A clammy hand on health care?

An item in *The Washington Star* of July 28 noted that Senate sponsors of a health bill, including Sen. Kennedy, managed to squeak through with a close victory. The bill contains an amendment that would extend government review of expenditures for new medical equipment costing more than $150,000 for private physicians' offices and outpatient clinics.

This bill, obviously conceived to control the purchase of Cat scanners by radiologists in private or hospital-based practice, may conceivably and rather easily be applied to any future innovations in diagnostic and therapeutic equipment, thus giving legislators or, for that matter, the federal government, the power to determine the very progress of medicine in this country.

Considering our rampant inflation and the deflation of the dollar, the arbitrarily fixed amount of $150,000 for sophisticated equipment is no longer a large amount of money and will be less so in the future, particularly if such equipment is purchased from foreign countries, as is the case rather frequently. I wonder what our good senators would think of voting on a bill that would subject to government review any other private enterprises, such as banks when purchasing expensive computers, car dealers when installing sophisticated equipment, road construction companies when buying heavy machinery, slaughterhouses when installing new refrigeration machinery, or steel companies when adding new melting ovens if these items exceed the sum of $150,000.

The health bill just passed by our senators during a hot day in the summer of 1978 impresses me as a misdirected attempt to control health-care expenditures. It is not only discriminatory but superfluous since the government has already established Health Systems Agencies throughout the United States which, by public law, are impowered to control and regulate expenditures in excess of $150,000 by private or public health-care facilities. Quite incidentally, the budget for the Northern Virginia Health Systems Agency exceeds $380,000 per annum, paid by the citizens of Northern Virginia through county, state and U.S. taxes. The total expenditures for all Health System Agencies and their effectiveness in saving health dollars, curiously, has never been made public.

The bill that established the Health System Agencies was passed in the form of an amendment attached to legislation not germaine to matters of health care. Rumor has it that quite a few legislators were unaware of the contents of the amendment when the bill was passed in 1974. I would find it most enlightening if *The Star* would soon report to its readers how many senators, aside from Sen. Kennedy, were actually present when this newest bill came to a vote; and how many of our tax dollars will be appropriated annually for its implementation.

Hans J. Klapproth, M.D.,
Past President,
Washington Metropolitan Medical Council
Annandale, Va.

Annandale, Va.

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Assessing medical technology

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be inferred from changes in the management of patients with heart attacks suggested by careful studies of recent years. Thirty years ago, six weeks was widely regarded as the appropriate length of hospital stay for convalescence from uncomplicated myocardial infarction.

Investigations since have shown four weeks, then three, then two and, recently, one week to be as good as longer periods. (Indeed, some English physicians have done experiments suggesting that patients with uncomplicated myocardial infarction

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can be cared for at home with no greater mortality than in the hospital.)

Since more than 400,000 Americans suffer this condition each year, general acceptance of briefer hospitalization would lead to significant savings without loss in quality of care. Diagnostic as well as therapeutic practices, surgical as well as medical procedures, should be subjected to evaluation before widespread adoption.

Economic savings are not the sole, or even the most important benefit of technology assessment. The history of medical practice includes many examples of dangerous procedures that were widely employed, only to be discarded when they were shown to be seriously flawed. Others were applied more broadly than evaluation ultimately indcated was appropriate.

Even now, radical mastectomy remains the most widely practiced operation for breast cancer: But there is no persuasive evidence that it is more effective than less mutilating procedures. Tonsillectomy is less frequently carried out now than previously, but many experts question the justification for a large fraction of the more than 700,000 operations still performed annually.

Over 80,000 Americans will undergo coronary artery bypass surgery this year at a cost exceeding $1 billion. The operation is clearly beneficial to some patients. But it is also being carried out on many others for whom there is considerable risk and little or no reason to expect benefit.

Some studies show that doctors' families have more surgery than do comparable groups in their communities. This is just one bit of a large body of evidence that most excessive or inappropriate procedures cannot be ascribed to venal physicians. Rather, the present situation reflects in large part our urgent need for better methods of medical technology assessment, including improvements in medical data collection.

In addition, we must find more effective ways of translating the results of well-performed analyses into changes in medical practice. These tasks require creative contributions not only from physicians, but also of a variety of other professional groups, often including statisticians, sociologists and economists, as well as from an enlightened public.

Up to now this area of inquiry has received little federal support. While the National Institutes of Health has supported an increasing number of clinical trials, the resources committed to the effort have not reflected the magnitude of the tasks.

A great increase is essential, but not at the expense of important bio-medical research. Legislation now pending before Congress is designed to provide $15 million next year for technology assessment, $25 million the second year and $35 million the third. The returns on such an investment would surely be great not only in dollars, but also in lives saved and suffering reduced.

As a society, we could confront more easily the ethcal problems that will always be implicit in refusing patients needed life-preserving technology on the basis of resource constrants if we were confident that medical resources were not being wasted elsewhere in the system.

For those who ask whether we can afford such research, the question is, rather, can we can afford the present neglect?

...as quite simply and exclusively Dr. Bourne.

Wash. Post 7/21/78

Hospital Costs: Out of Sight

AFTER LONG and hard thought about holding down hospital costs, Congress has arrived at a decision: It would rather not. The House Commerce Committee has voted against any sort of enforced limits on the rate at which hospital costs climb. That means no legislation this year. The committee's majority has given in to the hospitals, which argue that no legislation is needed in view of their splendid progress in holding down costs voluntarily. After all, the hospitals point out, their costs were rising at a rate of 16 percent a year in early 1977, when the Carter administration first proposed controls. Currently the rate is down to a mere 13 percent.

But 13 percent is intolerably high, and everybody including the Commerce Committee knows it. The sad fate of this bill is another illustration of this country's uncertain and hesitant attitudes toward controlling inflation. Everybody is against inflation in general. But each specific remedy is open to attack on grounds that it is unfair to someone, or it is too complicated or too harsh.

The Carter administration originally wanted to impose cost controls immediately on the hospitals. But direct controls are a dangerous instrument and need to be considered only as a last resort. A decent and useful compromise was worked out by Rep. Dan Rostenkowski (D-Ill.) in the Ways and Means Committee, giving the hospitals two years to slow down their inflation by their own voluntary means. If they had failed to meet specific targets, under this compromise, the hospitals would only then have come under federal controls. First the administration denounced the idea, then embraced it. Now it has collapsed altogether.

There was a time when rising hospital bills were a public issue of great emotional force. That's evidently no longer true. The explanation, we surmise, lies in the insurance system. Only about 10 percent of the population is not covered by some sort of health insurance. People have to pay heavily for that coverage, but most of them pay indirectly and unconsciously. Much of the cost is paid directly by employers to insurers. Unlike withheld taxes, or Social Security contributions, the health-insurance premiums are not even noted on paychecks.

As we have observed before, the typical family of four with an income of $16,000 a year is now contributing about $2,000 a year to the nation's medical care. The contribution is real, but few families are aware of it. As a political issue, hospital costs do not appear to have much of a public following. The support for the cost-control legislation has come largely from people who have a professional or business interest in the subject: public administrators, economists, some of the insurers. That's not enough to carry a bill as sharply opposed as this one.

The failure of this bill makes the prospect of national health insurance more remote than ever. The arithmetic of the federal budget, now and for some years to come, would make it very difficult to move toward a comprehensive national health plan in any case. But the defeat of this temperate and conciliatory legislation will hardly do much to diminish the fear that better insurance will only mean bigger hospital bills.

It's a paradox: The broader the present patchwork of health-insurance coverage becomes, the less motive Congress has to improve it. The more widely and fairly the financial burdens of illness are spread over the population, the less interest any particular voters show in arresting its further rise. Meanwhile, hospital costs continue to go up, at nearly twice the average rate of all other consumer prices.

14. Kuehne - University of Vermont

Total Synthesis of Vincadifformine

(DELAY: 1 month)

This invention is the synthesis of a naturally occurring alkaloid which is a precursor in the synthesis ofa drug to treat cerebral vascular diseases and high blood pressure. Because of political conditions in the country from which the natural substance is obtained, the alkaloid may soon become scarce, or even unobtainable. A synthetic product, therefore, will be very valuable in the treatment of hypertension and other vascular diseases. The University of Vermont is awaiting the waiver, so that their licensee, Omnium Chimique, can start developmental efforts, and United States and foreign patent applications can be filed.

C-11

File w/ tech assessment 102

Coping with technology's surprises

When technological change stirs up public alarm, can timely assessment help to ease the resulting strain?

"Technology and Social Shock" by Edward W. Lawless, Rutgers University Press, New Brunswick, N.J., 1977, 616 pages, **$6.95**

Reviewed by David M. Kiefer, assistant managing editor of C&EN, who has followed the technology assessment movement since its inception, writing and speaking frequently about it.

Technology long has had a knack for catching society off guard—often to society's chagrin or acute discomfort. And society frequently has lashed back, out of fear or dismay about the consequences of technological change, in an effort to gain better control over that process. As the pace of technological innovation has escalated since World War II, moreover, incidents in which technology has inflicted unexpected consequences on the world at large have multiplied, reaching in the past decade what may seem to be avalanche proportions.

Discovery of trace amounts of amitrole, a herbicide thought to be carcinogenic, on a small part of the annual cranberry crop brings warnings from government officials just prior to Thanksgiving that largely sweep cranberry sauce off holiday tables and threaten economic disaster to growers. An apparently safe and effective sleep inducer and tranquilizer, thalidomide, is found to be teratogenic four years after it was launched on the market and is withdrawn, but not before thousands of babies are born deformed. DDT wins wide acclaim as a miracle control for insects until fears about the ecological side effects of its global buildup lead to its being banned in the U.S. Growing industrial use of mercury, especially in chlor-alkali production, brings in its wake anxiety about contaminated waterways, restrictions on fishing, and legislation to control mercury discharge. A canal built to connect Lake Erie with Lake Ontario permits sea lampreys to bypass Niagara Falls and invade the upper Great Lakes, where many years later they devastate native fish. Replacing grass with synthetic turf in sports stadiums raises concern about sharply higher rates of injury to football players.

These are examples of 100 cases of "social shock" stemming from technological developments of the past 30 years or so that are documented and analyzed, 45 of them in considerable detail, by Edward W. Lawless, director of the technology assessment section of Midwest Research Institute. A majority of the cases have at least some "chemical" aspect, dealing with hazardous or controversial drugs, chemical pollutants, pesticides, food additives, and other products of chemistry. Lawless, in "Technology and Social Shock," attempts to find what, if any, common thread may run through these disparate episodes of public alarm. He examines how that alarm was generated (especially by the news media) and what policy decisions it triggered. In the process, he aims to stimulate discussion of what should or might have been done differently to soften the social impact of technologies or products that the public perceives to be defective or detrimental to its health or economic well-being.

A common thread, if indeed there is one, is not clearly evident. In many cases, certainly, flawed information—or flawed use of adequate information—seems to be a factor. In a majority of the 45 incidents examined in detail, for example, adequate technical information was critical to resolving the issue. Yet in most of them, whatever information was available to decision makers at the time public concern was being awakened proved to be insufficient, untimely, or in dispute. Experts often were in strong disagreement among themselves, throwing more heat than light on the questions at issue.

In many of the cases, too, early warning signals that, if recognized, might have alerted officials or ameliorated public alarm were missed. Questions that should have been raised never were. "We frequently have early warnings, but don't notice or don't recognize them," Lawless points out; "in fact, we have a propensity for overlooking early warnings." One result is that problem technologies may be allowed to evolve even after their inherent dangers have become evident, at least to some knowing observers. In most of the cases Lawless examines in detail, as well, the threat was not noticed until new technological information—improved analytical methods, for example, or a better understanding of the interrelationships of ecology—could be brought to bear on the issue at hand.

It is to overcome just this lack of early information or insensitivity to whatever early warning signals may appear that the concept of technology assessment was spawned about a decade ago. Technology assessment, as its proponents explain it, is a systematic weighing of the competing benefits and risks—present or potential, direct and indirect—to society and the environment that are intrinsic to technological change. It would provide a sort of "societal impact statement." Such an assessment, moreover, would be undertaken not in reaction to emerging technologies but in anticipation of them, before a development was unleashed on an unsuspecting and unprepared world, so that timely decisions can be made to avoid or minimize hazardous or otherwise undesirable side effects. An increasing number of technology assessments—of varying depth and sophistication—have been made in the past few years, especially for the Congressional Office of Technology Assessment or under the aegis of the National Science Foundation.

But would such an endeavor really have helped to avoid, or at least reduce, the social shock that occurred in the episodes that Lawless looks at? Only some of the time, he concludes, at least if it were done at the time during which the episode actually was developing. As often as not, a technology assessment "might have identified a future problem correctly if the group doing the assessment had asked just the right question, but the likelihood of this having happened appears to be remote," he notes, citing as examples the rise and fall of DDT and the invasion of lampreys into the Great Lakes. Although technology assessments may help avoid many unpleasant surprises, he adds, "strange cause and effect links in some of our cases indicate strongly that it will be most difficult to even guess at some of the future adverse effects of a new technology." On the other hand, failure to make assessments, Lawless contends, "is almost sure to produce unpleasant surprises."

