to assure ourselves and the American people that the development of health technology is matched by an assessment capability to allow us to know as early and precisely as possible the impact of technological developments on human health, on the cost and effectiveness of health care, and on the aggregate resources of the Nation. In the broadest context

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1. President John F. Kennedy, 1962: Surgeon General's Conference on Health Communication: Frontspiece, November 5-8, 1962 (PHS US Department of Health, Education and Welfare, Washington, 1963.

technology transfer issues begin with the decision to allocate resources for biomedical research. These decisions ultimately produce new procedures, practices, and technology -- the subject of today's hearing.

It is clear that the Department of Health, Education and Welfare, the biomedical research community, health professionals and the public must accept greater responsibility for the application and impact of research on the quality and cost of health care. Research in and of itself may have no direct answers for many of the problems in health care delivery, but the biomedical and health services research communities must make significant contributions by assuring that the safety and efficacy of therapies and technologies are evaluated, that pertinent research information is transferred into health services delivery, and that ineffective developments are halted.

I believe that HEW must help see to it that systematic attention is given to the evaluation of technology, from the scientific, economic and societal perspectives that influence its dissemination and use. In effect, we are talking of a five step process: the increase of knowledge leading to the development of technology; assesment of health benefits and risks; determination of the cost effectiveness of technology; the transfer of technology into effective practice, and evaluation of the use of that technology.

Assessment of technology

The biomedical research community can make significant contributions at the critical point where health research begins to have an impact on care through the following types of activity: formal identification and evaluation of new clinically-relevant research information; establishment of systems to reach technical consensus on the validity and significance of new findings and their readiness for clinical application; preliminary assessment of the non-medical implications of new technologies, including social, economic, and ethical considerations.

This activity demands a parallel effort in the health care system to bring to bear the expertise of practitioners, as well as economists, sociologists, and ethicists. Both the biomedical and health communities must also participate in demonstrations of the use of technology. In the area of drug utilization, we have many years of experience with a formal process for assessing new developments. The recent medical device legislation extends this technique still further. However, in the broader therapeutic arena, no such formal mechanism for assessment exists. My office is now reviewing a proposal developed by the National Institutes of Health (NIH) to formalize its role in the critical and complex process of knowledge application. The NIH has proposed that each NIH Institute establish procedures for technical consensus development, an important first step in a systematic process of technology assessment. Councils + study sections have a tradition of advancing in this area.

questions → NIH is superbly able to bring skills to bear in gauging the state of biomedical knowledge and achieving consensus on gaps in knowledge in research and certain

developmental activities. To address these deficits, NIH must continue to conduct clinical trials and other investigations to validate research findings.

But it is in the areas of validation of research on a broader scale, and consensus on social efficacy, that new paths and cooperative experiments with the health care delivery system must be developed. This would include, as I and benefits of technology; the translation, once these assessment have been made, into health care delivery; and the ongoing assessment of both current and newly emerging procedures. Apart from questions of technological development and assessment that fall rather comfortably within the purview of biomedical science, we must, as I have indicated, be prepared to address and answer a host of other questions that are more within the province of economics, sociology, public policy, and ethics -- disciplines with which the biomedical scientists clearly must communicate and collaborate a great deal more than they have in the past. For it is from such joint inquiries

and undertakings that we can uncover the unintended, unanticipated, and delayed impacts of technology, the effect of technology on society at large, and the demands that new technology imposes on many kinds of resources.

What, for example, are the cost consequences of the way health insurance encourages, or what is more likely, discourages the employment of technology for the delivery of preventive health care?

What are the societal consequences of the new technologies that permit severely impaired infants -- those suffering Down's syndrome, for example -- to survive into adulthood?

How do we gauge the overall benefit of dialysis knowing that the emotional demands of this technology contribute to an alarming rate of suicides among patients being maintained in end-stage renal disease?

Such determinations call for more than biomedical expertise in the conventional sense. Yet we lack

the means of making such determinations in a way that will help guide society's process of decision-making with respect to health care technology.

