I have given subject report considerable thought to determine why it has ~~is considered so~~ disturbed ~~any~~ so many Department elements ~~by both me and others in the Department~~ they [illegible] so [illegible] time. I have concluded as follows:

1. The subjects of technology transfer and commercialization are of considerable importance to the Department and ~~should be~~ their study should be undertaken ~~at considerable~~ in great depth.

2. The subjects are separable in that ~~they~~ the judgment on "how" to best promote transfer or utilization occur at different times in the development of a specific technology. ~~As the report seems to justify otherwise I deem it most~~ ~~I view this as its most serious~~ ~~important finding because:~~

a) The method of promoting transfer involves the creation of incentives in the innovating organization prior to the time that any assessment for the purpose of utilization can be made.

b) It is in error to equate transfer and,

For example decisions on [illegible] / or who should be delayed [illegible] ability to assess [illegible] on success [illegible] impact

it the seriously flawed at this time. I am this regard:

Mr. David I. Cooper, Jr.
Study Director
Office of the Assistant Secretary for
Planning and Evaluation

November 22, 1977

Patent Counsel
OS/GCB

Study on the Management of Health Technology

I have reviewed your study on the management of health technology. The major result appears to be a recommendation to establish a Department level management capability to enhance or impede the flow of technology. The report contains so many statements of opinion and inaccurate statements of fact that the recommendation of the report cannot be considered supportable.

Numerous reports on technology transfer in management have been generated in the last ten years, some of which make recommendations similar to subject study. Probably the most well known of the latter type was the proposed "New Technological Opportunities Program" (the so-called Magruder Report). It seems to me that review of this report and the criticisms that led to the abandonment of its recommendations should be reviewed prior to implementation of the recommendations of subject study.

I understand that the erroneous statements regarding Department patent policy will probably be touched upon by other commentators, making it unnecessary for me to comment further, other than attaching two pieces of testimony on Department patent policy made before subcommittees of the House Committee on Science and Technology.

Although I do not wish to devote my energies to numerous statements that I take issue with, I believe it necessary to comment on the drafters' indication that experts estimate that the number of existing and emerging technologies ranges from 8,000 to 150,000 (no citation on the source of this estimate was provided). Medical technologies are defined in the glossary as "the drugs, devices, medical and surgical procedures used in medical care." Whether the correct figure falls on the low or high side of the cited range, it seems highly improbable and optimistic to believe that any single group would be in a position to manage such numbers while taking into consideration all the factors identified in the study. It is the experience of the Patent Branch that what the report defines as medical technologies falls within the definition of a reportable invention, which reports in the past have been counted only in hundreds on an annual basis and have been managed well in cooperation with and the guidance of the operating

agencies and the Office of the Assistant Secretary for Health. No convincing evidence has been provided why this successful arrangement needs to be changed. It certainly could be improved, but that does not appear to be the thrust of your report.

Norman J. Latker

Enclosures

cc: Dr. Seymour Perry, OD/NIH
Dr. Lowell Hammison, ASH/HEW
Mr. Bernard Feiner, OGC/HEW
Mr. James Hinchman, OGC/HEW

HEW/OS/GCB NJLatker/ack 11-22-77

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : BID Representatives for Medical Applications of Research (OMAR)

DATE: November 14, 1977

FROM : Special Assistant to the Director, NIH

SUBJECT : Draft of the Technology Management Report from Assistant Secretary for Planning and Evaluation, dated November 8, 1977

Attached is a draft of the DHEW proposal for "The Management of Health Technology." Potentially, it has very serious implications for the NIH. It arrived last Friday p.m. The deadline for comments to the Department is very firm so I will need your reaction as soon as possible, but no later than c.o.b., Friday, November 18. You may make them directly in the text, but if you develop a memo, please limit it to one or two pages.

I also want to emphasize that in spite of the list of participants, no individual from the NIH played a role in writing the document.

Seymour Perry, M.D.