Timing is critical, of course; a technology assessment must be done while the threat can still be nipped in the bud. On the other hand, if it is done very early it may well miss important features of the emerging technology. And no matter how well done originally, it may need frequent updating. Lawless, who has been active in the technology assessment movement since its early days, suggests that "we may need several decision points in the development of a technology that indicate when additional research on potential hazards should be done, for example,

have at least some "chemical" aspect, dealing with hazardous or controversial drugs, chemical pollutants, pesticides, food additives, and other products of chemistry. Lawless, in "Technology and Social Shock," attempts to find what, if any, common thread may run through these disparate episodes of public alarm. He examines how that alarm was generated (especially by the news media) and what policy decisions it triggered. In the process, he aims to stimulate discussion of what should or might have been done differently to soften the social impact of notice or don't recognize them," Lawless points out; "in fact, we have a propensity for overlooking early warnings." One result is that problem technologies may be allowed to evolve even after their inherent dangers have become evident, at least to some knowing observers. In most of the cases Lawless examines in detail, as well, the threat was not noticed until new technological information—improved analytical methods, for example, or a better understanding of the interrelationships of ecology—could be brought to bear on the issue at hand.

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when the scale of production reaches certain orders of magnitude."

Lawless thinks, though, that a technology assessment also may be useful for reducing social shock in many cases even after a technological threat has surfaced. In such cases, timing is particularly critical, because the job must be done so quickly, perhaps within six months or less. But even a brief technology assessment, if done well, should provide information that may dispel some of the air of crisis that leads to hasty or unsound decisions.

Lawless has relied heavily on current news reports in newspapers and magazines in evaluating his 100 cases of social shock, on the reasonable assumption that public concern is reflected by what events the press covers and the amount of space devoted to them. At the same time, of course, the way the media handle technological news has a significant role in determining how the public reacts. And, he believes, there is much room for improvement. The news media, with their tendency to focus on the unusual or bizarre or to glamorize issues, have great difficulty in covering new technology in an evenhanded, factual, and credible manner. The problem is compounded by the need for reporters, often untrained in science, to reach knowledgeable sources of information while working under deadline pressures and to sort out and evaluate information that may be biased, conflicting, or inaccurate.

Lawless throws out an interesting suggestion in this regard. "What seems to be needed," he says, "is an independent scientific organization that can rapidly accumulate and evenhandedly organize whatever facts are known about an erupting crisis and could present the results to the news media under conditions that would inspire confidence." He admits, however, that it probably will be difficult to set up and operate such an organization that could, at the same time, keep itself free from charges of bias or news management. □

Paperbacks

The Acceptability of Risks. Council for Science and Society. 104 pages. Barry Rose Publishers Ltd., Little London, Chichester, Sussex PO19 1PG, U.K. 1977. $11.

Aquatic Pollutants and Biologic Effects with Emphasis on Neoplasia. H. F. D. Kraybill et al. 604 pages. New York Academy of Sciences, 2 East 63rd St., New York, N.Y. 10021. 1977. $52.

Crystallography and Its Applications. L. S. Dent Glasser. viii + 224 pages. Van Nostrand Reinhold, 450 West 33rd St., New York, N.Y. 10001. 1977. $12.50.

Decision Making in the Environmental Protection Agency. National Research Council. xvi + 249 pages. Printing & Publishing Office, National Academy of Sciences, 2101 Constitution Ave., N.W., Washington, D.C. 20418. 1977. $8.75.

People

Industry

James H. **Ackerman** promoted to technical project manager, Bixby International Corp., Haverhill, Mass. ... Robert M. **Aiken** appointed general managing director for Latin America and the Far East, Du Pont, Wilmington ... Thomas A. **Alexander** joins Norwich-Eaton Pharmaceuticals' scientific affairs department as a research biochemist, Norwich, N.Y.... Robert **Alvine** named v.p., corporate planning, Uniroyal, New York City ... B. J. **Anderson** promoted to executive v.p. and chief operating officer, Puritan/Churchill Chemical, Atlanta ... Ron **Andrade** promoted to product manager, Drew Chemical, Boonton, N.J. ... A. D. **Armstrong** joins Georgia-Pacific, Portland, Ore., as manager of pulp and paper engineering ... Richard A. **Arnold** appointed director of planning and corporate forecasting, Pennzoil, Houston ... Dr. Peter G. **Arvan** appointed executive v.p., operations, Beker Industries, Greenwich, Conn.... Robert F. **Avery** appointed paper products manager, thermoplastics division, Borden Chemical, Leominster, Mass.

Tariq M. **Baig** named perfumer, fragrance labs, Crompton & Knowles, Fair Lawn, N.J.... Robert F. **Baker** appointed product manager for Witco Chemicals' SACI rust preventive bases, New York City ... Raymond W. **Barclay** promoted to assistant patent counsel, Mobil Oil, New York City ... Dr. Allan V. **Bayless** promoted to research scientist V, organic chemistry section, Norwich-Eaton Pharmaceuticals, Norwich, N.Y.... Bennett E. **Bechtol** appointed executive v.p. and chief operating officer, Harper Oil, Oklahoma City ... Rodney P. **Becker** named plant manager, Deer Park PVC plant, Diamond Shamrock's plastics division, Cleveland ... Frank V. Z. **Benders** named director of chemical products, Borg-Warner Chemicals, Washington, W.Va. ... Leo **Berger** named assistant director of chemical research, Hoffmann-La Roche, Nutley, N.J.... Allan H. **Bergman** named v.p. and general manager, Permabond International, Englewood, N.J.

Dr. Narayan P. **Bhattacharjee** appointed director of process division, National AirOil Burner, Philadelphia ... William A. **Biggs** named marketing manager of biochemicals, PPG Industries' chemical division-U.S., Pittsburgh ... Edward J. **Blair** appointed technical service manager for paper coating chemicals, National Starch & Chemical, Bridgewater, N.J. ... Margaret Q. **Blevin** elected v.p.-administration, Prior Chemical, New York City ... James D. **Bogan** named general manager, esters, Armak Industrial Chemicals, Chicago ... Angela E. **Bova** promoted to sales representative, resource/synthetic department, process chemicals division of Diamond Shamrock, Morristown, N.J. ... Bette A. **Brown** named manager of administrative services, R&D, Chemagro agricultural division of Mobay Chemical, Kansas City, Mo. ... Charles N. **Bruner** promoted to manager, Olin's cellophane plant, Covington, Ind.

Woodfin **Caine** promoted to branch manager, distribution center, Thompson-Hayward Chemical, Jackson, Miss.... Donald R. **Calo** has formed D. C. Rogers Inc., New York City, a company dealing in domestic and imported chemicals ... Daniel J. **Carey** appointed executive v.p., Noville Essential Oil, North Bergen, N.J. ... R. Frank **Carmazzi** appointed sales representative, Southern Asbestos, Charlotte, N.C.... Steven A. **Cerefice** named research supervisor, Amoco Chemicals, Naperville, Ill.... Dr. Dennis **Chamot** appointed assistant director, AFL-CIO's newly created department for professional employees, Washington, D.C.... F. Norman **Christopher** named marketing manager, rigid urethanes, chemicals group, Olin, Stamford, Conn.... Dr. Frank **Chung** joins Stauffer Chemical, Dobbs Ferry, N.Y., as senior research chemist, food systems section ... Douglas A. **Church** appointed senior technical representative, lubricant sales, Climax Molydenum, Greenwich, Conn.

Rudolph **Cicchetti** named business development and process manager for pharmaceuticals and fine chemicals, Crawford & Russell, Stamford, Conn. ... William A. **Clark** appointed senior engineering associate, Exxon Chemical, Florham Park, N.J. ... Stuart C. **Cohen** promoted to manager, quality control and analytical, Valox products section, General Electric, Mt. Vernon, Ind. ... John S. **Cole** appointed polymers sales representative, specialty chemicals division, ICI Americas, Houston ... William M. **Connell** named executive v.p. and general manager, Wyrough & Loser, Trenton, N.J.... Rita J. **Cottrill** joins biochemistry section of Norwich-Eaton Pharmaceuticals, Norwich, N.Y., as a research scientist ... William N. **Creech** appointed assistant plant manager, Carus Chemical, La Salle, Ill.... John D. **Cullen** named chief engineer, Du Pont's engineering department, Wilmington.

Leland A. **Davis** becomes manager of R&D farm systems, Chemagro agricultural division of Mobay Chemical, Kansas City, Mo.... John **Deatcher** appointed associate chemist, polymer product development, Stauffer Chemical, Dobbs Ferry, N.Y.... Michael L. **Deelo** appointed market manager, coatings industries, St. Joe Zinc, Pittsburgh ... H. G. **Degitz** named assistant to president, operations, RMI Co., Niles, Ohio ... Andrew P. **Dunlop**, v.p. and scientific adviser, Quaker Oats' chemicals division, Barrington, Ill., retiring after 47 years' service with the company.

Peter **Epstein** promoted to production manager, salts and solutions production, Engelhard Industries, Newark, N.J.... Dr. E. E. **Erickson** becomes president of FilmTec Corp., newly formed manufacturing and R&D company related to thin polymer membranes, Minnetonka, Minn. ... Steven G. **Esakov** named manager, export sales, B. F. Goodrich Chemical, Cleveland ... Dr. Robert W. **Eyler** named assistant general manager, Hercules Europe, Brussels, Belgium.

Dr. Ellis K. **Fields** appointed research consultant, Amoco Chemicals, Naperville, Ill.... Gene J. **Fisher** appointed director of research, Celanese Chemical's technical center, Corpus Christi, Tex.... J. B. **Friederichsen** named director of planning, Gulf Oil Chemicals, Houston.

Jack I. **Glasser** promoted to director, inventory investment and planning, Parke, Davis & Co., Detroit ... Edwin W. **Gregory** elected v.p., Prior Chemical, New York City ... Robert W. **Grimble** appointed general managing director and named chairman-designate, Du Pont de Nemours International S.A., Geneva; he will be in charge of the company's international operations in Europe, Middle East, and Africa ... John J. **Guide** named engineering associate, Exxon Chemical, Florham Park, N.J. ... Dr. Robert Z. **Gussin** promoted to v.p. of research, McNeil Labs, Fort Washington, Pa.

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Coping with technology's surprises

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But would such an endeavor really have helped to avoid, or at least reduce, the social shock that occurred in the episodes that Lawless looks at? Only some of the time, he concludes, at least if it were done at the time during which the episode actually was developing. As often as not, a technology assessment "might have identified a future problem correctly if the group doing the assessment had asked just the right question, but the likelihood of this having happened appears to be remote," he notes, citing as examples the rise and fall of DDT and the invasion of lampreys into the Great Lakes. Although technology assessments may help avoid many unpleasant surprises, he adds, "strange cause and effect links in some of our cases indicate strongly that it will be most difficult to even guess at some of the future adverse effects of a new technology." On the other hand, failure to make assessments, Lawless contends, "is almost sure to produce unpleasant surprises."

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Coping with technology's surprises

When technological change stirs up public alarm, can timely assessment help to ease the resulting strain?

"Technology and Social Shock" by Edward W. Lawless, Rutgers University Press, New Brunswick, N.J., 1977, 616 pages, **$6.95**

Reviewed by David M. Kiefer, assistant managing editor of C&EN, who has followed the technology assessment movement since its inception, writing and speaking frequently about it.

Technology long has had a knack for catching society off guard—often to society's chagrin or acute discomfort. And society frequently has lashed back, out of fear or dismay about the consequences of technological change, in an effort to gain better control over that process. As the pace of technological innovation has escalated since World War II, moreover, incidents in which technology has inflicted unexpected consequences on the world at large have multiplied, reaching in the past decade what may seem to be avalanche proportions.

Discovery of trace amounts of amitrole, a herbicide thought to be carcinogenic, on a small part of the annual cranberry crop brings warnings from government officials just prior to Thanksgiving that largely sweep cranberry sauce off holiday tables and threaten economic disaster to growers. An apparently safe and effective sleep inducer and tranquilizer, thalidomide, is found to be teratogenic four years after it was launched on the market and is withdrawn, but not before thousands of babies are born deformed. DDT wins wide acclaim as a miracle control for insects until fears about the ecological side effects of its global buildup lead to its being banned in the U.S. Growing industrial use of mercury, especially in chlor-alkali production, brings in its wake anxiety about contaminated waterways, restrictions on fishing, and legislation to control mercury discharge. A canal built to connect Lake Erie with Lake Ontario permits sea lampreys to bypass Niagara Falls and invade the upper Great Lakes, where many years later they devastate native fish. Replacing grass with synthetic turf in sports stadiums raises concern about sharply higher rates of injury to football players.

These are examples of 100 cases of "social shock" stemming from technological developments of the past 30 years or so that are documented and analyzed, 45 of them in considerable detail, by Edward W. Lawless, director of the technology assessment section of Midwest Research Institute. A majority of the cases have at least some "chemical" aspect, dealing with hazardous or controversial drugs, chemical pollutants, pesticides, food additives, and other products of chemistry. Lawless, in "Technology and Social Shock," attempts to find what, if any, common thread may run through these disparate episodes of public alarm. He examines how that alarm was generated (especially by the news media) and what policy decisions it triggered. In the process, he aims to stimulate discussion of what should or might have been done differently to soften the social impact of technologies or products that the public perceives to be defective or detrimental to its health or economic well-being.

A common thread, if indeed there is one, is not clearly evident. In many cases, certainly, flawed information—or flawed use of adequate information—seems to be a factor. In a majority of the 45 incidents examined in detail, for example, adequate technical information was critical to resolving the issue. Yet in most of them, whatever information was available to decision makers at the time public concern was being awakened proved to be insufficient, untimely, or in dispute. Experts often were in strong disagreement among themselves, throwing more heat than light on the questions at issue.

