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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

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BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

TUESDAY, APRIL 27, 1978

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to appear before you today to discuss the renewal of authorizations for the National Centers for Health Statistics (NCHS) and Health Services Research (NCHSR). I will also discuss certain proposals put forth in H.R. 11763 concerning statistics to aid in assessing the impact of environmental factors on health; studies on the costs of illness as well as proposals in H.R. 10839 and H.R.12166 regarding technology assessment and use and a proposed change in the structure of our health services research and statistics programs.

Research and statistics expenditures are an investment in the future--in our ability to make sound decisions that can improve our health care delivery system. Your support and that of your Subcommittee over the years for our health services research and statistics activities is greatly appreciated.

The work of the Centers makes invaluable contributions to policy deliberations, health legislation, Federal health programs, and the decisions of health care providers. The comprehensive program of the National Center for Health Statistics includes more than 20 data systems, which produce information on the health status of the population, health resources, utilization of health services, nutrition, family growth, and the nation's patterns of births, deaths, marriages, and divorces. A few examples will illustrate their importance.

Among the specific contributions of such information is an awareness of the health care trends that form the factual backdrop for many important decisions in the health field, in cost containment, quality, distribution of services, and control of toxic substances. For example, the Hospital Discharge Survey has shown the incidence of hysterectomies rising substantially (from 734 per 100,000 females 15 years and older in 1971, to 850 in 1974). More recently, there appears to be a downturn, perhaps due to heightened visibility of the phenomenon. The Health and Nutrition Examination Survey measures the prevalence of hypertension among adults and indicates that the prevalence rate among blacks is nearly twice as high as that among whites indicating where service programs should be concentrated. New epidemiologic techniques in mapping infant mortality and other mortality rates to

determine geographic differentials can identify variations due to lack of access to care or exposure to environmental hazards. Here again these data allow us to target prevention and service delivery programs.

The National Center for Health Statistics intends to complete three of the six components of the Cooperative Health Statistics System in all States during the next two years. For the first time we will have comparable data in all States on vital statistics, health manpower and health facilities.

The National Center for Health Services Research plays a parallel role in health services research. NCHSR-supported research and demonstration activities have often produced the factual justification for new legislation such as that providing for reimbursement of physician assistants and nurse practitioners practicing in rural clinics. Other NCHSR research has produced the health scarcity index for identifying shortage areas. The Experimental Medical Care Review Organization project, initiated in 1970, provided the working model for Professional Standards Review Organizations. The Center has become increasingly sensitive to the demand for policy-relevant research and is preparing to fund research on cost containment that is specifically tailored to the needs of local health systems agencies. It has initiated a series of National Medical Care Expenditure studies as a major component of its intramural program. Data for this study are being developed in collaboration with the

National Center for Health Statistics. The product of this study will provide crucial information for evaluating alternative financing mechanisms for health care in the United States.

More detailed information about the activities of the Centers is being submitted for the record.

I consider the research and statistics functions performed by these Centers to be extremely significant. Only if their full potential is realized will we have sound factual and conceptual bases for planning and management of the health care system, at every level--from Federal, State, and regional policy level to the individual provider of health care.

I would now like to comment on a few important components of the National Centers' programs that are addressed in some of the legislative proposals we are discussing today.

We support the proposals in H.R. 11763 to strengthen the activities of NCHS and NCHSR in the areas of environmental influences on health status and the costs of illness. However, we continue to recommend the level of funding authorization put forth in the President's budget ($43,000,000 and $31,000,000 respectively) in lieu of the authorization in the bill and oppose the personnel authorization under section 208(g) included in the bill. This new mandate would build on several activities already underway. The National Center for Health Statistics has already begun work on epidemiologic data systems including the operation of a National Death

Index. Our new computerized geographic mapping of morbidity and mortality across time allows us to detect any unusual changes or "hot spots" which should be further investigated.

Considerable groundwork for cost of illness studies is already well underway. Collaboratively the NCHS and NCHSR have recently undertaken a nationwide panel survey designed to determine more accurately the total cost of medical care in this country. This includes direct out-of-pocket expenditures by individuals and families, the contribution of employers, and the amounts expended by private third party payers, States, and the Federal government. NCHSR has funded major studies of catastrophic illness costs. We have also established a Public Health Service task force with the specific charge of reviewing cost of illness activities throughout PHS. This task force will develop proposals to improve and standardize statistical and analytic methods so that the results of different studies will be comparable.