Attachment

12-1-77

Cys sent

Joe Keyes

Hutchinson

Harmison

NOTE.--DO NOT USE THIS ROUTE SLIP TO SHOW FORMAL CLEARANCES OR APPROVALS | DATE

TO: Ms Latka

AGENCY BLDG. ROOM

☐ APPROVAL ☐ REVIEW ☐ PER CONVERSATION

☐ SIGNATURE ☐ NOTE AND SEE ME ☐ AS REQUESTED

☐ COMMENT ☐ NOTE AND RETURN ☐ NECESSARY ACTION

☐ FOR YOUR INFORMATION

☐ PREPARE REPLY FOR SIGNATURE OF

REMARKS.

PATENT BRANCH, OGC
DHEW

NOV 30 1977

(Fold here for return)

To

From Thomas Perry

PHONE | BUILDING | ROOM

FORM HEW-30 Rev. 11/56 ROUTE SLIP GPO : 1973 O - 546-153

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : The Assistant Secretary for Planning and Evaluation

DATE: November 21, 1977

FROM : Director, NIH

SUBJECT : Comments on ASPE Draft Report, "Health Technology Management at the Department of Health, Education, and Welfare," dated November 7, 1977

This Report is the product of a one-month study by staff at the Department level. It is billed as part one of a two-phase study of how to achieve "health technology management" at HEW. The problems identified in the Report are real and getting more serious, as the Department embarks upon health care standards-setting and other attempts at cost containment.

These needs will be particularly felt by the HCFA and the burden will fall mainly on the agencies of H. The one plus of the report in question is the suggestion of a Department-level focus which will blend, coordinate, and arbitrate the numerous contributions of different agencies, particularly those of H, required to help reach useful solutions to questions of health-care regulation. We will work under an appropriate organizational arrangement, cooperatively and constructively, provided that it is designed to have some chance of success in accomplishing an extraordinarily difficult set of tasks.

A great deal more sensitivity and skill in setting up such an organization will be required than one glimpses in this "phase one" plan. The suggestion seems to be that a single Department focus will determine an annual list of interventions that seem ripe for determination of their usefulness. A small team of experts, who have acquired, or perhaps been born with, some special qualities or capacities for "CBA" and "CEA", will guard a central ark of technology assessment. The Agencies will be assigned tasks or supporting roles to sustain the busy rituals within

[illegible] Team perceived to be
[illegible]cises seems

During this period, the Institutes all have become converted to acceptance of a major role in technology transfer, and the Office of the Director has moved to create an Office for Medical Applications of Research (OMAR) to set a common style for seeking "technical consensus" on a continuing series of subjects which relate to both emerging and existing technologies. Special attention has been given to assure that NIH and its expert community not attempt to add all the value judgments inherent in the decisions required on interventions, nor to attempt to set regulatory standards. Instead the NIH intent would be to collaborate with its sister agencies in all shared areas of concern so that each could make contributions appropriate to its responsibilities.

It is inevitable that the Department will have to depend upon NIH for much of the technical work envisioned in this paper. Its expert resources, budget and activities cannot be duplicated to find answers to scientific questions inherent in judging or modifying technology. When the academic medical centers are the focus of "transfer" of such technology, it is again NIH which has the close ties with this community. With specific mandates which increase yearly, the Congress is busily altering the boundaries of NIH activities in creation of subspeciality centers with responsibilities for transfer of knowledge, including new technologies, to both academia and the profession in general. Also, over one hundred million dollars in clinical trials are included in our annual inventory.

For NIH, the question posed is no longer "whether" we shall engage in the activities that are the subject of this report. The question is "how?"

For example, how far can we go in transfer activities relating to existing technologies? How can we arrange to amortize the costs of these--particularly through separate authorizations that protect "conventional explorations," on the one hand, and transfer, demonstration, and dissemination on the other, and how to tie the latter needs to the current cost of health? How can component agencies within the PHS--particularly those engaged in service or regulatory activities--be assured the resources so that we can begin to share certain responsibilities within our growing medical centers and otherwise have the complementarity so long needed within the Public Health Service?

Finally, a parochial question: Can further delay be avoided in strengthening NIH capacity for "technical consensus"--an element that is so essential a part of modern health research? We need to open up the proposed OMAR office at NIH. The Institutes are now seeking to

---

hundred million dollars ...

recruit personnel essential to these activities; we cannot proceed until the central office is in place.