In many of the cases, too, early warning signals that, if recognized, might have alerted officials or ameliorated public alarm were missed. Questions that should have been raised never were. "We frequently have early warnings, but don't notice or don't recognize them," Lawless points out; "in fact, we have a propensity for overlooking early warnings." One result is that problem technologies may be allowed to evolve even after their inherent dangers have become evident, at least to some knowing observers. In most of the cases Lawless examines in detail, as well, the threat was not noticed until new technological information—improved analytical methods, for example, or a better understanding of the interrelationships of ecology—could be brought to bear on the issue at hand.

It is to overcome just this lack of early information or insensitivity to whatever early warning signals may appear that the concept of technology assessment was spawned about a decade ago. Technology assessment, as its proponents explain it, is a systematic weighing of the competing benefits and risks—present or potential, direct and indirect—to society and the environment that are intrinsic to technological change. It would provide a sort of "societal impact statement." Such an assessment, moreover, would be undertaken not in reaction to emerging technologies but in anticipation of them, before a development was unleashed on an unsuspecting and unprepared world, so that timely decisions can be made to avoid or minimize hazardous or otherwise undesirable side effects. An increasing number of technology assessments—of varying depth and sophistication—have been made in the past few years, especially for the Congressional Office of Technology Assessment or under the aegis of the National Science Foundation.

But would such an endeavor really have helped to avoid, or at least reduce, the social shock that occurred in the episodes that Lawless looks at? Only some of the time, he concludes, at least if it were done at the time during which the episode actually was developing. As often as not, a technology assessment "might have identified a future problem correctly if the group doing the assessment had asked just the right question, but the likelihood of this having happened appears to be remote," he notes, citing as examples the rise and fall of DDT and the invasion of lampreys into the Great Lakes. Although technology assessments may help avoid many unpleasant surprises, he adds, "strange cause and effect links in some of our cases indicate strongly that it will be most difficult to even guess at some of the future adverse effects of a new technology." On the other hand, failure to make assessments, Lawless contends, "is almost sure to produce unpleasant surprises."

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Peter **Epstein** promoted to production manager, salts and solutions production, Engelhard Industries, Newark, N.J.... Dr. E. E. **Erickson** becomes president of FilmTec Corp., newly formed manufacturing and R&D company related to thin polymer membranes, Minnetonka, Minn. ... Steven G. **Esakov** named manager, export sales, B. F. Goodrich Chemical, Cleveland ... Dr. Robert W. **Eyler** named assistant general manager, Hercules Europe, Brussels, Belgium.

Dr. Ellis K. **Fields** appointed research consultant, Amoco Chemicals, Naperville, Ill.... Gene J. **Fisher** appointed director of research, Celanese Chemical's technical center, Corpus Christi, Tex.... J. B. **Friederichsen** named director of planning, Gulf Oil Chemicals, Houston.

Jack I. **Glasser** promoted to director, inventory investment and planning, Parke, Davis & Co., Detroit ... Edwin W. **Gregory** elected v.p., Prior Chemical, New York City ... Robert W. **Grimble** appointed general managing director and named chairman-designate, Du Pont de Nemours International S.A., Geneva; he will be in charge of the company's international operations in Europe, Middle East, and Africa ... John J. **Guide** named engineering associate, Exxon Chemical, Florham Park, N.J. ... Dr. Robert Z. **Gussin** promoted to v.p. of research, McNeil Labs, Fort Washington, Pa.

Gloria C. **Harllee** joins Aromatics International, Marietta, Ga., as manager of tobacco flavor R&D ... Michael W. **Hawker** promoted to district manager, southwestern U.S., Engelhard Industries, Houston ... Jaroslaw R. **Hawrych** appointed technical director, Badger Ltd., London ... William B. **Hayes** named v.p. of chemical products manufacturing, Kerr-McGee Chemical, Oklahoma City.

of Sciences, 2 East 63rd St., New York, N.Y. 10021. 1977. $52.

Crystallography and Its Applications. L. S. Dent Glasser. viii + 224 pages. Van Nostrand Reinhold, 450 West 33rd St., New York, N.Y. 10001. 1977. $12.50.

Decision Making in the Environmental Protection Agency. National Research Council. xvi + 249 pages. Printing & Publishing Office, National Academy of Sciences, 2101 Constitution Ave., N.W., Washington, D.C. 20418. 1977. $8.75.

Woodfin **Caine** promoted to branch manager, distribution center, Thompson-Hayward Chemical, Jackson, Miss.... Donald R. **Calo** has formed D. C. Rogers Inc., New York City, a company dealing in domestic and imported chemicals ... Daniel J. **Carey** appointed executive v.p., Noville Essential Oil, North Bergen, N.J. ... R. Frank **Carmazzi** appointed sales representative, Southern Asbestos, Charlotte, N.C.... Steven A. **Cerefice** named research supervisor, Amoco Chemicals, Naperville, Ill.... Dr. Dennis **Chamot** appointed assistant director, AFL-CIO's newly created department for professional employees, Washington, D.C.... F. Norman **Christopher** named chairman-designate, Du Pont de Nemours International S.A., Geneva; he will be in charge of the company's international operations in Europe, Middle East, and Africa ... John J. **Guide** named engineering associate, Exxon Chemical, Florham Park, N.J. ... Dr. Robert Z. **Gussin** promoted to v.p. of research, McNeil Labs, Fort Washington, Pa.

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38 C&EN Jan. 30, 1978

November 9, 1977

NOTE TO AGENCY AND OS PARTICIPANTS IN THE TECHNOLOGY MANAGEMENT STUDY

Attached is your copy of the next-to-last draft of the Technology Management Report, and the Decision Memorandum on this issue that P has prepared for the Secretary. Some of you -- at least one person in each agency -- will also find enclosed a complete set of the reports that the agencies prepared in response to the Study Team's request.

The Executive Secretariat has officially transmitted the Report and Decision Memorandum to Assistant Secretaries and the HCFA Administrator with the request that (a) factual corrections and (b) program- and policy-related comments be submitted to Exec Sec not later than COB Novermber 21, a firm deadline. Copies are to be sent to me (Rm 437E, Humphrey Building). We expect to change the Report where factual errors exist, and Exec Sec will prepare a memo for the Secretary identifying policy disagreements. We also expect to meet with the Secretary to brief him on this.

As you learn of technology management-related activities outside of the Department, I would appreciate being advised of them.

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

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

Penultimate Draft

HEALTH TECHNOLOGY MANAGEMENT

AT THE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

A Report for the Secretary

November 7, 1977

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- A. Development of the Proposed Technology System
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- C. Recommended Approach

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APPENDICES

INTRODUCTION

-- How many tonsillectomies performed in this country are necessary?

-- What are the health outcomes from coronary bypass surgery versus drug therapy for treatment of angina?

-- How can relevant laboratory findings be linked with bedside practice?

-- What institutional or professional qualifications should be required of those proposing to perform open heart surgery?

-- What market incentive mechanisms can be used to stimulate development of lagging or absent beneficial and cost-saving health technologies?

There is widespread agreement that twentieth century biomedical research and technological innovation have been responsible for profound improvements in human health. Some diseases have been eradicated; others can now be prevented; life itself has been extended; and much pain and suffering has been alleviated.

There is also, however, an emerging consensus that many technologies have been widely adopted into medical practice in the face of disturbingly scanty information about their health benefits, clinical risks, cost-effectiveness, and societal side-effects; that the use and overuse of other technologies has persisted long after it was evident that they were of marginal utility, outmoded, or even harmful; and that still other well-validated innovations have been inordinately slow in finding their way to patient care.

As a result, DHEW is currently seeking a new strategy for the management of medical technologies to assure that they are more carefully scrutinized for their efficacy and effect on health outcomes, more rapidly introduced or phased out of practice, more equitably organized and distributed, and more appropriately and effectively used. In addition, a new strategy must be able to provide the Department with a balance between controlling costs of health care and over-controlling technological innovation at the expense of the quality of health care.

The alternative to adopting a new management strategy is to continue the current

equitably organized and distributed, and more appropriately and effectively used. In addition, a new strategy must be able to provide the Department with a balance between controlling costs of health care and over-controlling technological innovation at the expense of the quality of health care.

The alternative to adopting a new management strategy is to continue the current

essentially laissez-faire approach which in most (but not all) areas of medical care leaves development and adoption of technologies to the intellectual curiosity of researchers, the marketing strategies of manufacturers, the slowly evolving consensus of practitioners, the demands of consumers, and the drive of a relatively unconstrained health market.

This Department is deeply involved with medical technologies (drugs, devices, and medical and surgical procedures) in three primary ways:

-- it develops technologies both intramurally through employee scientists and innovators and extramurally through support of research and development activities;

-- it evaluates existing and emerging technologies to attempt to understand their value and their implications for health and society;

-- it recognizes technologies by regulating them, by buying them, by reimbursing for them, or by otherwise contributing to their use or non-use.

Yet for all of its involvement, the Department has no strategy for systematically managing the life cycle of technology development, evaluation, transfer, diffusion, utilization, and phase-out.

-- The "knowledge development" agencies (like NIH, NCHSR,) each decide independently what technologies they will examine and what they will do with the results.

-- The "action" agencies (e.g., BHPRD, Medicare, Medicaid and PSRO programs) lack both the staff to do technical evaluations of technologies and the links to knowledge development agencies through which they could ensure examination of technologies for which they need action-supporting information.

-- Results of evaluations trickle out into the research literature, but often do not come to the attention of the practicing physicians or the DHEW officials

lack both the staff to do technical evaluations of technologies and the links to knowledge development agencies through which they could ensure examination of technologies for which they need action-supporting information.

-- Results of evaluations trickle out into the research literature, but often do not come to the attention of the practicing physicians or the DHEW officials

responsible for developing regulations, legislation, and standards.

-- Evaluation activities are extensive, but existing technologies (particularly medical and surgical procedures) receive too little attention.

-- Much effort is placed on efficacy and safety evaluation, but considerably less is done about the cost-benefit, cost-effectiveness, or general societal impacts of technologies.

-- The linkages between technology studies and action to impede or stimulate technology transfer and utilization are ad hoc and often fail.

The Technology Environment

The evidence of a raised technology consciousness is accumulating: within the past year there have been major conferences at Boston University and Sun Valley, and two more are in the planning; Senator Kennedy has held hearings, and Congressman Moss has proposed technology control-related legislation; the American Hospital Association and the Association of American Medical Colleges have assigned staff specialists, and the American College of Physicians has formed a special subcommittee.

While there is increasing (though far from universal) advocacy for managing technology toward serving the public more efficiently and effectively, there is no consensus over w is to be charged with the responsibility for integrating efforts toward that end, and the means to be employed. Senator Kennedy and Congressman Moss and this report propos a stronger Federal role. But it can be expected that arguments will be raised against such a role, postulating threats to the physician-patient relationship, the independence of professional judgement, the objectivity of scientific research, the dynamic of the medical supplies marketplace, and the rapid flow of innovation to bedside practice.

On the other hand, public interest representatives are raising consumer protection issues, and third-party payers and employers are associating the proliferation of

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On the other hand, public interest representatives are raising consumer protection issues, and third-party payers and employers are associating the proliferation of

technologies with increased costs. They may feel that the initiatives proposed in this report will fail to sufficiently control technology.

The multiple problems arising from technology development and utilization have not emerged overnight, and even the most carefully devised management system is unlikely to provide a "quick fix" to the deep-seated problems. This report proposes a major approach to that solution, but it is only a step toward a long-range solution which takes into account the divergent perspectives of the various parties-at-interest to the health system.

The Charge to the Study Team

On July 20, during his testimony before the Senate Subcommittee on Health and Scientific Research, Dr. Richmond was asked by Senator Kennedy if the Department could develop an outline for a DHEW systems approach to technology management. At the same time, the Assistant Secretary for Planning and Evaluation had advised the Secretary that his staff was preparing a decision memorandum on technology management in the Department. As a result, the Office of the Assistant Secretary for Planning and Evaluation (P), in collaboration with the Office of the Assistant Secretary for Health (H), was asked to conduct a month-long Phase I Study of the matter. P and H staff jointly met with representatives of the Department's agencies and asked them to produce, within ten days, reports of their technology-related activities. (See Appendix, Tab 2 for the Agency Report Outline). The resulting reports (Tabs 3 through 11) were analyzed and integrated with the Study Team's conceptual framework for technology management to form the basis of this report.

Focus of this Phase I Report

The focus of this report is a Departmental strategy for managing medical technologies. It provides a model of a comprehensive and integrated technology system (and proposes its adoption in principle). It compares current agency and Departmental activities with

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The focus of this report is a Departmental strategy for managing medical technologies. It provides a model of a comprehensive and integrated technology system (and proposes its adoption in principle). It compares current agency and Departmental activities with

each component of the model, identifies gaps and deficiencies, and recommends remedi actions. In addition, the report suggests that the proposed technology system requires full-time management and recommends endorsement, in principle, of a new Departmen level unit to be charged with the responsibilities and authorities for such management.

The proposed strategy is to create a systematic Department-level process through whic we identify annually a relatively small number of high-priority technologies, scrutinize them thoroughly, reach explicit conclusions regarding the implications of the resulting information, and link our decisions directly to the full array of intervention mechanisms available through Departmental authorities.

The strategy recognizes that at the Department-level, we cannot hope to systematically address all existing and emerging medical technologies, expert estimates of which range from 8,000 to 150,000. Consequently, the strategy calls for establishment of a Department-level unit not only to manage and oversee the process for the highest priority technologies which are selected annually, but also to provide a technical assistance and coordination role for the agencies for the handling of lower priority technologies. This will assure that the most systematic techniques are applied to the high-priority technologies and that the lessons learned from the process are adopted by the agencies in their handling of other technologies.

