HEW's NEW STRATEGY FOR HEALTH TECHNOLOGY

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The title of this session is Technology and Cost Reduction, but your Chairman, Dr. Cesar Caceres has asked me to talk about health technology on a more global scale. To be more specific, he has asked me to describe HEW's recent study on technology management and the Department's new program initiative to orchestrate the way in which technology is developed, validated, utilized, and phased-out of use.

Until recently, there has been wide-spread agreement that twentieth century biomedical research and technological innovation have brought about profound improvements in human health. Today, however, various parties-at-interest to the health system are becoming increasingly critical of technological innovation. They are demanding major changes in the way in which technology is developed and used. Unfortunately, inasmuch as these different parties have made vastly different diagnoses of "the technology problem", they are also proposing divergent prescriptions for change.

Some diagnose the problem solely in terms of how to contain spiralling costs of health care. Others perceive the problem as how to harness "the technological imperative" which has produced some technologies with unintended perturbing societal side-effects. Still others are particularly concerned about either delays in development and diffusion of effective technologies, or the reverse side of that coin which is premature transfer and diffusion of ineffective, or even harmful, new technologies. And others are more concerned about the

insufficiency of efficacy and safety studies as well as cost-benefit and cost-effectiveness studies or comprehensive technology assessments.

You will note that I haven't even mentioned a host of other significant diagnoses such as:

- o Continued use of outmoded technology.
- o Or inappropriate use of technology.
- o Or proliferation of "halfway" technology.
- o Or maldistribution of technology.
- o Or insufficient Federal funding for biomedical research and technology development.
- o Or suppression of technology development.
- o Or excessive intrusion in the health market through over-regulation.
- o Or lack of health-system incentives to stimulate preventive, system management, mental health, and rehabilitation technologies.
- o Or obsolescence of the medical ethic which requires the best without regard to costs and benefits.
- o Or the lack of consumer knowledge of technology.
- o And many more.

My point in taking you through that laundry-like list is to illustrate why I contend that there is no such thing as "the health technology problem." It is a long and multifaceted set of complex problems. It has many competing and conflicting perspectives, priorities, and parties-at-interest. And your own perspective is likely to depend on your occupation, your values, and your Weltenshauung.

As a result of the expanding list of perceptions and divergent demands for changes, the Secretary of HEW recently asked the Offices of the Assistant

Secretary for Planning and Evaluation and the Assistant Secretary for Health to conduct an in-house study on Health Technology Management at HEW. Since I was Principal Investigator of the study, my remarks will draw heavily on the December 1977 Report.

The assignment to the study team was threefold:

(1) To inventory the medical technology-based activities taking place in various HEW agencies (namely drugs, devices, and medical and surgical procedures);

(2) To determine gaps and deficiencies among these activities; and

(3) To develop a Departmental strategy to cope more effectively with the life cycle of technology development and utilization.

To do that the study team developed a conceptual framework for a six component technology system from the HEW perspective. This framework may turn out to be the most important contribution of the study since it enables the agencies to perceive how their activities potentially interface with each other and with the life cycle of technology. Moverover it establishes a common vocabulary which is important because there has been no agreement about even the terms that we use when we talk about technology. Thus, some of our most heated arguments have been based on different definitions of such terms as technology development, technology assessment, and technology transfer which are as you, in this audience know, not synonymous.

The study team sent this framework and report outline to each of the Public Health Service agencies to use as a format to describe their activities. The team then compared the agencies' reports with the framework to identify gaps and deficiencies (and, I might add, to refine the framework).