Technical consensus exercises must proceed at NIH, both as an essential part of what the DHEW is seeking to organize, and independent of it, as a means of determining research priorities in a complex world.

We request that the OMAR proposal proceed directly to the Secretary without further delay related to the study subject of this memorandum.

In summary, with respect to the problems identified in the Report, NIH stands ready to work toward these common objectives of the Department.

D S Fredrickson

Donald S. Fredrickson, M.D.

ROUTING AND TRANSMITTAL SLIP	Date 1-5-78	
TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. BID Representatives to NIAR		
2. OD Staff		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate	XX	For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Attached is a memorandum from Dr. Richmond and a decision memorandum for the Secretary dealing with the latest version of the Technology Management proposal you received last week.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Seymour Perry, M.D. Special Assistant to the Director, NIH	216/1
	Phone No. 496-1143

☆ U.S. G.P.O. 1977-241-530/3090
OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

TO : See Addressees Below

DATE: JAN 3 1978

FROM : Assistant Secretary for Health

SUBJECT: Technology Management Report

Attached is a copy of the final report on Health Technology Management at DHEW. Both the report and the decision memo have been revised particularly in response to the comments that the Report was not sufficiently clear on the following points:

(1) that the proposed Technology Management Unit would collaborate extensively with DHEW agencies and private sector parties at interest;

(2) that the proposed unit will not be conducting the kinds of technical studies now handled by the agencies;

(3) that the front end of the proposed technology system should include monitoring and screening of both technologies and health needs; and

(4) that the Department has neither provided the mandate nor the resources for the agencies to engage in such systematic analysis and decisionmaking on health technologies.

RECEIVED JAN 5 2 10 PM '78

As you can see on page 4 of the decision memo, H's position is that the proposed technology unit should be assigned to OASH and that the unit should undertake--following an OS-approved implementation plan--a demonstration of the technology system, selecting five to eight high-priority technologies, subjecting them to the process, and developing a redefinition of the unit's role on the basis of the lessons learned from the demonstration. This position was developed largely in response to your reactions to the November 7 draft report.

ES/NIH Distr. 1/4/78: Dr. Perry - necessary action
Info: Fredrickson (without attachment)

See Addressees Below

If you have any further comments on the Report or the H position, please let me or Ruth Hanft know before c.o.b. January 5 because the decision meeting with the Secretary has been tentatively scheduled for January 6.

s/ Julius B. Richmond

Julius B. Richmond, M.D.

Enclosures

Addressees:
Administrator, ADAMHA
Director, CDC
Commissioner, FDA
Administrator, HRA
Administrator, HSA
✓ Director, NIH
Director, NCHS
Director, NCHSR

OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

December 29, 1977

NOTE TO: Robert Derzon
Charlie Miller
Peter Libassi
Julius Richmond
Dick Warden

Attached is a draft of a memorandum from the Assistant Secretary for Planning and Evaluation which represents a revision of his management technology paper. A meeting with the Secretary will be scheduled to allow him to review finally the options set forth in the paper as soon as possible at the end of the first week in January. Although the final version of the attached memo may differ slightly, the current draft will allow you to begin preparing comments to go to the Secretary prior to his decision meeting.

Could you please plan to submit your comments on this paper by COB Thursday, January 5. If the meeting is not scheduled for next Friday, the date for submitting comments will be extended.

RC
Rick Cotton
Deputy Executive Secretary

Attachment

P-4770

TRACER#14417

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : The Secretary
Through: US_____
ES_____

DATE: NOT VET Signed

FROM : Assistant Secretary for Planning and Evaluation

SUBJECT: Departmental Management of Medical Technology — INFORMATION

BACKGROUND

You asked P to develop a strategy for management of medical technology. Senator Kennedy addressed a similar request to Dr. Richmond. In response to these two requests, P and H formed a joint Study Team that has

— prepared the outlines of a Departmental management system for dealing with medical technologies,

— compared existing practice in HEW with that design to identify possible changes in the way we do business, and

— prepared recommendations for action by you.