Limitations of the Phase I Study

The Phase I inquiry was not intended to result in a full-fledged prescription for DHEW technology managment, but to produce a conceptual framework to be used as the foundati for designing such a system in the future. Consequently, this report does not attempt to provide information on (1) the technical abilities of the knowledge development agencie and their staffs to conduct or oversee the types of technical studies that need to be applied; (2) the quality of such studies as are now being done; (3) the abilities of the action agencies or their staffs to wield the intervention mechanisms through which DHEW

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can impede or stimulate development or utilization of a technology; (4) options with pros and cons for resolving the deficiencies identified by the Study Team.

Important study limits were:

(1) information was limited to reports prepared by the agencies within ten days; the Study Team had no time to do independent data gathering or verifiction;

(2) activities within DHEW only were examined; excluding significant and relevant activities of such Federal agencies as the VA, DOD, NSF, NASA and such private entities as manufacturers, medical specialty groups, academic health science centers, provider and consumer groups;

(3) analysis was restricted to programmatic and systems approaches; and specifically did not consider which organizational elements within DHEW might be assigned such functions; and

(4) medical technologies only were examined; thus, health care system management, rehabilitation, mental health and environmental technologies were excluded as were research and development activities per se.

Consequently, it is recommended that a Phase II Study be promptly initiated and that it focus on those aspects which will not be included in this first report. The dimensions of the Phase II Study are described in appendix tab 13.

Two Important Distinctions

The technical terms used in this report are presented in the Glossary (Appendix Tab I). However, two distinctions are needed at this point to sharpen the discussion:

(1) the technology system vs. "technology assessment"

This report focuses on a management process and structure (a system) for examining and influencing technologies as they move from development into practice. The popular term "technology assessment" refers only to one type

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This report focuses on a management process and structure (a system) for examining and influencing technologies as they move from development into practice. The popular term "technology assessment" refers only to one type

of technical study that may be applied to a given technology and is addressed as one part of Section IV.

(2) knowledge development agencies vs. action agencies

For the purpose of this report, the Study Team has come to view agencies (or parts of agencies) as having as a primary orientation either the development of knowledge about technologies (e.g., NIH or NCHSR) or the use of that knowledge to undergird or justify actions taken to impede, promote, or otherwise set conditions on the use of a technology (e.g. BHPRD or HCFA). It is recognized that this distinction is over-simplified--most knowledge development agencies have some action dimension (even if it is confined to publication of information) and some action agencies have developed considerable knowledge development capability. Subsequent studies of management changes will need to weigh the desirability of maintaining these duplicative and overlapping functions. The typing of agencies' primary functions is useful for purposes of examining missing or ineffective linkages and their costs.

A Note About Legislative Steps in the Process

Several legislative authorities will expire this fiscal year (e.g. NIH, NCHSR, NCHS). The Study Team believes that no new legislative authority is required for the initial steps necessary to initiate the proposed technology managememt process and structure. It is within the Department's administrative authority, and there is considerable Congressional interest in having the Department move forward on the matter. However, should new legislation prove desirable for such proposals as increased appropriations and positions, the time available to advance them for Congressional consideration will be very short.

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I. THE CONCEPTUAL FRAMEWORK FOR A PROPOSED TECHNOLOGY SYSTE

Medical technologies move from a developmental stage through a fragmented and haphazard process into utilization in the health care system where they may assume a life of their own unrelated to proven efficacy, costs, risks, or benefits. Similarly, the process of technology development and transfer within DHEW 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 medical technologies. Moreover, study results from knowledge development agencies are seldom linked to action agency mechanisms to restrict or stimulate transfer and utilization of technologies.

Recognizing that the Department currently has neither a strategy for managing medical technology nor an analytical paradigm upon which to develop such a strategy, the Study Team has developed a concept for a proposed technology system and has structured this report in terms of the proposed system. Figure 1 on the next page depicts the conceptual framework for the system and elucidates the six components of the process:

1. Identification and screening of candidate technologies
2. Centralized priority setting of technologies to be scrutinized
3. Conduct or monitoring of the technical studies
4. Translation of technical findings for relevant users
5. Coordinated decisionmaking to restrain or stimulate the technology
6. Intervention mechanisms to implement the decisions

As shown in the following sections of this report, some of the system components already exist within the Department while others are absent or very weak. The Study Team has concluded that it is important to correct the deficiencies of the existing components and to establish the absent components because all of them

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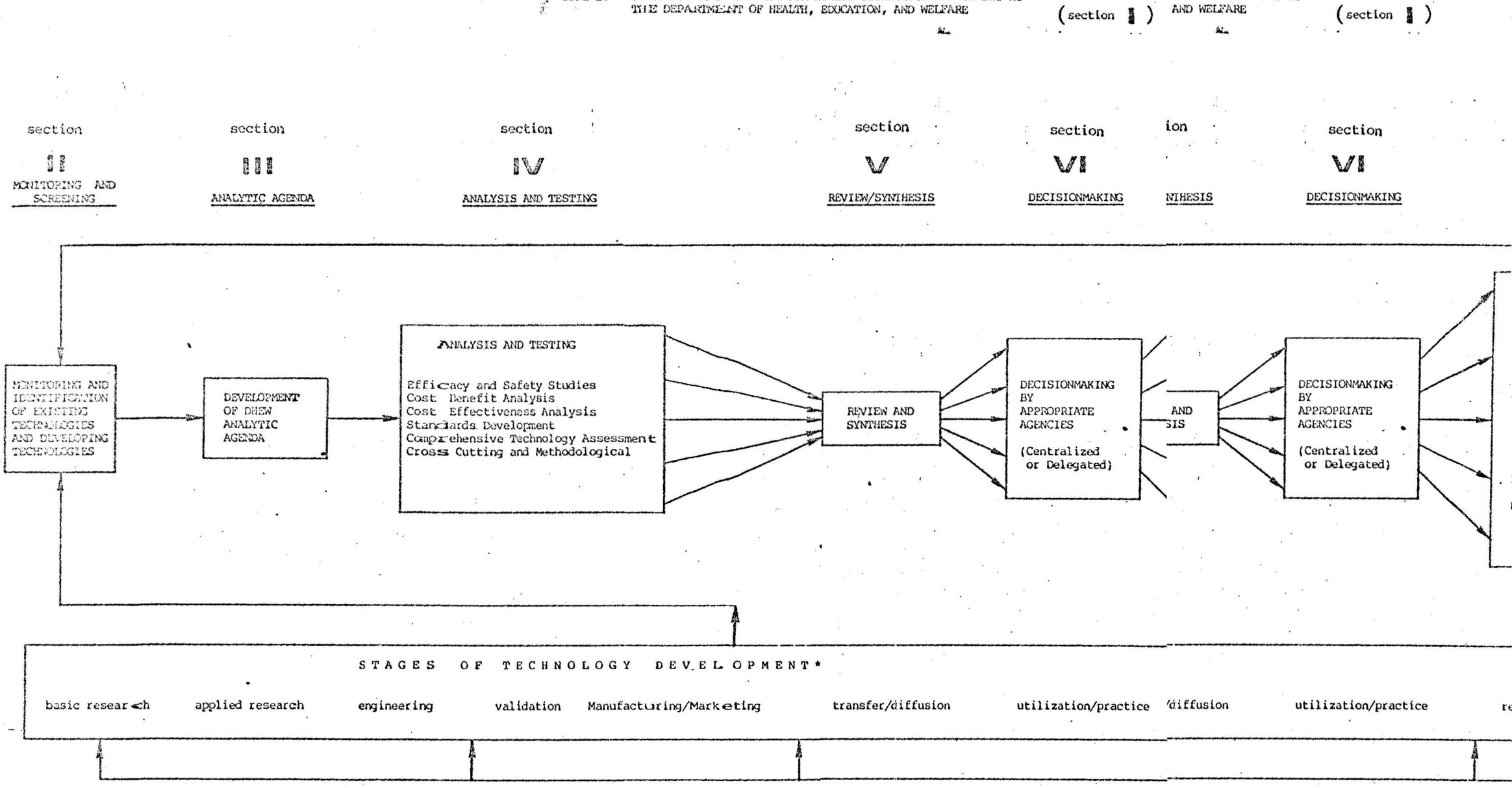
FIGURE 1: CONCEPTUAL FRAMEWORK FOR HEALTH TECHNOLOGY MANAGEMENT AT THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE



* Because Technology Development is not a linear process, a technology does

ess, a technology does

are needed to assure that medical technologies are examined and that explicit decisions are made about their values and limits.

The components of the proposed system and an analysis of what is now being done, as well as what is not being done, within each component constitute the subsequent sections of this report:

Monitoring and Screening (Section II); proposes development of a technology information base, and a process for "coarse screening" of existing and developing technologies to be analyzed or tested.

Development of an Analytic Agenda (Section III): proposes a process of subjecting technologies which pass the "coarse screen" to a fine screen resulting in approval of an Annual Technology Analysis Agenda for the Department. It also includes decisions about what types of studies are to be conducted and their assignment to appropriate agencies.

Analysis and Testing (Section IV): outlines five classes of technical studies by which medical technologies might be scrutinized.

Review and Synthesis (Section V): discusses synthesis and "translation" of results of technical studies and other expert opinion into a format for policy and program actions.

Decisionmaking (Section VI): proposes development of a process for explicit departmental decisions which link findings with coordinated interventions to restrain development or stimulate technology transfer and utilization.

Implementation/Intervention Mechanisms (Section VII): outlines intervention actions flowing from coordinated agency decisions and feedback of the intervention impacts to the monitoring and screening component.

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Implementation/Intervention Mechanisms (Section VII): outlines intervention actions flowing from coordinated agency decisions and feedback of the intervention impacts to the monitoring and screening component.

II. MONITORING AND SCREENING

- What system is available to identify and catalog existing and emerging technologies?

- How could the universe of existing and emerging technologies be screened to determine which might warrant high priority scrutiny?

A. Description of Monitoring and Screening Component

The Monitoring and Screening component identifies those technologies which should be studied. It consists of a data base of information about the universe of existing and developing technologies and the criteria for "coarse screening" to identify candidate technologies for detailed study. The screening criteria might be based on such factors as present or potential dollar and social costs; efficacy or safety considerations; problems that relate to the utilization or appropriateness of an existing technology, or the need for a technology that is absent or lagging.

B. Agency Activities and Deficiencies

Analysis of the agency reports reveals that there is currently no system to identify the universe of existing and developing technologies or to provide the "coarse screen" to select candidate technologies to be studied. Not only is there no catalog of such technologies, but expert estimates of the total number involved range widely from 8,000 to 150,000 major and minor procedures and products. While none of the agencies have a systematic monitoring and screening mechanism four of them report activities which could contribute to the development of the needed system.

NCHS reports that its 20 data systems include considerable macro data on utilization and diffusion of selected existing medical technologies and that it would be feasible to add to its on-going surveys questionnaire items about additional technologies. For example, NCHS can currently provide macro data which show

tion and diffusion of selected existing medical technologies and that it would be feasible to add to its on-going surveys questionnaire items about additional technologies. For example, NCHS can currently provide macro data which show

increases or decreases over time of different types of surgical procedures such as cardiac catheterization and hip arthoplasty. Similarly, the annual hospital survey supported by NCHS includes items which enable the center to track the diffusion rate of such hospital-based technologies as open heart surgery units, radioisotope facilities and hemodialysis (Appendix Tab 9, pages 3-6).

FDA reports that it maintains a computerized system for post-market surveillance of approved drugs. This system stores adverse drug reaction reports received from manufacturers, hospitals, physicians, the World Health Organization and other sources, including the literature.

NIH reports that developing technologies are under continuous surveillance by the Institutes as part of their on-going cycle of program planning, but this surveillance activity is informal.

NCHSR reports that its intramural staff have developed a concept design for an "ideal system" to identify, screen, track, and forecast developing technologies, and that this concept design for a computerized system has now been embodied in an RFP in order to have an outside contractor examine both its feasibility and its cost-effectiveness. The system is designed to provide NCHSR with a systematic way of identifying the universe of public and privately funded emerging technologies that should be candidates for its technology studies program and, more particularly, to provide the base for determining the optimal time at which to conduct these studies -- i.e., before the technology is too far advanced to modify through public policy intervention and yet sufficiently developed so that it is possible to obtain adequate information about the technology and its potential applications. Since it will take 2-4 years for such a sophisticated system to become operational, the agency has also developed an interim informal approach for identifying and setting priorities for the study of developing technologies.

public policy intervention and yet sufficiently developed so that it is possible to obtain adequate information about the technology and its potential applications. Since it will take 2-4 years for such a sophisticated system to become operational, the agency has also developed an interim informal approach for identifying and setting priorities for the study of developing technologies.

Thus, it appears that considerable work is already under way to determine the feasibility of the systematic monitoring of developing technologies which might warrant serious study, but that comparable work has not been done for existing technologies. Such a mechanism needs to be designed and developed in the near future since it constitutes the front end of a Departmental system for technology management. Without such a system, it is quite possible that the most critical technologies will be overlooked, or that the limited funds available will be invested in the study of lower priority technologies.

Not possible — peer review?