The provisions in H.R. 11763 will give added impetus to these activities. However, we do feel it necessary to point out the difficulty inherent in estimating the component of the cost of a disease that can be attributed to any specific environmental factor or combination of them.

Attempts to estimate the cost of illness attributable to working and living conditions go back to the 17th century (Petty and Graunt, 1662) and have repeatedly been an important root both of modern bio-statistical methods and of public health, sanitary, occupational health and welfare reforms. However, modern methods for estimating the costs of illnesses only go back to the 1966 studies of Mrs. Dorothy Rice, Director of our National Center for Health Statistics. Intensive work is presently going on to improve and standardize these methods. We are much less advanced in the methods for allocating the cost of illness to the various factors involved in causation of those diseases--as will be necessary for the environmental studies being proposed under your bill. For this reason we believe it will require at least a year to develop a comprehensive and adequate method and data base to begin studying the problem of the magnitude suggested in the bill. You have set out an agenda for many years to come. We welcome the mandate but do not want to promise too much too soon. We will move as expeditiously as possible.

In order to assist the National Centers in meeting the challenge of providing leadership to health services research and statistics throughout the Department, I have recently moved them into my office, where their activities are being coordinated more effectively with the other agencies of the Public Health Service as well as with the Health Care Financing Administration. We fully recognize the need to improve coordination of those critical activities and thus concur with the goal set forth in H.R.10839 of strengthening the two National Centers and their roles in the Department. However, we do not believe the organizational structure suggested in this bill is the best way to achieve this.

For one thing, as conceived in H.R. 10839, the proposed National Institutes of Health Care Research would take over activities that are integral to other PHS operations. THe NCHS is now undertaking some epidemiologic analyses but these are designed to complement the ongoing activities of the National Institutes of Health (NIH) and the Center for Disease Control (CDC). Removal of epidemiological and statistical activities from NIH and CDC or control of them from the outside would interfere with the overall mission of these agencies.

Further, the proposed change in orientation of NCHSR from health services research to health policy research fails to recognize real differences between these disciplines. They are not the same. Both are necessary. It is our goal to provide research that is responsible not only to short-term policy considerations, but to independent and long-range research needs as well.

We have recently had a major study of NCHSR's research agenda and structure. A list of experts who served as consultants in this review is being submitted for the record. The Institute of Medicine is also conducting a broad-based study of health services research, that will not be completed for several months. These studies should help us fine tune the mission of the Center. To address the need for Department-wide coordination of health services research we have established an HEW committee to review HCFA and NCHSR research.

We have also established a PHS Committee for Coordination of Health Statistics Systems, chaired by the Director of the NCHS. This complements a Health Data Advisory Committee, which will serve as a permanent and formal body to advise the Secretary on major

The proposed new Institutes would supposedly be responsible for coordinating health services research and statistics activity in the Department, but I fear such separate independent status would lead to exactly the opposite.

Transferring the two Centers again, just as we are in the process of undertaking these efforts to strengthen their roles, would be counterproductive. One of the major reasons for moving them into OASH was to allow them to serve as coordinating agencies for the entire PHS and, where appropriate, for the entire Department. Placing them in a separate agency again, parallel to the other six agencies of PHS, would make it more difficult to enhance the role of the Centers in promoting quality and coordination of all health services research and statistical activities. For example, I have given NCHS the mandate to review all statistical activities of our agencies to ensure the quality of that work. The Office of Statistical Policy in my office reviews and approves all statistical reporting requested by

PHS agencies. This should greatly improve the health statistical activities of the Department. This important authority can obviously be exercised more easily from my office than from a separate agency parallel to, but much smaller than the other six.

Similarly, I am developing an evaluation capability at NCHSR which will be used to review and oversee the health services evaluation research activities of the PHS. In addition, beginning in FY 1979 NCHSR will itself directly undertake two or three major evaluations of PHS programs each year as a means of improving their quality and effectiveness. Again, this mandate can be exercised more effectively in the present organization setting than within a separate Institute.