PROBLEM

"Medical technologies" — drugs, devices, and medical and surgical procedures — have improved the quality of health care. But we are becoming increasingly aware of serious inadequacies in the ways emerging and existing technologies are applied:

— some technologies move too slowly from laboratory to bedside practice while others enter practice before we adequately understand their implications for safety, costs, and efficacy;

— some technologies remain in use even after they are outmoded or proven ineffective or even hazardous; and

— some effective technologies are inappropriately used.

The impact of our programs on the development, diffusion, and use of medical technologies is pervasive. Nevertheless, the Department is poorly organized at present to evaluate technologies systematically, to synthesize information about them, and to take coordinated action to impede or stimulate their development and use:

— "action agencies" do not get the information they need from "knowledge development" agencies;

— some types of needed studies are not being conducted because no agen has been assigned the mandate or chosen to devote resources to them;

— some studies we do conduct look at low priority technologies;

— because of fragmentation and gaps between agencies and programs, technical findings are often not incorporated into reimbursement, standards, regulation, and other types of policy decisions;

The Department cannot ignore these glaring deficiencies, and the activities of other Federal and non-Federal entities will not overcome them for us.

There are considerable pressures promoting greater Federal involvement in t management of the technology stream:

— technologies add significantly to the national health costs through both high-cost new hardware (e.g. CT scanners) and high-volume medic and surgical procedures (e.g. coronary bypass operations);

— technologies are increasingly making their impact felt beyond the health care field (e.g. ethics of genetic engineering);

— consumers are unable to assess the value of technologies, and the financial incentives promote their use even when they are of dubious value, suggesting significant consumer protection considerations;

— considerable Congressional pressure is being exerted (particularly by Senator Kennedy and Congressman Moss) to promote closer DHEW scrutiny of technologies;

On the other hand, some will raise strong objections:

— the medical profession may argue that increased Federal management of technology would curb independent medical judgment and step betwee the practitioner and his patient (an intrusion now restricted to drugs and devices);

— scientists may argue that such management would restrict scientific inquiry, and stifle or delay innovation;

— manufacturers may argue that Federal management would interfere with free enterprise.

From our experience with drugs, we know that expanding technology manage-ment will place difficult and sensitive decision-making authorities in the hands of government. Government officials will have to weigh uncertain evidence of scientific inquiry against their estimates of the value of quality of life and costs.

After weighing these considerations, the Study Team has concluded that without more systematic monitoring, evaluation and decisionmaking about medical technologies, they will continue to find their way into use or remain in use on the basis of the intellectual curiosity of researchers, the marketing strategies of manufacturers, and the slowly evolving consensus of health care providers.

THE ATTACHED REPORT

The Study Team has defined a six-component framework for systematically examining technologies; has measured current Departmental activities against that framework; has identified deficiencies; and has recommended adoption of a process and structure that

— would enable us to manage at the Departmental level — in collaboration with our agencies, other Federal agencies, and outside parties at interest — an integrated process for annually selecting, examining and taking explicit action on a limited number of highpriority technologies; and

— would form the basis for incremental improvement of agency and inter-agency processes, authorities, and responsibilities as they address other technologies.

The six-component framework is depicted in the schematic at Tab A, and each component is described briefly at Tab B. The Report recommends that you approve in principle adoption of this system.

The Report also recommends establishment of a new Department-level unit to manage high-priority process, interact with the agencies to improve their technology management practices, promote technology management collaboration with other Federal and non-Federal entities, and be the catalyst for the development of Departmental technology management policy.

A six month Phase II study is proposed to identify the explicit changes in agency authorities, responsibilities and resources necessary to fully implement the system to plan how to incorporate into the system the non-medical technologies not included in this study (e.g., mental health, environmental health, health systems management and to plan how to systematically integrate our efforts with the interests of other Federal and non-Federal parties.