We are exploring a variety of proposals to establish centers which would have an ongoing role in the assessment of medical practice and technology. The National Center for Health Services Research has begun an effort to examine the state-of-the-art of this broader concept of technology assessment. Emerging technologies, such as the nuclear powered heart, artificial pancreas, male birth control pills, anti-senility drugs, computer-based diagnostic algorithims, prenatal sex selection, and gene replacement, to name a few, may create more profound societal effects. These repercussions transcend the relatively simple issues of dollar costs and medical effectiveness -- issues we have only recently begun to address.

For example, a technology assessment conducted on a computerized EKG is likely to result in a judgment that

it is a straight-forward technology which raises no significant psychological, cultural, environmental, ethical and political questions. An appropriate follow-up study might be a straight-forward cost-benefit or cost-effectiveness study. On the other hand, a technology assessment conducted on a nuclear-powered implantable heart is likely to reveal that it raises profound questions not only about technical feasibility, but about the environmental radiation effects, the psycho-social side effects, the dollar costs, the ethics of such allocations, and political-legal problems.

With respect to the transfer of technology to practice, there are several aspects or facets that demand attention: the dissemination of information to the health care professions and to third-party financing systems; appropriate allocation of the resources that are captured by high cost technology -- manpower, equipment, and so forth; and the need for credible means of withholding or stopping the use of inappropriate or harmful practices.

The dissemination of information in a timely manner to the practicing community requires a number of sources of information. The National Institutes of Health must play a continuing role in information dissemination through clinical investigation, clinical trials, and the wide publication of results of trials and demonstration projects. We are submitting, for the record, summaries of current activities of the NIH directed toward the dissemination of new knowledge.

Academic health centers also can and do play a substantial role in the transfer of knowledge through undergraduate and graduate medical education and their links with the professional societies. In recent years the professional societies, particularly the various specialty organizations, have become a bridge between the academic and practicing communities.

There is also a new potential resource for the dissemination of knowledge into the health care delivery system: the Professional Standards Review Organizations.

This program is in its infancy, but will provide a network across the country that has the potential of reaching all practicing physicians. My office, through the Office of Quality Standards and the National Professional Standards Review Council will be considering how PSROs can be used effectively as a systematic source of information on new medical techniques, obsolete techniques, and appropriate standards for currently accepted techniques.

The Public Health Service, through the FDA and NIH, already provide ad hoc advice to Medicare and Medicaid on coverage of appropriate and effective services. One of the major reasons for retaining the Office of Quality Standards in my office, after the creation of the Health Care Financing Administration (HCFA), is to develop a more formal, ongoing service to HCFA by providing current information from the scientific community on effective and ineffective medical techniques and practices.

The appropriate allocation of resources is a critical final step in the transfer of technology and its

cost-effective use. As we all know, knowledge is meaningless if the resources to provide the services do not exist. Substantial savings may be realized through eliminating the misuse of resources in support of ineffective or excessively costly technologies. Health Systems Agencies and certificate of need programs are also in their infancy, but have the potential, with the development of federal guidelines, to assure that high cost technology is appropriately distributed and regionalized without proliferating an excess of unneeded services.

As you are all aware, certain technologies and procedures require a high level of use to maintain the quality of services. Infrequent performance of open heart surgery, for example, is associated with high morbidity and mortality rates. Because of the pressure of more rational planning we intend to develop national health planning guidelines for the distribution of CAT scanners, maternity beds, and open heart units and as consensus develops, regarding current and new technologies.

Technology Use

The development of knowledge, its validation and dissemination, find ultimate application in health care delivery. We are all familiar with the recurring charges of unnecessary surgery and continued use of outmoded and inefficacious procedures. A wide variety of professional groups and government agencies are beginning to meet the challenge of insuring appropriate use of procedures and technologies.

I have barely done more than suggest the complexity of the issue before us, and I have given you only an indication of the important activities that we and others in the health enterprise are engaged in to improve the transfer and assessment of biomedical and health care technology. We believe that NIH, under Dr. Fredrickson's leadership is making sifnificant progress toward developing the means of arriving at consensus on the validity and effectiveness of new knowledge. However, it is clear

that other organizations within and outside the government must also assume responsibility so that a full range of skills is brought to ear on these vital and urgent issues.

I want to assure you that the Department of Health, Education, and Welfare is fully committed to accepting a major role in what must be a national effort to make certain that technology can and does truly contribute to improving the health of the American people.