C. Recommended Approaches

It is recommended that the Department develop a system to identify, monitor, and screen existing technologies which should be studied. The system should be capable of serving both the knowledge development and the action agencies of the Department. Since a systematic approach to monitoring existing technologies is less complex than a similar system for investigating developing technologies, and since both FDA and NCHS have developed some of the needed elements, it is possible that such a system could be built in one year.

III. THE ANALYTIC AGENDA

- How are the highest priority technologies selected for scrutiny from among the pool of candidate technologies?
- How can a better balance be struck between the information needs of the action agencies and the research interests of the knowledge development agencies?
- How can it be assured that those agencies capable of conducting the needed studies will apply them to the priority technologies in a timely manner?

A. Description of the Analytic Agenda Component

This component comprises the annual preparation of a Technology Analysis Agenda which reflects the Department's priority needs for technical information about existing, new, and emerging technologies.

The process of developing the analytic agenda serves as a fine screen which subjects the list of candidate technologies (identified earlier through the Monitoring and Screening component) to a more selective set of criteria such as the resources and skills of the knowledge development agencies, the information needs of the action agencies, the concerns of outside parties-at-interest, and the time constraints. For each technology that passes through the fine screen, the process also determines what types of studies are most appropriate to the technology to be studied, which agencies will be responsible for conducting the studies, and which potential users are likely to be most interested in implementing the study results. The Agenda formalizes the Department's intent to carry out 15-20 high priority studies per year, but does not replace the development of analytic agendas by the individual agencies. After the Agenda is approved by the Secretary, or his designate, the Departmentally-assigned studies form the core and first priority of the analytic responsibilities of the agencies.

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B. Agency Activities and Deficiencies

Agenda-setting occurs at the agency and sub-agency levels, influenced by prioritie (not necessarily technology-related) identified through some of the following:

- the annual Departmental Planning Guidance
- OS review of the Agencies' evaluation plan submissions
- Congressional mandates and requests
- staff, peer and constituent contacts

Proposed agency agendas filter up to bureau and agency heads coordinated by review committees or by the agency planning office. Decisions are made in consideration of resource availability and perceived salience of the candidates, with the decisions then remanded to the working staff for implementation.

The primary deficiencies of this agency-based process are:

1. The needs of the action agencies for studies of specific technologies are no being incorporated into the agendas of the knowledge development agencies, and there are no mechanisms to enable that to occur systematically.

2. There is no assurance that the types of studies initiated are conducive to policy-relevant questions being raised about the target technologies.

3. Opportunities for potentially valuable collaborative efforts are often misse because agencies are not aware of each other's capabilities and needs.

4. There is no Department-wide clearinghouse which serves as an information point for the agencies and private sector groups which need to know what studies are in progress or have been conducted on a particular technology-based problem.

point for the agencies and private sector groups which need to know what studies are in progress or have been conducted on a particular technology-based problem.

These deficiencies give rise to action agencies either attempting to develop staff capability to conduct studies relating to their own needs, or awarding technology study contracts that may duplicate other efforts.

C. Recommended Approach

It is recommended that the concept of a Departmental Technology Analysis Agenda be adopted, and that the responsibility for management of the annual process be lodged at the Department level.

IV. ANALYSIS AND TESTING

-- What types of technical studies should be used to examine technologies?

-- Does the Department currently conduct such studies, and where is improvement required?

A. Description of the Analysis and Testing Component

The Analysis and Testing component develops technical information and data about existing, new, and developing medical technologies. This information will include th which is now unknown, as well as the validation or refutation of what is believed.

In the preceding component (setting the Analytic Agenda), the Secretary, or his designee, would decide which types of technical studies should be applied to given technologies, and would assign responsibility for their conduct to certain agencies. Different types of studies are employed to address the diverse questions germane to different medical technologies. Classes of studies conducted are:

-- efficacy and safety

-- cost-benefit or cost-effectiveness

-- standards development

-- comprehensive technology assessment

-- cross-cutting and methodological

Each type of study is designed to provide information about a different facet of a technology; each is conducted using different methods and analytic tools; and each type requires different combinations of skills, disciplines and resources.

B. Agency Activities and Deficiencies

The one month time constraint limits this report to: (1) specifying whether or not such studies are now being conducted and (2) identifying what the agencies and the Study

B. Agency Activities and Deficiencies

The one month time constraint limits this report to: (1) specifying whether or not such studies are now being conducted and (2) identifying what the agencies and the Study

Team perceive as the problems associated with their conduct. Independent judgments about the quality of studies or staffs could not be made without on-site evaluation. Problems include the following:

-- Agencies doing the analysis and testing are seldom linked effectively to action agencies. As a result, questions of interest to action agencies are usually not incorporated into the study designs;

-- Action agencies frequently do not have the time or expertise to overcome chronic state-of-the-art limitations that compromise the quality of the studies they undertake themselves. Hence, they hesitate to implement the results of studies they sponsor;

-- Similar types of studies are conducted or sponsored in several agencies, but a "critical mass" of skills are not necessarily assembled in one place; and

-- Because certain types of studies are seldom conducted (e.g., cost-benefit and comprehensive technology assessment) agencies are not able to maintain skills at a high level for either the conduct or contract monitoring of such studies.

Efficacy and Safety Testing

Efficacy and safety studies are conducted to obtain evidence about the medical usefulness and risks of drugs, devices and procedures. Since neither efficacy nor safety measures are absolute, these studies weigh probable health benefits against probable risks. Agency reports indicate a strong base for the conduct of efficacy and safety studies, particularly of new drugs and medical devices:

-- NIH, in FY 1975, conducted some 750 clinical trials at a cost of over $100 million (about 60% were solely drug, vaccine, or biologics trials);

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-- NIH, in FY 1975, conducted some 750 clinical trials at a cost of over $100 million (about 60% were solely drug, vaccine, or biologics trials);

-- NIH reported small scale efforts hampered by state-of-the-art problems in applying such studies to disease research. NIH's report expresses the opinion that such studies are more appropriately the responsibility of other DHEW agencies.

-- CDC reports studies on costs and effectiveness of different venereal disease tests, screening techniques, and treatment schedules.

CBAs and CEAs are highly technical, specialized techniques that should be conducted by personnel trained in quantitative and economic analysis. Such staff should be located in an environment where their skills are kept sharp through constant use, where several can collaboratively address state-of-the-art problems, and where a "critical mass" of experience and knowledge can collegially sustain high quality initiative. This objective suggests the centralization of such activities rather than their partition among several biomedical or health services research-oriented agencies.

Development of Standards

Standards development activities usually proceed from a base of technical information developed through one or more of the previously described types of studies. But the analysis and synthesis of that information creates new information that justifies the classification of standards development as a class of studies.

-- FDA sets standards for the quality, efficacy, and safety of drugs and devic being considered for market approval;

-- HCFA develops medical necessity, quality, and appropriateness standards to guide PSROs in their local review activities, e.g., the agency awarded contracts totalling $1.8 million to eight health professional groups to develop sample criteria and standards sets for medical necessity of hospit-

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-- NIH reported small scale efforts hampered by state-of-the-art problems in applying such studies to disease research. NIH's report expresses the opinion that such studies are more appropriately the responsibility of other DHEW agencies.

-- CDC reports studies on costs and effectiveness of different venereal disease tests, screening techniques, and treatment schedules.

CBAs and CEAs are highly technical, specialized techniques that should be conducted by personnel trained in quantitative and economic analysis. They should be located in an environment where their skills are kept sharp through constant use, where several can collaboratively address state-of-the-art problems, and where a "critical mass" of experience and knowledge can collegially sustain high quality initiative. This objective suggests the centralization of such activities rather than their partition among several biomedical or health services research-oriented agencies.

Development of Standards

Standards development activities usually proceed from a base of technical information developed through one or more of the previously described types of studies. But the analysis and synthesis of that information creates new information that justifies the classification of standards development as a class of studies.

-- FDA sets standards for the quality, efficacy, and safety of drugs and devices being considered for market approval;

-- HCFA develops medical necessity, quality, and appropriateness standards to guide PSROs in their local review activities, e.g., the agency awarded contracts totalling $1.8 million to eight health professional groups to develop sample criteria and standards sets for medical necessity of hospit-

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alization and appropriateness for use of a variety of procedures, tests, and drugs; and

-- BHPRD develops standards for access, supply and distribution (through the National Health Planning Guidelines) to assist State and local health planning bodies.

A major problem cited by nearly every agency developing or using standards is the need to implement viable standards as quickly as possible and the inadequacy of the technical knowledge base for doing this. It is in large part this mismatch between the important need and the lack of data which makes this area of analysis particularly deserving of attention.

Moreover, the absence of linkages between agencies responsible for standards development and other knowledge development agencies means that the data necessar to undergird standards development is not being produced; the methodology for transferring technical data into standards is weak and the process for doing so superficial As a result, the standards evolved are more normatively than empirically based. In part, this state of affairs can be attributed to pressures to produce standards withou delay. However, these failures will not be overcome without a far more integrated process.

Comprehensive Technology Assessment

Comprehensive technology assessments examine holistically the potential future consequences of new or emerging technologies on such societal systems as the economy, the physical environment, the law, institutions, mores, ethics, and broad social fabric. These interdisciplinary assessments scrutinize what the proposed technology is intended to achieve, whether those achievements are socially desirable, who might benefit or lose from the achievement, what unintended consequences are likely, and what policy options are available to

economy, the physical environment, the law, institutions, mores, ethics, and broad social fabric. These interdisciplinary assessments scrutinize what the proposed technology is intended to achieve, whether those achievements are socially desirable, who might benefit or lose from the achievement, what unintended consequences are likely, and what policy options are available to

either avert side effects or to prepare more effectively for the unintended social change likely to be triggered by the new technology. Currently, there are isolated instances of examinations of discrete societal areas:

-- economic impacts have been examined by NIH, FDA and NCHSR. (For example, FDA examined the cost to manufacturers and consumers of complying with new performance standards of x-ray machines);

-- behavioral aspects of venereal disease carriers and treatments have been studied by CDC;

-- environmental impact assessments have been conducted by NIH (on Recombinant DNA Molecule research) and FDA (on radiation technology); and

-- societal impact has been examined in three NIH studies. The study on the totally implantable artificial heart is considered a forerunner of comprehensive technology assessment despite its small scale because it involved a multidisciplinary team which analyzed a broad range of societal implications of the device.

No agencies are currently conducting comprehensive technology assessments. This deficiency should be remedied in light of the increasing recognition that societal impacts of some technologies may be more profound than their direct economic cost. Lack of technical knowledge, resources, and a mandate for such analysis have apparently precluded its development, although last year NCHSR examined the feasibility and utility of such studies (see Part D of this section) and NIH has considered "preliminary" impact assessments as part of its "consensus building" strategy (see Section V-D).

Methodological and Cross-Cutting Studies

These studies are typically undertaken to provide background information to the

considered "preliminary" impact assessments as part of its "consensus building" strategy (see Section V-D).

Methodological and Cross-Cutting Studies

These studies are typically undertaken to provide background information to the

agency or to overcome state-of-the-art research limitations. Agency-reported activities of this type include:

-- case studies of technology adoption and diffusion by HRA and NCHSR;

-- use of computers for biomedical information transfer by NIH;

-- development of models for assessing the quality, safety and performance of drugs, devices and biologics by FDA;

-- identification of new technologies and their implications for manpower, operating costs and capital expenditures by BHPRD;

-- development of models to predict treatment outcomes, control measures, and prevalence of venereal disease by CDC; and

-- development of a model to forecast net social value of dental caries prevention procedures by NIH.

No significant work is being done to relate magnitude and seriousness of health problems to absent or lagging technology development and allocation of R&D resources. For example, heart disease is by far the leading cause of death, but it commands approximately 10 percent of the R&D allocations. Little theoretical work is being done on adoption and diffusion of medical technologies and this is particularly important since comparable studies in other technological fields which show slow rates of diffusion may be misleading in light of the absence of a classical market structure in the health field.

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C. Recommended Approaches

It is recommended that:

-- there should be more cost-benefit and cost-effectiveness analyses which would serve the needs of the action agencies;

-- there should be a new program initiative for conducting comprehensive technology assessments;

-- increased attention should be paid to studying the efficacy and safety of existing technologies, particularly medical and surgical procedures;

-- increased research emphasis should be placed on health problems for which insufficient R&D is allocated and for which the current incentive structure does not suffice; and

-- increased emphasis is needed on methodological studies to improve the state-of-the-art of technology-based analysis and testing.

D. NCHSR Proposal for Comprehensive Technology Assessment

The NCHSR has advanced a proposal calling for the creation of a 3-6 person Technology Studies Group to add the capability for conducting comprehensive technology assessment to NCHSR's existing capabilities for studying cost-benefit, cost-effectiveness, and technical feasibility. The NCHSR proposal states:

> "Unlike the more discrete studies which concern themselves with particular aspects of a health technology, the new interdisciplinary technology assessment strategy provides a comprehensive analysis of their likely future effects.
>
> "NCHSR proposes to conduct holistic assessments, representing significantly different levels of effort ranging from $10,000 to $350,000 per study. The research strategy is to use micro or mini-technology assessments as a small scale screening tool to refine the research problem involved in the candidate technology and to decide what type and scope of follow-up study is really appropriate.

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"NCHSR proposes to conduct holistic assessments, representing significantly different levels of effort ranging from $10,000 to $350,000 per study. The research strategy is to use micro or mini-technology assessments as a small scale screening tool to refine the research problem involved in the candidate technology and to decide what type and scope of follow-up study is really appropriate.