CONGRESSIONAL INTEREST

On December 9, OS staff met with Senator Kennedy's staff for the second time on this subject. They continue to express a strong interest in seeing the Department take vigorous technology management action, and refer in very general terms to the legislative opportunities presented by the expiration next year of key health legislation (e.g., NIH, health planning, the National Center for Health Services research). However they express no specific ideas beyond providing new money to support the initiatives and the Report concludes that legislative initiatives are not necessary at this time.

DEPARTMENTAL REACTION TO THE REPORT

The Report recommends that you endorse in principle (a) adoption by the Department

of the system outlined in Tabs A and B; and (b) establishment at the Department level of a technology management unit. There is considerable support for this proposal, but some of the agencies — particularly in PHS — believe that it is premature.

Decision: yes, endorse in principle the system outlined and establishment of the technology management unit _____

no, do not endorse them in principle _____

other _____

Four major areas of disagreement have surfaced in Departmental reaction to the repor

(1) Next Steps in the Process

P's recommendation (as reflected in the Report) — with which HCFA concurs — is that you should appoint a Special Project Manager (a) to provide you with a decision memo within 45 days recommending where the technology management unit should be located (e.g. as part of your immediate office; as part of one of the OASH offices) and what its authorities, responsibilities and resources should be; and (b) to simultaneously begin the Phase II described on the preceeding page.

H and M&B believe (a) that the technology unit should be assigned to OASH at once; and (b) that the unit should immediately undertake — pursuant to an OS-approved implementation plan — a "demonstration cycle" (18-24 months H indicates) of the technology process, selecting 5-8 high-priority technologies, subjecting them to the process, and developing organizational change recommendations at the end of that cycle.

Decision: as the Report, P and HCFA recommend _____

as H and M&B recommend _____

other _____

(2) The Role of the Technology Management Unit

P's recommendation (as reflected in the Report) is that the unit's mission should be defined from the outset, because delay could cause confusion and resistance, a continuation of our lack of relationships with extra-Departmental activities, continued fragmentation and gaps in our processes, and could signal a lack of commitment to making badly needed improvements.

H argues that the unit's mission should be initially defined as limited to the conduct of the 18-24 month "demonstration cycle", and then redefined on the basis

of lessons learned from the demonstration.

Decision: as the Report and P recommend_____

as H recommends_____

other_____

(3) Decisionmaking Based on Technology Evaluation Findings

The Report proposes in the "Decisionmaking" component that once a high-priority technology has been technically evaluated and the results combined with expert judgments about the conclusion(s) that should be reached, a decision memo would be prepared for the Secretary. The memo would recommend formal and visible adoption o the conclusion(s) and would specify what action steps should be initiated (such ste having been developed in collaboration with the "action agencies"). The Secretary (or his designate) would then charge the "action" agencies with responsibility for carrying out those steps (e.g. changing standards, preparing a legislative initiati designing a provider education project, terminating reimbursement, etc.).

P and H support this process.

HCFA believes that decisions on what steps to take on the basis of the findings shou be left up to the head of the "action" agencies.

Decision: as the Report, P and H recommend_____

as HCFA recommends_____

other_____

(4) Action on the NIH and NCHSR Technology-related Proposals

NIH has prepared a proposal to establish an Office of Medical Applications of Research and to fund a number of "consensus building" conferences similar to the one held in October on breast cancer screening.

NCHSR has proposed establishment of a Technology Studies Group to examine comprehensively the potential impacts of developing technologies on the health system and othe societal systems and institutions including the law, the family, and mores and ethics

The P recommendation (as reflected in the Report) is that, because these two proposal are so related to each other and to the overall technology initiative, they should be examined as part of the overall Phase II study. However, if the pace of Departmental change will be slow to occur, more prompt consideration would be appropriate.

HCFA believes that decisions

H believes that both proposals should be the subject of an immediate Decision Memorandum to you.

Decision: as the Report and P recommend _____

as H recommends _____

other _____

Henry Aaron

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : The Secretary
Through: US_____
ES_____

DATE: NOV 8 1977

FROM :Assistant Secretary for
Planning and Evaluation

SUBJECT: The Management of Health Technology — SUMMARY AND DECISION

BACKGROUND

You asked P to develop a strategy for management of medical technology. Senator Kennedy addressed a similar request to Dr. Richmond. In response to these two requests, P and H formed a joint Study Team that has

— prepared the outlines of a Departmental management system for dealing with health technologies,

— compared existing practice in HEW with that design to identify possible changes in the way we do business, and

— prepared recommendations for action by you.