It should also be added that the administrative overhead needed to support such separate Institutes incorporating only the National Centers and the proposed Center for the Evaluation of Medical Technologies (which I will discuss later) would be far out of proportion to the costs required to support the same activities within OASH--$8.1 million as opposed to $0.9 million.

Many have voiced concern that health services research and statistics programs are fragmented throughout the Department, leading to overlap and even competition between agencies. Some believe that creating the Institutes would centralize these activities and avoid duplication and poor coordination. Although we are working hard to enhance coordination, I must stress that there is little or no duplication of effort within the Department. Most of the health services research done outside of NCHSR is program research to aid agencies in planning and improving their own programs. The same can be said of most statistics gathering and analysis outside the NCHS. It is essential that this feedback be readily available for program administration and therefore it is properly conducted by the agencies themselves. As stated before, we do believe that NCHS and NCHSR should review, evaluate and coordinate these activities and we are moving rapidly in this direction. Even outside the PHS we are in the process of developing a strong collaborative research and statistics relationship between the two National Centers and HCFA. My staff is meeting frequently with HCFA to review areas of joint interest, and cooperative research strategies are being mapped out. For instance, in order to provide necessary

planning data for HCFA, the NCHSR/NCHS National Medical Care Expenditures Survey was oversampled for the Medicaid population group. This makes it possible to obtain more precise estimates of expenditures by certain groups that would otherwise represent too small a portion of the total to make accurate estimates possible.

Now, Mr. Chairman, I would like to turn to the issue of health technology. H.R. 10839 proposes a National Institutes of Health Care Research. H.R. 12166 proposes a Center for the Evaluation of Medical Technology. Both, as you know, have spurred considerable thought about a problem that had not previously received the attention it deserves. We also have been concerned about the technology problem and share the goal that the bill embodies of creating a more rational system for assessing and managing the introduction of new medical technologies.

In response to issues raised in Congressional hearings ings last summer on technology development and use, the Department conducted a comprehensive analysis of technology management activities and problems. We surveyed the technology-based activities that are now taking place in the agencies, to identify gaps and deficiencies in those activities, and identify options for coping more effectively with those deficiencies.

While many share a commitment to come to grips with "the technology problem," our analysis quickly showed this seeming consensus to belie many different conceptions and priorities:

- To some, it's a problem of cost containment, because technology is perceived as a major culprit in the spiraling costs of health care.
- To others, it's a problem of reducing the time that it takes to get effective new technologies into medical practice.
- To others, it's a problem of preventing premature transfer of technologies which are unproven and perhaps even harmful.
- To others, it's a question of harnessing the technological imperative in order to enhance, rather than endanger, our social and ethical values.
- To some the problem seems to be lack of adequate dissemination of the information produced by knowledge development agencies.
- Still others are particularly concerned about our under-investment in efficacy and safety studies, cost-benefit and cost-effectiveness analyses, or comprehensive technology assessments.

- Additional divergent objectives include the need to address:
  - Obsolescent technologies;
  - Inappropriate utilization of technology;
  - Maldistribution of technology;
  - Inadequate market incentives for promotion of preventive, system management, and mental health technologies; and
  - The need for public input into technology decisions.

All of these concerns illustrate that "the technology problem" is a grossly misleading form of shorthand. In fact, there are many technology problems. A broad range of views and goals must be taken into account if we hope to develop a better balance between controlling the costs of health care while not stifling technological innovation and improvements in the quality of care.

Our study (which I am submitting for the record) has also made us keenly aware that while the Department is extensively involved with technology as a developer, an evaluator, a purchaser, and a regulator, it has no comprehensive strategy to systematically link steps in the process of technology development, evaluation, transfer, diffusion, utilization and phase-out. Consequently,

- The "knowledge development" agencies (such as NIH, FDA, CDC, ADAMHA, NCHSR and NCHS) interact only sporadically and decide independently which technologies they will examine, how they will examine them, and what use will be made of the results;

- The "action agencies" (such as HSA, Medicare, Medicaid, and the PSRO program) lack adequate technical information to carry our their responsibilities and effective links to the knowledge development agencies which would promote development of information on technologies of interest;