> "Thus, for example, a micro assessment conducted on a computerized EKG is likely to result in a judgment that it is a straight forward technology which raises no significant societal questions and the appropriate follow-up study might be a cost-effectiveness study. On the other hand, a similar assessment conducted on a nuclear powered heart is likely to reveal that it raises profound questions about the environmental radiation impacts, the psycho-social side-effects, the ethics of allocation, the dollar costs, the technical feasibility, and political-legal problems for which a full scale follow-up assessment is warranted."

The proposal has obvious advantages: it would provide the Department with a needed capability which is now absent, and it fits into the mission of NCHSR. There are also negative aspects: significant dollar costs are involved, and there may be overlaps in function between this proposal and NIH's OMAR proposal (see Section V). There was insufficient time to evaluate this proposal or develop alternative options for institutionalizing comprehensive technology assessment. We recommend that this be done in Phase II. If Phase II takes an extended period of time, however, we then recommend that the Secretary request that a decision paper be prepared on the NCHSR proposal.

V. REVIEW AND SYNTHESIS

-- How can the Department collect and reduce to a useable form the technical information needed to make Departmental decisions regarding a technology?

-- How can the Department facilitate the flow of technology-related technical information to those outside the Department who effect and are affected by medical technologies?

A. Description of the Review and Synthesis Component

DHEW Decisionmakers and other users are unable to effectively locate and use much of the new and existing information about technologies because they are unaware of its existence; it is not in a form understandable to them; or they lack the resources to integrate such information and bring it to bear in a timely manner.

This component is designed to review and synthesize (1) reports generated during the preceeding analysis and testing stage, (2) other reports and technical information and (3) advice and recommendations from various parties-at-interest (such as manufacturers, providers, physicians, and consumers). The resulting syntheses are (1) presented to the Secretary (if it deals with a high priority technology) or other Departmental decisionmakers in a form suitable for making reimbursement, standard-setting, R&D funding, and other decisions that promote or impede technologies; and (2) transmitted to other Federal and non-Federal entities to encourage collaborative and consistent responses to technologies. The Department-level technology management unit would manage the review and synthesis process for high-priority technologies, and work with agencies to promote improvement in their internal and interagency review and synthesis activities.

B. Agency Activities and Deficiencies

The agency reports indicate an increasing awareness of the need for structured review and synthesis, but it is clear that additional emphasis and new initiatives are needed.

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B. Agency Activities and Deficiencies

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NIH, in some instances, provides the results of its studies to other agencies needing this information -- for example, vaccine research findings are given to the FDA and CDC. NIH has, as a result of their increasing awareness, recently begun to synthesize test results. A recent project involved synthesis of existing information on hypertension in order to develop consensus-based recommendations for diagnosis and treatment.

A similar exercise, on breast cancer screening, has just been completed. NIH has also submitted a formal proposal (see part D of this section) to OASH for a major "consensus-building" initiative which is designed to increase the agency's capability for synthesizing and transferring scientific findings to the health care community.

NCHSR reports that it channels the results of studies to decisionmakers and other users through two mechanisms: 1) by involving them actively in the setting of research priorities and in the development of individual projects, and 2) by issuing an ad hoc series of non-technical reports which synthesize research findings from several related projects in progress or shortly after completion.

CDC has an explicit process by which test results are reviewed and synthesized. In some cases recommendations are given to other agencies (for example, FDA or State agencies) but they are primarily used in CDC program planning.

FDA has the most formal and structured synthesizing processes. These are legislatively mandated reviews of efficacy and safety test results. These technical reviews result in recommendations to approve or not approve marketing of the product, with such recommendations then being acted upon within the FDA itself. Thus, for pre-market approval, the review, synthesis, and decisionmaking at FDA constitute a continuous formal process. No similar process exists for review of data resulting from market surveillance. FDA is aware of this deficiency and is investigating ways to solve it.

TRADE secrets

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TRADE secrets

OQS. When a Medicare coverage question is triggered by a claim for a new or unusual medical service, the former Office of Quality Standards (now the Office of Health Practice Assessment) synthesizes available efficacy and safety information on that service to develop recommendations for reimbursement. The Office reported five serious deficiencies with the current ad hoc approach to synthesis:

1) it is a reactive approach which provides no structured way to anticipate questions about technologies about to enter medical practice;
2) coverage questions are not being raised about outmoded or ineffective technologies;
3) dollar costs of the technologies in question are not included in the review criteria;
4) the ad hoc process of searching the literature, or telephoning experts, to respond to the coverage question, provides no assurance that the best and most reliable data are obtained; and
5) there is no pathway for raising the question of whether the technology warrants a serious study to produce currently unavailable data.

To respond to this current set of deficiencies, the Office of Quality Standards is sponsoring a Medical Practice Information Demonstration Project in collaboration with NIH, HCFA, and ADAMHA (See addendum to Appendix Tab 11). This project is an attempt to demonstrate the feasibility of gathering, validating, and synthesizing the most authoritative data on three disease categories (depression, malignant melanoma and rheumatic heart disease). The findings are designed for use in three ways: in quality assurance programs (such as PSRO), in setting biomedical and health services R&D priorities, and in medical education. If the project is successful, it may be desirable to replicate it on a larger scale.

The problems cited by OQS were also raised by HCFA, which is both a major user of

ways: in quality assurance programs (such as PSRO), in setting biomedical and health services R&D priorities, and in medical education. If the project is successful, it may be desirable to replicate it on a larger scale.

The problems cited by OQS were also raised by HCFA, which is both a major user of

study findings and a potential feedback agent to the front end of a technology management process (by articulating the need for studies and identifying types of technologies which should be developed for more effective medical practice). HCFA is especially interested in a more structured approach to review and synthesis of the findings of cost-benefit and cost-effectiveness studies. HCFA would like this synthesized information channeled to the PSROs for use in their reviews of medical necessity, quality, and appropriateness of those health services funded by Medicare, Medicaid, and the Maternal and Child Health programs.

In addition to these agency-based problems, there are a number of Department-level deficiencies. Within DHEW, very few inter-agency agreements exist by which study findings are transferred from the agency conducting the study to an agency which will use the findings. In general, there is no mechanism for assuring systematic "translati of bulky scientific and technical information into a form relevant for policymaking or for ultimate users such as providers and consumers. This deficiency has serious consequences for the Department. If the results of a study are not channeled to relevar decisionmakers and other users, much of the cost of conducting that study is wasted. Department decisions may be delayed or made without the benefit of information which is, in fact, available; studies may be started which duplicate existing or recently conducted efforts; and medical practice may remain unaffected by relevant findings.

C. Recommended Approaches

It is recommended that a Department-level capability be established to stimulate and coordinate the following: 1) agency review and synthesis activities; 2) translation of technical material into policy relevant form for decisionmakers and into understandable form for other non-technical users; and 3) dissemination of results to relevant parties.

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D. NIH Proposal for an Office for Medical Applications of Research

NIH proposes to establish a capability in each Institute for reaching a "technical consensus" on specific medical technologies or disease areas. Consensus-building involves: 1) identifying and evaluating new information on a technology, 2) reaching technical consensus on the validity and significance of research findings and on their readiness for wide clinical use, 3) preliminarily assessing non-medical implications and 4) producing recommendations in a form for ready acceptance and application by the health care community. Central support and coordination would be provided by an Office for Medical Applications of Research (OMAR) in the Office of the Director of NIH. The proposal has both positive and negative aspects: For example, it would complement a Department-level review and synthesis function, and is aimed at an area in critical need of improvement. On the other hand, NIH does not specify what criteria are to be used in selecting technologies for examination; significant dollar costs are involved; and the preliminary impact assessments appear to duplicate proposed activities of NCHSR (see Section IV, Part D).

In Section IX of this report, the Study Team recommends a follow-up (or Phase II) study relating to the implementation of recommendations for overcoming the deficiencies that have been identified. We believe NIH's OMAR proposal (and the NCHSR proposal) should be evaluated in the context of an array of alternative approaches to overcoming these deficiencies. If it should be decided, however, that the Phase II study should take place over an extended period, we recommend that these two proposals be presented to the Secretary as decision papers. While approval of the proposals would limit future alternatives, continued absence of the capabilities proposed would have adverse effects on the Department's interest in improving its technology-based activities.

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VI. DECISIONMAKING

-- How are technology evaluation results converted into reimbursement, market aggregation, certificate of need and other kinds of technology impeding or stimulating actions?

-- Who should have the responsibility for taking the study findings and expert opinion collected during the review and synthesis process, and choosing among action alternatives?

A. Description of Decisionmaking Component

Decisionmaking is the bridge between the development of technical information about a technology and the action steps which might be taken to impede or promote use of a technology. The preceding review and synthesis component presents a technology for decision; this component assures that decisions are made and that they are coordinated.

Once the Secretary (or his designate) has reached a decision about a technology on the Department's high priority list, he would select which intervention mechanism(s) to employ, and would charge the relevant action agencies to alter regulations, draft standards, reallocate R & D funds, design a targeted practitioner education initiative, etc. Implementation would be coordinated by the Departmental-level management un and would be related to budget and legislative decisions and integrated, if feasible, with actions of other Federal agencies or non-Federal organizations. For technologi which are not on the Department's high priority list, the Department-level unit will oversee the agency-based decisionmaking process to assure coordinated and consiste decisionmaking.

B. Current Agency Activities and Deficiencies

Where a single agency develops knowledge about a technology, internally decides on t significance of that information, and then exercises intervention mechanisms over wh

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it has control to influence the use of the subject technology (a "closed loop" process), the process typically appears to be relatively well-defined, integrated and purposeful. For example, where FDA's multi-disciplinary technical staff makes a recommendation to a Division Director regarding a new drug application, the Director knows (based on its degree of innovation classification) whether he can make the final decision or must raise it to the Bureau's Assistant Director for New Drug Development. The action lever--approval/denial to market, and associated conditions--lies wholly within FDA's control, and the transition from decision to action is integrated and routine. As we have stated previously, FDA is exceptional in this regard.

No — it isn't

On the other hand, the decision-implementation relationship becomes significantly less efficient and effective where, for a given technology,

-- the pertinent response mechanisms are located outside the knowledge-development agencies; or

-- the intervenrion mechanisms are scattered across several action agencies; or

-- there is no external pressure (as there is from the applicant drug or appliance manufacturers) to reach a clear, timely and supportable decision.

Examples of problems culled from Agency reports include:

-- "At the NIH, explicit formal processes have not generally been utilized in dealing with decisions concerning medical technologies and assessment results." Although some interagency agreements and coordinating committees are alluded to, it is clear that NIH confines its implementation activities to the information dissemination process, and that findings are not well-linked to external action agencies.

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and coordinating committees are alluded to, it is clear that NIH confines its implementation activities to the information dissemination process, and that findings are not well-linked to external action agencies.

-- Medicare obtains reimbursement guidance from the PHS Office of Quality Standards through working staff contacts. The recommendations appear to have been generated in an ad hoc manner which failed to assure that useful complementary actions are employed by other arms of the Department. (This is expected to improve under the PHS reorganization and the establishment of the Office of Health Practice Assessment).

-- HRA's Bureau of Health Planning and Resources Development developed technical standards and criteria monographs relating to 16 technologies as guidance for health planning agencies. While these monographs are available through NTIS, "There has been no final determination as to the value of the monographs (and) they have not been endorsed..." In addition, although case studies have been developed under contract for eight other technologies, only one has been released (in response to high demand) and it has received no endorsement.

-- PSRO: "Unfortunately, (efficacy/outcome information on medical technologies) is generally not available, and the more difficult and time consuming approach of attempting to get a (standard-setting) consensus based on practice experience must be used." "From the perspective of (HCFA's Health Standards and Quality Bureau), decisions on results of technology assessment research are not systematically occurring, nor is there a structured approach for feeding decisions into medical practice."

the perspective of (HCFA's Health Standards and Quality Bureau), decisions on results of technology assessment research are not systematically occurring, nor is there a structured approach for feeding decisions into medical practice."

The Study Team believes that there needs to be a visible and predictable decision-making process which converts the weight of technical information and expert opinion into broadly coordinated interventions which affect the generation, adoption, diffusion, or phase-out of technologies. For high-priority technologies, such decisions should be made by the Secretary or his designee to lend the influence of his office to agencies' commitments to take indicated actions, and to promote collaboration by other Federal and key non-Federal entities.

C. Recommended Approach

It is recommended that one of the primary functional responsibilities of a Department-level technology management unit be to assure that (1) Secretarial decisions on high-priority technologies are implemented, (2) responsibilities for making decisions on other technologies are clearly defined and appropriately delegated to the relevant agencies, (3) relevant decisions of one agency are consistent with those of another, (4) agency decisions take into consideration potential for collaboration with other Federal agencies and non-Federal entities, and (5) that agency decisions are consistent with Departmental policies or are used as triggering devices for formulating new policies.

VII. INTERVENTION MECHANISMS

-- What mechanisms does the Department have to impede or stimulate development, utilization and phase out of medical technologies?

A. Description of Overall Component

Intervention mechanisms are the Department's means to affect the development, adoption, diffusion, utilization, and phase-out of medical technologies to ensure the availability of quality health care. Specifically, policy, fiscal, educational and other mechanisms can be used to ensure that:

-- needed cost-effective technologies are brought into appropriate use more quickly;

-- existing technologies which are outmoded, inefficacious, or inappropriately used are curtailed;

-- developing technologies which may impact negatively on the health care system or on society are appropriately modified or arrested.