PROBLEM

"Medical technolcgies" -- drugs, devices, and medical and surgical procedures — have improved the quality of health care. They have also contributed to the staggering increase in its cost. We are becoming increasingly aware of serious inadequacies in the ways emerging and existing technologies are applied:

— some technologies move too slowly from laboratory to bedside practice while others enter practice before we understand their implications for safety, costs, and efficiency;

— some technologies remain in use even after they are outmoded or proven ineffective or even hazardous; and

— some effective technologies are overused or misused.

At present, the Department is poorly organized to evaluate technologies systematically, to make qualitative decisions about them, and to take coordinated action to impede or stimulate their development and use. "Action agencies" do not get the information they need from "knowledge development" agencies. Some types of needed studies are not being conducted.

Some studies we do conduct look at low priority technologies. No other Federal or non-Federal entity is systematically examining the high-priority health technologies and linking results to a coordinated set of actions.

Moreover, there are considerable pressures promoting greater Federal involvement in the management of the technology stream:

- technologies add significantly to the national costs of delivering health care through both high-cost new hardware (e.g. CT scanners) and high-volume medical and surgical procedures (e.g. coronary bypass operations and tonsillectomies);

- technologies are increasingly making their impact felt beyond the health care field (e.g. invasion of privacy, change in the sex ratio of the population, ethics of genetic engineering);

- consumers are unable to assess the value of technologies, and the financial incentives promote their use even when they are of dubious value, suggesting significant consumer protection considerations;

- considerable Congressional pressure is being exerted (particularly by Senator Kennedy and Congressman Moss) to promote closer DHEW scrutiny of technologies;

On the other hand, countervailing considerations are being raised and will be raised to argue against increased DHEW involvement:

- the medical profession may argue that increased Federal management of technology will intrude into professional practice, curbing independent medical judgment, forcing rigidities, and stepping between the practitioner and his patient (an intrusion now restricted to drugs and devices);

- scientists may argue that such management would restrict scientific inquiry, and stifle innovation or subject it to inappropriate delays;

- manufacturers may argue that Federal management interferes with free enterprise.

From our experience with drugs, we know that expanding technology management will place difficult and sensitive decision-making authorities in the hands of government. Government officials will have to weigh uncertain evidence of scientific inquiry against their estimates of the value of quality of life and costs.

After weighing these considerations, the Study Team recommended, and I endorse their recommendations,

(1) that increased monitoring, evaluation, and decisionmaking about technologies is appropriate and needed. Without them, technologies will continue to find their way into use or remain in use on the basis of the intellectual curiosity of researchers, the marketing strategies of manufacturers, and the slowly evolving consensus of providers.

(2) that this Department take the lead in such an effort. The scope of our knowledge development activities is extensive, and the impact of our other programs on the application of new and existing technologies will continue to be pervasive. Other Federal and non-Federal entities with which we will want to integrate our activities will not perform needed activities for us. The Department can ill-afford to continue to ignore the glaring deficiencies in our own fragmented processes and structures.

SUMMARY OF THE ATTACHED REPORT

The Study Team identifies six discrete components of an effective system by which HEW can help curb abuses of existing technologies and bring new technologies "on line" at the right time and in the right ways. These generic components (described below)

— would enable us to manage at the Departmental level activities related to "high priority" technologies, and

— would form the basis for incremental reform of agency and interagency processes, authorities, and responsibilities as they address other technologies.

The report also identifies the need for a new Department-level unit to manage the proposed technology system.

The six generic components and a summary of current activities follow.

MONITORING AND SCREENING - There is a need for a comprehensive cataloguing and monitoring of existing and emerging technologies. In addition, we need criteria for "rough screening" to identify technologies that merit high-priority scrutiny. Agencies do not now systematically or formally catalogue technologies or review them for study priority.