- Results of technical evaluations appear in the research literature and the NIH is conducting a series of "consensus exercises," which help achieve professional consensus about the efficacy and appropriateness of medical technologies and also disseminate that information. Nevertheless adequate information often does not come to the attention of practicing physicians, consumers, or those officials responsible for making reimbursement, regulatory, or standard development decisions;

- o Considerable effort is focused on efficacy and safety evaluations, but little is directed to evaluation of cost-benefit and cost-effectiveness implications, and virtually nothing is being done to assess unintended societal side effects;
- o Inadequate emphasis is placed on methodological studies to improve the reliability and validity of technology-based analysis and testing; and finally
- o linkages between technology studies and public or private actions to impede or stimulate technology transfer and utilization occur on a completely ad hoc basis.

In summary, while DHEW agencies currently engage in many technology-based activities, it has become increasingly clear that the Department needs a more coherent management strategy for the development of new technologies, comprehensive evaluation of both new and existing technologies, and the dissemination of these findings to health practitioners and third party payers. Most components of such a strategy are currently being addressed in various agencies in the Department.

The most critical need is for development of a managerial approach to technology transfer which is precisely what we have underway. We are systematically attempting to set priorities within knowledge development agencies to rationalize technology assessment activities and, most importantly, we must forge more effective links with the health practice community and reimbursement agencies in order to encourage application of the most efficacious and cost-effective techniques.

We share the goal of Congress to rationalize the application of health research in the delivery system. However, our study, drawing on the best expertise from all Public Health Service Agencies and the Health Care Financing Administration, clearly demonstrated that the conceptual, methodological, and managerial underpinnings of a coherent technology management strategy are in their infancy. It is for that reason that legislation incorporating significant reorganization, would be inappropriate.

We believe that creation of a new Public Health Service Agency would impede, rather than advance, our technology management objectives.

The proposed Center for the Evaluation of Medical Technologies simply establishes another knowledge development agency with few new functions not already found in existing agencies. It fails to deal with the central problem of interface between knowledge development and action identified by our study. In fact, this approach is antithetical to the key need for coordination and management of existing resources. Only from the organizational perspective of the Office of the Assistant Secretary for Health can we hope to conceive and implement a plan for capitalizing on existing capacity and providing the necessary linkages within the Public Health Service and with HCFA.

Thus, H.R. 10839 addresses certain deficiencies in current assessment capabilities, but fails entirely to meet the need for the coordination that can assure application of that knowledge both within the Department and in the practicing community. Unless expansion of these activities is undertaken within a rational framework that addresses the current capacities of Departmental agencies and the gaps in communication between them, such expenditures could be wasted.

We also question whether the state of the art in technology assessment can support a significant infusion of new resources at this time.

We fear that premature hopes and promises could amplify the awareness of our inability to make technology judgments and lead to eventual disappointment, and subsequent underfunding of this critical activity. Pieces of a technology management strategy have been tried, but a comprehensive technology management system has never been implemented.

Many difficult questions remain to be answered before a full scale institutionalization of technology management can be implemented. How should priorities be set? When are expensive clinical trials required? How and when should social, economic and ethical implications be taken into account? In what way and to what extent should the practice of medicine be influenced? What kind of educational efforts are effective? What contribution can health planning make to technology management? How should we utilize reimbursement controls?

Our opposition to the Kennedy/Maguire bill, however, should not be construed as reflecting any limitation of our commitment to develop comprehensive policy in this area. To the contrary, we believe the administrative actions we have taken, through the establishment of an Office of Health Technology in the Office of the Assistant

Secretary for Health to work with PHS and other Departmental agencies, constitutes the soundest approach to aggressive policy development in this area.

Even the most carefully devised technology initiative is unlikely to solve all the extraordinarily complex set of problems involved. Nevertheless, we have developed a new technology strategy which we believe will enable us to significantly reduce the gap between analysis and action.

As you can see from the diagram attached to my testimony, our technology management strategy is comprised of six linked steps:

1. Identification and screening of candidate technologies and health needs for analysis.
2. Annual priority setting for a Departmental study agenda.
3. Conduct or sponsorship of studies.
4. "Translation" and synthesis of technical findings.
5. Explicit decisionmaking to restrain or stimulate development and use of a target technology.
6. Implementation of decisions through a spectrum of such intervention mechanisms as allocation of R&D resources, market approval, incentives, utilization guidelines, and professional and consumer education.