Four classes of intervention mechanisms need to be employed by the Department:

- o Regulatory mechanisms
- o Transfer and/or phase-out mechanisms
- o Pre-market incentive and/or disincentive mechanisms
- o Market incentive mechanisms

These classes of mechanisms and the specific types within each class come into play at different stages of the life cycle of a technology. Further, the role of responsible departmental agencies in the administration of the specific controls varies. In some cases, the agencies have direct responsibility, while in other cases, primary responsibility is at the State and local level and the Federal agencies only provide guidance, exemplary standards, and oversight.

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Figure 2 is a matrix of technology life cycle stages and specific types of controls and incentives within each class of intervention mechanism which may be applied to them at various stages of development.

The potential application of current intervention mechanisms is depicted on the figure. The matrix shows that there are numerous controls applicable to the adoption, use and replacement stages and only three for the research and development stages. This apparent imbalance implies that the Department has considerably more power to affect later stages of the life cycle. In fact, this is misleading. It is not the number of controls applicable to the various stages which is important; rather it is how effectively those controls are used. R&D resource allocation controls, for example, are a powerful mechanism if their full potential is realized through effective policy and decisionmaking. These considerations are addressed in more detail in the following sections.

Further, when considering intervention mechanisms, it is important to realize that medical technology development, adoption, diffusion and utilization is driven by the following factors:

- Most hospitals are paid retrospectively and on a cost basis for technology-based capabilities; and, therefore, may tend to be indiscriminate in their purchase and use practices.

- The medical ethic essentially says that there is "nothing too good for the patient" and this coupled with financial benefits to the physician for technology based services, also contributes to indiscriminate practices.

- Consumers generally are not sensitive to, or responsible for financial aspects of medical care and, therefore, may be similarly indiscriminate in their demands. A large portion of medical services, for example, are

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STAGES OF DEVELOPMENT / INTERVENTION MECHANISMS	BASIC RESEARCH	APPLIED RESEARCH	ENGINEERING/ FEASIBILITY	VALIDATION	MANUFACTURING/ MARKETING	ADOPTION/ TRANSFER/ DIFFUSION	UTILIZATION/ PRACTICE	REPLACEMEN OBSOLESCEN
Regulatory Mechanisms								
*Market Approval/Disapproval					●	●		
*Certificate of Need/Sec. 1122						●	●	
*Professional Standards Review							●	
*Reimbursement						●	●	●
*Health Planning Guidelines							●	●
Transfer and/or Phase Out Mechanisms								
*Demonstrations				●		●	●	●
*Information Dissemination	●	●	●	●	●	●	●	●
*Professional Education						●	●	●
*Consumer Education						●	●	●
*Patent and Licensing Policy		●	●	●	●	●		
Pre-Market Incentive and/or Disincentive Mechanism								
*Allocation of R&D Funds	●	●	●	●				
Market Incentive Mechanisms								
*Development Subsidies			●	●	●	●		
*Tax Subsidies					●	●		
*Market Aggregation					●	●		

Figure 2: Relationship between Intervention Mechanisms and Stages of Technology Development

reimbursed by third party payers, and many consumers are covered by insurance programs where all or a part of the premium is paid by their employer.

Basically, these factors operate as uncontrolled incentive mechanisms. The Department presently is taking initiatives, including legislative action now pending, to deal with problems resulting from these factors.

REGULATORY MECHANISMS

A. Description of Component

There are five specific regulatory controls employed by the Department:

(1) Market Approval/Disapproval

FDA approves or disapproves the introduction of drugs and medical devices into the marketplace based upon a determination of the efficacy and safety of the technology. FDA also may issue conditional approvals which restrict where and how the technology can be used.

(2) Certificate of Need/Section 1122

Certificate of Need (CoN) and Section 1122 require the review and approval of specified capital expenditures and proposed changes in health-services. States implement these mechanisms with input from local health planning agencies and in accordance with minimum regulations established at the Federal level by BHPRD. CoN regulatory authority and practices vary across the States. Only one State is without either mechanism.

(3) Health Planning Guidelines

The forthcoming National Guidelines for Health Planning will have to be considered by local health planning agencies in developing their plans, and in conducting appropriateness reviews and the review of proposed services. Although not strictly a regulatory mechanism, the guidelines will affect decisionmaking at all levels

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through their expression of national policy on the appropriate supply, organization and distribution of health resources.

(4) Professional Standards Review

Professional Standards Review, conducted by local Professional Standards Review Organizations (PSROs), determines the necessity, quality and appropriateness of health services (and, therefore, medical technologies) reimbursed under Medicare, Medicaid and the Maternal and Child Health Program. PSROs receive guidance from the Health Standards and Quality Bureau within HCFA in the form of sample sets of norms, criteria and standards but may adapt these to local practices. PSROs exist in a little over half the designated areas and have concentrated their initial activities on the use of hospitalization.

(5) Reimbursement

Reimbursement mechanisms employed by the Department are limited to the approval or disapproval of reimbursement under Medicare for health services and technologies. HCFA makes such determinations, which often guide the reimbursement practices of Medicaid and other third party payers which are not within the jurisdiction of the Department.

B. Agency Activities and Deficiencies

Overall roles and responsibilities of the various agencies were discussed above. Specifically, the problems reported by the action agencies are of two types: those inherent in the regulatory mechanisms themselves and those resulting from analytic deficiencies, notably the difficulty in establishing standards. Many of the regulatory mechanisms, although available, are currently in a developmental state either because their legislative mandate is relatively new (Medical Device Amendments; P.L. 93-641), or because established policies and procedures are not adequate to address the complex issues posed by modern medical technologies.

mechanisms, although available, are currently in a developmental state either because their legislative mandate is relatively new (Medical Device Amendments; P.L. 93-641), or because established policies and procedures are not adequate to address the complex issues posed by modern medical technologies.

The Bureau of Medical Devices has not yet completed formulation of pre-market and post-market assessment procedures and performance standards which are comparable to those of the Bureau of Drugs. Though the state-of-the-art of developing standards for technologies was identified as a limiting factor, the Bureau of Medical Devices also reported that FDA procedures and the process of promulgating regulations have further hampered the process.

Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) are new State and local planning agencies in many cases, and the resource materials and technical assistance structure which will support their regulatory functions are not all in place. Appropriateness Review is not yet a required HSA and SHPDA function and issues surrounding its regulatory aspects are unclear. The draft National Guidelines for Health Planning are too recently issued to have had an effect on the health care system. PSROs are established in only a little more than half the designated areas and sample criteria sets have been issued only for pre-admission and continued-stay-review for hospitalization. From the agency reports, it is obvious that the newness of these regulatory mechanisms or their present state of development constitute a major set of deficiencies.

Other programmatic problems identified by the Study Team include an overall lack of coordination and the exclusion of some medical care providers from regulation. Further coordination is needed between the various regulatory mechanisms in order to assure consistency in their decisions. The fact that CT head scanning was approved under Medicare while BHPRD was stating that it did not have sufficient information to issue guidelines about CT services, exemplifies the lack of consistency between the action agencies. The Study Team also considers that the regulatory mechanisms of CoN and Section 1122 approval are weakened by the exclusion of physicians' offices and other ambulatory care providers from the requirements. Without the authority

to issue guidelines about CT services, exemplifies the lack of consistency between the action agencies. The Study Team also considers that the regulatory mechanisms of CoN and Section 1122 approval are weakened by the exclusion of physicians' offices and other ambulatory care providers from the requirements. Without the authority

to control the acquisition of technologies outside health care facilities, local and State planning agencies cannot, in our opinion, effectively plan and regulate the health care delivery system for which they are responsible.

The action agencies identified the lack of technical consensus about emerging and existing technologies as a major analytic problem to their regulation. Although BHPRD has developed monographs addressing 16 health services and has a contractor working on a series of case studies describing specific technologies, neither of these efforts resulted in specific standards that planning agencies could use for decisionmaking under CoN and Section 1122 because of lack of consensus. HCFA also reported the lack of technical consensus as a major problem in the development of model sets of standards for PSROs to use in reimbursement decisions and quality assurance. The recently issued National Guidelines established quantitative standards which (when issued in final form) must be considered by health planning agencies. These may contribute to a movement towards consensus about medical technologies and assist in the development of standards on which to base CoN and Section 1122 approval.

The scarcity of data about existing technologies was identified by the agencies as a factor contributing to the difficulty of reaching consensus. Information was reported to be urgently needed for State and local health planning decisions and for PSROs. The inadequacy of the existing knowledge base and the lack of dissemination of research findings also were cited by BHPRD, HCFA, and OQS as major impediments to the development of standards.

HCFA identified a need for more comprehensive review of new technologies in order to assist in the development of Medicare reimbursement policies. In addition, HCFA reported that additional research on the appropriate conditions for use of particular technologies is needed to assist PSROs and reimbursement mechanisms in the development of standards-for-use and thus the establishment of payment policies.

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Lastly, it should be noted that, while the Study Team agrees with the action agencies about the need for a more structured approach to obtaining technical information about medical technologies, we are in no position to comment on the extent to which the current lack of this information affects their performance, since evaluation of their performance and productivity is beyond the scope of this Phase I inquiry.

TRANSFER AND/OR PHASE-OUT MECHANISMS

A. Description of Component

There are five specific types of mechanisms employed by the Department to stimulate the transfer or diffusion of a desirable technology and/or to phase-out an outmoded or unsafe technology:

- o Demonstrations
- o Information dissemination
- o Professional education
- o Consumer education
- o Patent and licensing policy

Demonstration projects are undertaken primarily to obtain information from which the future course of development and application of a technology can be determined. Demonstration projects also have the potential for directly stimulating or arresting the diffusion of the technology.

Information dissemination and professional and consumer education activities, which are often interrelated, are intended to influence the decisionmaking of practitioners, other health professionals, researchers and consumers on the use of medical technologies. This is accomplished by using such media as medical journals, pamphlets, professional meetings, and conferences to inform these parties about the important positive and negative aspects of technology.

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Similarly, patent and licensing policy may be used to encourage or discourage the introduction, diffusion or application of drugs and devices developed with Federal support.

B. Agency Activities and Deficiencies

The agency reports overall indicated only modest use of these mechanisms to transfer technologies, and virtually no use to curtail or phase-out outmoded or inefficacious technologies.

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NIH, however, reported substantial and increasing activity in the dissemination of information, physician and consumer education, and demonstration projects. For example, NIH established a Task Force on Communications in 1975 in the Office of the Director to recommend steps to improve the dissemination of information to health professionals and the general public. The various Institutes sponsor a variety of meetings for biomedical researchers and medical practitioners; publish journals, monographs, bibliographies and pamphlets; write a monthly section for the Journal of the American Medical Association dealing with emerging technologies relevant to medical practice; produce radio and television announcements; conduct seminars for scientific writers; and operate an information clearinghouse in specific disease categories (e.g., the Cancer Information Clearinghouse at NCI). NIH also undertakes the majority of demonstration activities of the Department. The NHLBI and NCI, in particular, are required by their legislation to conduct demonstrations and education programs for professionals and the public. Further, under the auspices of the various Institutes, more than 50 research centers have been established throughout the country. In addition, the NIH's National Library of Medicine is able to provide continuously updated information from its guide to Medical Literature, Index Medicus, by means of the computerized "Medline" system. This is available nationwide through 750 terminals in hospitals, medical schools, and libraries, and is backed up by 11 Regional Medical Libraries.

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NCHSR funds demonstration projects of various computer-based diagnostic, therapeutic and screening technologies. These projects focus on obtaining further information about validity, efficiency, cost-effectiveness, and user acceptance, but also aid in the diffusion of worthwhile innovations. To facilitate adoption of some of its projects and elimination of barriers to the transfer of viable innovations, NCHSR has produced user guidelines and supported "user group organizations."

An Office of Health Information and Health Promotion was established recently in OASH to provide the Department with a focus for consumer education activities. This office, which plans to concentrate its efforts in areas where there is an absence of current activities, will assist the agencies in carrying out any aspects of their missions which involve or could involve consumer education, and will develop programs for the "education of the public in the maintenance of personal and family health and in the appropriate use of the health care system." This program is likely to encounter many of the problems commonly associated with the inadequacy of hard technical information about the effectiveness of many technologies. Also, the methodologies used in affecting consumer behavior are imperfectly developed.

These same informational and methodological problems apply to professional education activities. In this case, the problems are compounded because there is no departmental focus for activities relating to the continuing education of physicians and other health professionals. Practicing physicians currently do not have an adequate source of information about the technologies that they are using or could use, and medical literature often is not directed towards the needs of practitioners or written in terms familiar to them. In fact, the quality of that literature has been called repeatedly into question.

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in this report (e.g., the Medical Practice Information Demonstration Project and the Department-level Review and Synthesis component described in Section IV) could aid in resolving these information and education problems.

NIH, however, reported that any further involvement in professional education might be inappropriate or infeasible. "Infeasibility" was related principally to resource limitations, and "inappropriateness" suggested unwillingness. Since NIH currently is the most active agency in this area, it appears unlikely that substantial improvements in professional education will take place without a new locus for such activity elsewhere in the Department.

There was no explicit request in the Agency Report Form for information on patent and licensing policies or activities. Agency reports, therefore, provided no basis for discussion of these mechanisms. The Study Team is aware, however, that the Department has not articulated a policy which recognizes the dual use that patents and licenses can perform in encouraging or discouraging innovations resulting from DHEW-funded R&D.