The study revealed that while HEW is extensively involved with technology as a developer, an evaluator, a purchaser, an educator, and regulator, it has no strategy to systematically link its analytic and intervention activities. Nor

has it expected such a strategy of its agencies (with the exception of FDA) or provided them with the resources to construct one. Consequently:

- The "knowledge development" agencies (like NIH and NCHSR) each decide independently which technologies they will examine; how they will examine them; and how they will handle the results;
- The action agencies (such as the Health Services Administration, and Medicare) lack both the technical information to carry out their responsibilities and the link to the knowledge development agencies to negotiate for studies of their high-priority technologies;
- There is currently no system to monitor and screen either existing and developing technologies or health needs which can be used as the basis for selecting high-priority technologies for study.
- Results of technical studies reach other researchers through the professional literature, but often fail to reach such potential users as practicing physicians, consumers, insurers, planners, or even the Federal officials responsible for making reimbursement decisions or otherwise regulating technology.
- Considerable effort is focused on efficacy and safety evaluations, but little is done about the cost-benefit and cost-effectiveness implications, and virtually nothing is being done to assess unintended societal side-effects of the developing future technologies;
- The vast majority of efficacy and safety studies are focused on new and developing technologies, but rarely are studies conducted

on existing technologies to determine if they are outmoded or as effective or safe as generally believed (except when they are used as controls in testing developing technologies).

- o Insufficient attention is paid to stimulating market incentives for those absent and lagging technologies which are not covered by the normally overgenerous health care system such as preventive, rehabilitation, mental health, and environmental technologies.

- o The linkages between technology studies and public-private actions to stimulate or to restrain technology transfer and utilization are ad hoc and often fail.

- o HEW is under-investing on methodological studies to improve the state-the-art of technology-based analysis and testing and cross-cutting background studies to improve the state-of-knowledge on transfer and diffusion of medical technology (which is quite different from other technology sectors).

In summary: Medical technologies are too frequently moving from a developmental stage through a fragmented and haphazard process into the health care system where they may assume a life of their own unrelated to proven efficacy, costs, risks, benefits or equity. Similarly, the process of technology development and transfer within HEW is at least as fragmented and haphazard. Different types of technology studies are scattered throughout the Department, and there is no central clearinghouse to provide information about existing, new, and emerging health technologies. Moreover, study results are not linked systematically to actions, and no cross-cutting Departmental unit is responsible for technology policy.

This situation did not emerge overnight, and even the most carefully devised program initiative is unlikely to provide a "quick fix" to the extraordinarily complex set of problems involved. Nevertheless, after much discussion of these are other findings, Secretary Joseph Califano has decided to launch a new management initiative to reduce the critical gap between study and action. This is an important step toward a long-range solution to the more global set of problems.

Very shortly a new Office of Health Technology will be created in the immediate Office of the Assistant Secretary for Health, Dr. Julius B. Richmond. Headed by an outstanding health scientist with credibility in both the research and health care community, the new office will get started with about 20 multidisciplinary professionals detailed temporarily from different parts of the Public Health Service.

The new Office will create a mechanism and a process to demonstrate that existing and emerging technologies can be systematically evaluated and that results of those evaluations can be linked to explicit public and private interventions to encourage, discourage, or modify development and utilization. Such a strategy must meet the test of providing a reasoned balance between controlling the cost of health care and overcontrolling technological innovation at the expense of the quality of health care.

To some people this sounds like a relatively straightforward task. I know that you, in this audience, however, will appreciate the enormous complexity of building a mechanism and process which enables HEW to engage in collaborative

action with such divergent parties-at-interest as institutional providers, insurers, practitioners, technology developers and manufacturers, academic health science centers, specialty societies, public interest groups and the numerous other Federal agencies which have a major stake in health care.

Earlier I mentioned a proposed framework for a technology system to undergird the new initiative of OHT. For those of you who are sitting too far away to read the slide, I have passed out copies of the framework which is labeled Figure I. Let's walk through the six components very quickly.

The first component is labeled Monitoring and Screening of Technologies and Health Needs. It recognizes that at the front end of a technology system we need a dynamic information base to identify candidate technologies and to monitor developments. We also need a set of coarse criteria (such as cost, volume, or ripeness of a technology) to screen out candidate technologies to be studied.