Since such a strategy will require considerable orchestration among the agencies and extensive collaboration with the private sector, a Department-level locus is needed to provide the necessary managerial leadership and coordination.

The Secretary has assigned that responsibility to my office, and I have already taken important steps to establish an Office of Health Technology. One of the major tasks of the new office will be to conduct technology assessments and subsequent management strategies with four to seven high-priority technologies.

These technologies will demonstrate various approaches to comprehensive technology assessments. These studies will serve to shed further light on the capacities and deficiencies within the Department and will form the basis for recommendations regarding structural change that might increase research capacity and promote effective communication and collaboration within the Department.

These demonstrations will focus on technologies which typify such current concerns as premature or delayed transfer from bench to bedside practice, unwarranted cost in relation to anticipated benefits, and the need for early warning on controversial societal side-effects.

To head the new Office of Health Technology, we will recruit an outstanding scientists with credibility in both the research and health care community.

To support this demonstration phase, we will shortly ask Congress to reprogram $5 million of Public Health Service funds in FY 1978 to support the necessary studies and evaluate innovative approaches to communication of findings to such diverse users as practicing physicians, consumers, and policymakers.

Plans for establishment of this Office are proceeding rapidly. The Functional Statement for publication in the Federal Register is presently awaiting Secretarial approval. The request for a reprogramming of funds is soon to be transmitted to Congress and an interim Director, with extensive experience in this emerging field, has been selected.

In addition to conducting selected technology assessments, the new Technology Office will:

- Serve as a catalyst and Departmental focal point for policy formulation;
- Develop a process through which the Department can collaborate on technology decisionmaking with other Federal agencies and the private sector.
- Provide technical assessment and transfer activities throughout the Department in order to identify gaps and deficiencies;
- Assess the feasibility and cost effectiveness of developing a long-range system to identify and screen technologies and health needs;
- Provide recommendations to the Health Care Financing Administration on the advisability of reimbursement under the Medicare and Medicaid programs for the selected technologies;
- Finally, the Office of Health Technology will be charged with developing recommendations regarding possible institutional changes that might contribute to achieving our technology management objectives. After more extensive

experience with actually managing the processes of technology assessment and transfer, we may indeed find that institutional restructuring is necessary. The Office of Health Technology should be the first to recognize those needs as they become apparent.

The Waxman bill (H.R. 12166) proposes a Center for Evaluation of Medical Practice to be located in the NIH and charged with many of the same functions suggested for the Center for the Evaluation of Medical Technology in the Kennedy/Maguire bill. As noted regarding H.R. 10839, we support the objectives of this bill. However, we believe the different approaches to achieving these objectives included in these bills highlight the uncertainty that surrounds institutionalization of these functions. Representative Maguire and Senator Kennedy have vested responsibility for technology studies in a new PHS agency. Congressman Waxman has chosen NIH as the site for these activities. Each proposal has advantages and disadvantages. What we propose is to evaluate these and other approaches to arrive at the best solution which will take full account of existing capacities.

Institutional change along the lines embodied in these bills may indeed be warranted as we gain more experience and perspective on the technology problem. We are forced, however, to oppose these proposals at this time because we believe that it would be premature and disruptive for the Department to undergo such a major structural change without a more fundamental understanding of the complexities involved. Be assured, however, that we plan to move quickly. We believe that the efforts of this pilot Office of Health Technology will provide essential information that will enable us to return in two years with further recommendations.

We must be aggressive in our efforts to build a technology management capability, but we must not overpromise. The stakes are too high. We believe that deliberate efforts to demonstrate various approaches to technology management are more judicious than quick legislative answers and institutional reordering. Those concerned with the expensive proliferation of new technologies and persistence of outmoded ones all seek the same goal. However, the path to that goal is not yet clear. We intend, through

working with the Congress, to shed light on that path. We believe the mandate conceived for the Office of Health Technology can meet these objectives.

That concludes my prepared testimony at this time, Mr. Chairman. My colleagues and I will be happy to respond to any questions you may have.