AGENDA-SETTING - Certain technologies are of such high priority for analysis that they deserve special Departmental attention; other technologies can be addressed through Agency processes. Some Departmental entity must identify the high-priority technologies. The Study Team suggests that the Secretary approve an Annual Technology Analysis Agenda and assign to the agencies responsibility for conducting certain kinds of analyses on specific technologies. Such studies would form the core of Agencies' analytic agendas around which Agencies would plan which other technologies to examine. At present, Agencies may not be choosing nationally important technologies for examination; research agendas of knowledge development Agencies may not address technologies about which action agencies need information (e.g., HCFA for Medicare reimbursement or PSRO standards; BHPRD for health planning guidelines); Agencies conduct efficacy and safety studies but too seldom

should be good to know!

The report also identifies

conduct other kinds of badly-needed studies (see next section), and they focus on emerging technologies, virtually ignoring existing ones.

ANALYSIS AND TESTING - The Study Team urges that Agencies design, conduct and report findings from technical studies of:

— efficacy and safety

— cost/benefit or cost/effectiveness

— standards development

— comprehensive technology assessment

— methodology and background

Time constraints did not permit the Study Team to make independent judgments about the quality of current Agency studies or staffs. It did, however, conclude that while there is a strong base for efficacy and safety studies, Agencies lack the skills, resources and mandate for cost/benefit, cost/effectiveness, comprehensive technology assessment, or methodological state-of-the-art improvement studies; that knowledge development Agencies fail to incorporate action Agency data and information needs into study designs; and that little work is being done on deriving from health problems implications regarding absent or lagging technologies.

REVIEW AND SYNTHESIS - Results of technical studies and expert opinion should be reviewed and summarized to make them easier to use. At present, there is little effort to translate technical information into forms suitable for Departmental decisionmaking and for dissemination to such private sector interests as providers, insurers, medical specialty groups, academic health science centers, manufacturers, etc. At present, analytical results often fail to move outside the knowledge development Agencies, or simply become the subjects of scientific monographs, articles, or conferences. Yet, because of an absence of attention at a level high enough to bridge Agency lines, results fail to trigger single or multiple changes in standards, reimbursement, R & D support, or other policy areas.

DECISIONMAKING - Once the Secretary or his designee has reached a decision regarding a technology on the Department's priority list, he would select which intervention mechanism(s) to employ, and would charge the relevant action agencies to alter regulations, draft legislation or standards, design a targeted practitioner education initiative, etc. Implementation would be coordinated by the Department-level management unit, would be related to budget and legislative decisions, and would be integrated, where feasible, with actions of other Federal agencies or non-Federal organizations. For technologies that are not on the Department's high-priority list, the Department-level unit would oversee the agency-based decisionmaking process

to assure coordinated, consistent and action-linked decisionmaking. At present, decisionmaking is often informal and internal to a knowledge development agency, poorly linked to action agencies, rarely tied to more than a single avenue of intervention, and poorly communicated to interested extra-Departmental parties.

INTERVENTION MECHANISMS - The Department promotes, controls, or inhibits the development and use of technologies through one or more of four classes of mechanisms:

- regulation (FDA approval/disapproval, Certificate of Need, Section 1122, health planning and PSRO standards, and reimbursement);
- transfer or phase-out (demonstrations, information dissemination, professional education, consumer education, patent and licensing policy);
- premarket incentives or controls (allocation of R & D resources);
- market incentives (development subsidies, tax subsidies, and special market privileges).

At present, none of these intervention mechanisms addresses technologies in a systematic way:

- reimbursement decisions are made in an ad hoc manner based on fragmented data;
- professional education does not communicate consensus to practicing providers;
- consumer education is very limited;
- R&D is neither seen nor used as an intervention mechanism;
- there is little focus on market mechanisms to stimulate absent or lagging technologies; and
- there is no policy relating patent or licensing actions to impeding or stimulating Department-funded R&D innovations.

RECOMMENDED STEPS

STEP 1: that you endorse in principle the development of a Departmental technology system along the lines of the six components outlined and the establishment, at the Departmental level, of a unit with the responsibility for managing such a system.

approved_____ disapproved_____ date_____