The second component is labeled Development of a DHEW Analytic Agenda. This component recognizes that HEW cannot study everything that is important, but through a collaborative process (among the HEW agencies and with input from private sector parties-at-interest) we can achieve a better balance between the needs of the action agencies (such as the Health Care Financing Administration) and the knowledge development agencies (such as NIH). We also need some fine screen criteria (e.g., researchability and policy relevance) to select 15 to 20 high-priority technologies to form the core of an annual Department agenda. This agenda-setting process would also include reaching agreement on the

kinds of questions to be addressed in the studies, the type of studies to be conducted, the potential users of the results, and the agency responsible for handling each study.

The third component -- Analysis and Testing -- arrays the six classes of studies we are concerned about. Since each of these studies ask different questions, hence utilizes different tools and methodologies, and requires different skills and resources, the component illustrates the importance of reaching agreement on what questions we want to ask recognizing that questions which are of primary interest to NIH may not be high on the agenda of HCFA or of the practicing physicians.

The fourth component -- Review and Synthesis -- recognizes that all ~~to~~ too many studies end up on the shelves or in the esoteric literature for other researchers and fail to reach the potential users in the public and private sector. Thus we have included a separate component to highlight the need for synthesizing findings obtained from the high-priority technical studies and translating them into policy and program recommendations for those users identified in the agenda setting process.

The fifth component -- Decisionmaking -- reflects the need for a mechanism and process to reach explicit decisions which link study findings with consistent and coordinated actions to stimulate or discourage transfer and utilization. It is also the milestone ~~which~~ to assures that decisionmaking by appropriate HEW agencies takes place in collaboration with health system parties-at-interest ~~to assure that~~ so that these decisions are not made in a vacuum

but serve to leverage each other.

As you can see the sixth component -- Intervention Mechanisms -- arrays four classes of mechanisms to affect technology development, adoption, diffusion, utilization, and phaseout of technologies. We classified them by function: regulatory mechanisms, transfer or phase-out mechanisms, pre-market incentive or disincentive mechanisms, and market incentive mechanisms. AAMI members will be especially pleased to know that the study makes a special point about the need to develop new Federal incentives to stimulate development and use of those absent and lagging technologies which currently fall between the cracks of the health system incentive structure, e.g., preventive, system management, mental health, and rehabilitation technologies.

Now the first priority of the new Office of Health Technology will be to conduct a pilot demonstration of the strategy outlined in this framework with about five high-priority technologies. This will enable us to test the strategy and to determine how it or some refinement of it can be institutionalized at HEW.

Other functions of the new technology office will include:

- o Serving as a catalyst and Departmental focal point for policy formulation;
- o Development of a process through which the Department can collaborate on technology decisionmaking with other Federal agencies and the private sector;
- o Provision of technical assistance to HEW agencies;
- o Evaluation of technology assessment and transfer activities throughout the Department in order to

identify gaps and deficiencies;

- o Assessment of the feasibility and cost-effectiveness of developing a formal long-range system to monitor and screen technologies and health needs;
- o Provision of recommendations to the Health Care Financing Administration on the advisability of reimbursement for drugs, devices, and procedures under the Medicare and Medicaid programs;
- o Finally, the Office of Health Technology will be charged with developing recommendations regarding possible institutional changes that might contribute to achieving technology management objectives.

When the staff of the new Office is assembled, its first order of business will probably be to obtain reactions from private sector parties-at-interest and other Federal agencies on how to operationalize the plan of action I have just described. This will be done systematically through one or more conferences and individual discussions with representatives of key interest groups. In the meantime however, the main reason I accepted this invitation to join you this morning is that I saw it as an opportunity to get some early feedback on your reactions to the overall strategy and particularly on how we at HEW can help you, and what you can do to help us.

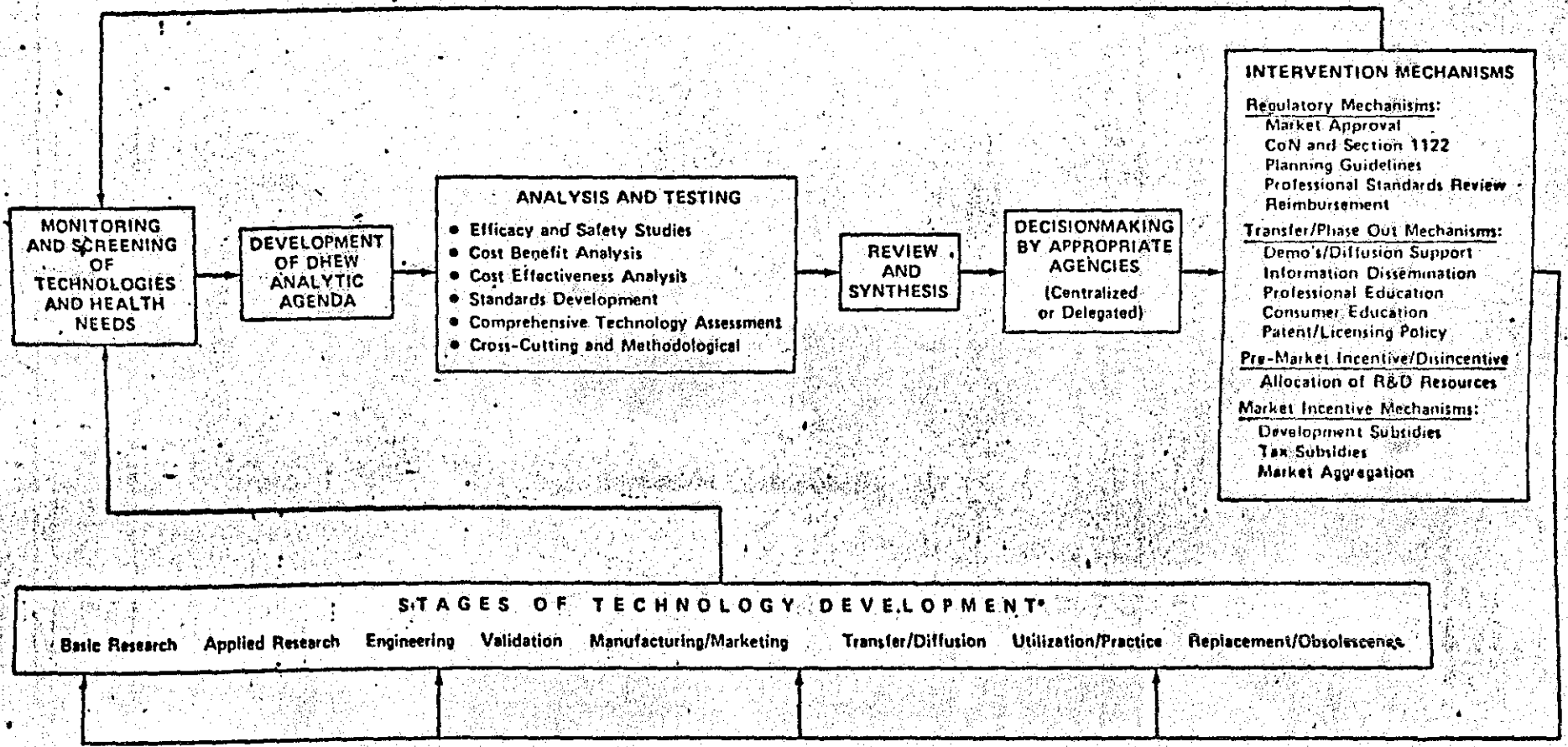
I know that many of you have long recognized that while HEW has many

technology-based activities, they have lacked cohesion, and they have had no locus. The bottom line of our study of technology activities at HEW is essentially the same as Gertrude Stein's description of the sprawling city of ~~Los Angeles~~ Oakland. She said, you will recall: "When you get there, there is no there, there.". I hope you will be as pleased as I am ~~to report~~ that the Department has now recognized the need for ~~putting a~~ establishing there, there at the top to articulate a technology policy and to carry out a technology strategy.

To do it we will need your collaboration and help. I look forward to starting that process today during the discussion period. Thank you.

Figure 1:

Conceptual Framework for Health Technology Management at the Department of Health, Education, and Welfare



*Because Technology Development is not a linear process, a technology does not necessarily pass through each of the indicated stages or pass through them in the indicated order.