PRE-MARKET INCENTIVE AND/OR DISINCENTIVE MECHANISMS

A. Description of Component

The allocation of R&D resources is an effective means for directly affecting technology development. Pre-market mechanisms can be used to stimulate, retard or redirect technology development. Decisions on the type and amount of R&D resources to be applied in any given area would be based, for example, on criteria such as the overall mission of the Department, the nature of the problem, the importance of the problem, and the availability of funds.

B. Agency Activities and Deficiencies

Agencies reported no conscious or formal use of R&D resources allocation policies

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B. Agency Activities and Deficiencies

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as pre-market incentive or disincentive mechanisms. Such policies, however, are de facto control mechanisms, which reflect major judgments about health needs and national priorities. The problem for the Department is that the agencies simply do not review allocation of R&D as an intervention mechanism even though the Agency Report Outline explicitly labeled it that way.

This gap in the agencies' perception and planning is particularly striking since it occurs despite the recent barrage of criticism of DHEW for investing too much money on what Dr. Lewis Thomas has termed "halfway technologies" such as renal dialysis which is palliative, and too little money on technologies such as vaccinations which are preventive, or antibiotics which are curative.

It indicates that one of the Department's most powerful intervention mechanisms is not being employed for technology management purposes.

MARKET INCENTIVE MECHANISMS

A. Description of Component

Market incentive mechanisms are intended to encourage private corporations to develop and commercialize medical technologies which meet a unique public need but which lack a sufficiently attractive market from the perspective of the industry. Such mechanisms include:

- o Development subsidies
- o Tax subsidies
- o Market aggregation

Development subsidies essentially are direct payment schemes by which all or a part of the costs to take a technology from the "breadboard" or prototype model to the production stage are paid by the Government.

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Development subsidies essentially are direct payment schemes by which all or a part of the costs to take a technology from the "breadboard" or prototype model to the production stage are paid by the Government.

Tax subsidies basically are indirect reimbursement schemes by which all or a

part of the costs to develop actual manufacturing capabilities and/or produce a technology can be deducted from the taxable income of the organization.

Market aggregation refers to Government action to guarantee an exclusive market for a given technology which it desires, but which private corporations consider not cost-effective (i.e., manufacturing and sales costs cannot be sufficiently recovered and/or free market profit margins are too small or uncertain). This mechanism, therefore, assures a minimum sales volume and/or exclusive access to specific interested buyers (e.g., VA, PHS, DOD, GSA) for a given length of time.

B. Agency Activities and Deficiencies

Agencies essentially reported no @ctivities to develop and apply market incentive mechanisms. The Study Team concluded, therefore, that either little was being done with this class of intervention mechanisms, or that the utility of such activities have not been recognized by agency managers. The situation appears to be comparable to the agencies' lack of a strategy for allocation and reallocation of R&D resources as an intervention mechanism.

While the agency reports demonstrated considerable concern with the problem of restricting technology use, they demonstrated no comparable concern with identifying and stimulating beneficial but lagging technologies which are not being developed because they fall between the cracks of the health care market. For example, preventative, rehabilitation, mental health and environmental technologies could reduce costs, but many are lagging in development because the normally overgenerous medical reimbursement system does not cover their use.

This gap in agency planning should be addressed at the Department level. It calls first for systematically identifying lagging or absent beneficial technologies and then, on the basis of the identification, for developing a more balanced strategy for managing technology development.

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It is worth noting that the Experimental Technology Incentives Program of the Department of Commerce has the explicit mission of helping Federal agencies conceptualize and implement experimental approaches to technological innovation. This Federal resource should be used, particularly because some of the lagging technologies mentioned above are likely to fall beyond the traditional purview of DHEW (e.g., air pollution and automobile safety) and these call for collaborative efforts with other Federal Departments.

The Study Team believes that there are unrealized opportunities for the Department to promote incentive actions within its purview and to influence incentive actions in areas in which it does not have direct responsibility but which may impact both departmental resources and the overall health of the American public.

C. Recommended Approaches

Overall, we recommend that the Department undertake a comprehensive review to determine why most of its intervention mechanisms are not working effectively; and then to develop and implement policies to expand their scope and improve their effectiveness. In addition, we recommend that:

- The research requirements to establish standards and policies for departmental regulatory mechanisms be clearly articulated and given consideration as research funds are allocated. All of the action agency reports identified some research needs, and we recommend that they be asked to prepare a proposed research agenda.

- Formal linkages be established between HCFA and other reimbursement organizations in both the public and private sector in order for reimbursement decisions to be more consistent, and therefore effective as a regulatory device. All third party payers should have access to information

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relevant to the establishment of policies, and although private third party payers and Medicaid programs can not be compelled to act in concert with Medicare, further coordination between payers should be encouraged to increase the likelihood of a consistent approach to the regulation of technologies through reimbursement.

- o The acquisition of technologies by private physicians and other ambulatory care facilities be subject to the same CoN and Section 1122 review and approval as other prospective purchasers.

- o Current information dissemination and professional and consumer education activities be evaluated from the standpoint of their output (e.g., quality of information disseminated and relevancy of subjects covered), and their impact on the target audiences (e.g., consumers and physicians).

- o A new locus for professional education be developed to coordinate activities among the agencies and to stimulate needed new program initiatives. We recommend that the responsible organization develop a collaborative relationship with the Medical Specialty Boards and academic health centers so that departmentally-generated information may be systematically channelled to them for use by physician recertification programs and other relevant activities.

- o Specific departmental and agency policy be developed for identifying absent or lagging medical technologies and that R&D allocation plans be based on a critical comparative evaluation of health needs relative to the availability of medical technologies to meet those needs.

- o A Departmental policy be developed relating patent and licensing actions to decisions to encourage or discourage innovations resulting from HEW funded R&D.

stupid.

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- A study be conducted to identify those beneficial technologies which are not being developed because current health care policy overlooks them. For example, prevention, rehabilitation, environmental and system management technologies offer the potential for improving health and reducing health care costs, yet HEW appears to be underinvesting in their development.

- A study be conducted of other Government organizations to determine the effectiveness of their activities to promote development and commercialization of critical health-related technologies. As part of this study, the Department should identify both those technologies and activities in other fields which may impact beneficially on health problems (e.g., pollution control technologies), and those technologies and/or fields where the application of appropriate incentives might be encouraged to reduce the occurrence or severity of specific health and medical problems.

VIII. DEVELOPMENT AND MANAGEMENT OF A DHEW TECHNOLOGY SYSTEM

A. Development of the Proposed Technology System

Chapters II through VII compare the Study Team's concept for a DHEW technology management system with the current activities of the Department. To consider how the Department could move from the existing fragmented arrangements to a coherent management system, it is useful to summarize the current deficiencies and the types of needed initiatives.

COMPONENTS	CURRENT ACTIVITIES	DEFICIENCIES	PROPOSED INITIATIVES
toring/Screening	- Three agencies report some activities which could contribute to an identification and monitoring system for existing technologies and NCHSR has concept design for developing technologies	- no catalog of existing, new, and developing technologies - no systematized approach to identifying and screening technologies to be studied	- develop and implement syste for identifying, monitoring, and coarse screening of technologies to be scrutini
-setting	- Agenda -setting occurs at individual agency levels based primarily on those agencies' perceptions of their missions, ad hoc Congressional Requests, and on resource availability	- imbalance between needs of action agencies and interests of knowledge development agencies - no assurance of agencies' focus on Nation's priority needs - no clearinghouse for information and data about technology-based studies	- create a Department-level mechanism and a fine screen process for an annual techn analysis agenda of 15-20 hi priority studies
is and Testing	- There is a strong base for technology-based studies in several agencies - NIH conducted in FY '75 clinical trials of efficacy and safety at a cost of over $100 million; FDA and CDC are also involved in efficacy and safety analysis - NCHSR spent one-fourth of its budget for FY '76 on cost-benefit and cost-effectiveness analysis as part of comprehensive evaluations; NIH, HCFA, and CDC report small-scale efforts in this area - FDA sets standards for quality, efficacy, and safety of drugs and devices, and reviews data and testing procedures of developers; HCFA develops medical necessity, quality and appropriateness standards to guide PSROs; BHPRD develops standards for organization, supply and distribution of health technologies and services. - There are isolated instances of discrete societal impact studies (by FDA, NIH, CDC, NCHSR), and NCHSR has developed a proposal for comprehensive technology assessment. - Examples of cross-cutting and methodological activities: studies of diffusion by HRA; use of computers for information transfer by NIH; development of models to predict treatment outcomes by CDC and to assess technologies by FDA.	- insufficiency of studies of existing technologies, particularly medical and surgical procedures - lack of critical mass of skills for conducting cost-benefit and cost-effectiveness studies - imbalance between action agencies' needs for standards development and knowledge development agencies' capabilities for providing them - no comprehensive technology assessments being conducted and insufficiency of discrete societal impact studies - insufficient effort to identify lagging and absent beneficial and cost-saving technologies - Little theoretical work being done on adoption and diffusion of medical technologies - Insufficient emphasis on methodological studies to improve the state-of-the-art of technology-based analysis and testing studies - ineffective linkage between study findings and agency actions to stimulate or impede technology development	- correct current imbalance o agency agendas - launch new analysis and test efforts in appropriate agenc - evaluate quality of agency studies and staff capabilit and use findings as basis fo realigning agency responsibi - consider NCHSR proposal for comprehensive technology ass ment

developers; HCFA develops medical necessity, quality and appropriateness standards to guide PSROs; BHPRD develops standards for organization, supply and distribution of health technologies and services.

- There are isolated instances of discrete societal impact studies (by FDA, NIH, CDC, NCHSR), and NCHSR has developed a proposal for comprehensive technology assessment.
- Examples of cross-cutting and methodological activities: studies of diffusion by HRA; use of computers for information transfer by NIH; development of models to predict treatment outcomes by CDC and to assess technologies by FDA.

- insufficient effort to identify lagging and absent beneficial and cost-saving technologies
- Little theoretical work being done on adoption and diffusion of medical technologies
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- ineffective linkage between study findings and agency actions to stimulate or impede technology development

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COMPONENTS	CURRENT ACTIVITIES	DEFICIENCIES	PROPOSED INITIATIVES
iew and Synthesis	- NIH has begun to formally synthesize test results (e.g., on hypertension and breast cancer screening) and has developed a proposal for extensive review and synthesis activities - FDA has a formal, structured synthesizing process for reviewing efficacy and safety test results - NCHSR has begun to issue ad hoc non-technical reports synthesizing research findings from related projects in progress	- primarily conducted retrospectively in response to ad hoc questions e.g., reimbursement for Medicare - no mechanism for assuring systematic "translation" of scientific and technical information for DHEW policy and decision-makers or for non-DHEW users	- create a Department-level capacity for oversight and management of review, synthesis and translation of study findings to relevant users in and outside of DHEW - consider NIH proposal for creation of an Office of Medical Applications of Research
isionmaking	- FDA has an explicit process for decision-making regarding approval for marketing of drugs and devices	- no mechanism to assure consistency and coordination of agency decisionmaking - no mechanism to assure that relevant study findings are used to formulate new Departmental policies integrated across program lines	- assign responsibility to Department-level unit to facilitate coordinated agency decisionmaking and policy development and to involve outside parties-at-interest in collaborative effo
tervention Mechanisms	- FDA approves or disapproves the introduction of drugs and devices into the marketplace - National Guidelines with quantitative standards have recently been published in Federal Register - Planning agencies, BHPRD, and PSROs are in early stages of implementing their respective programs - HCFA makes ad hoc decisions about Medicare reimbursement for questionable technologies - NIH reports substantial technology transfer activities in information dissemination, professional and consumer education and demonstration projects - NCHSR supports user groups to facilitate adoption of validated technologies - An Office of Health Information and Health Promotion was recently established in OASH	- most intervention mechanisms still in developmental stages standards for medical devices not yet developed - PSROs not yet established in close to half of the designated areas - appropriateness review standards not yet developed - National Guidelines for Health Planning delayed, and technical assistance structure for HSAs and SHPDAs still evolving - regulatory decisions hampered by lack of technical consensus on standards for efficacy, safety, cost-benefits, and cost-effectiveness, and appropriate conditions for use of technologies - professional education efforts insufficient to needs of practicing physicians for information about appropriateness and effectiveness of technologies - information dissemination effort inadequate to need - consumer education efforts still in definition stage - allocation and reallocation of R&D not perceived by the agencies as an intervention mechanism - inadequate attention paid to market incentive mechanisms to stimulate lagging or absent beneficial and cost-saving technologies which fall between the cracks of health system incentive structure	- create a Department-level capacity for oversight and management of a balanced strategy for impl and/or stimulating technology development, adoption, and uti zation - evaluate and strengthen action agencies' capabilities for management, adoption, transfer, utilization and phase-out of technologies - create a new locus for professional education on utilizatio of technology - establish formal linkages betwe Department and other Federal entities and private sector to develop collaborative efforts for managing technology - launch a new initiative to ider lagging and absent beneficial technologies which fall outside of the health system incentive structure - develop a departmental policy f relating patent and licensing actions to DHEW decisions to encourage or discourage innovations resulting from DHEW-funde R&D

To emplace the proposed technology management system, there will need to be jurisdictional clarifications and realignments among the agencies as well as assignment of new responsibilities and authorities and resources. There are two general approaches to development of the proposed system:

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(1) A "tabula rasa" approach is the most free form (but it might be considered politically naive). It would assume no constraints on shifting existing institutional capabilities or responsibilities, and would thus be unfettered in developing a set of jurisdictional assignments, component linkages, etc. The agencies' roles would then be reformed around the new responsibilities.

(2) An "organizational-change-on-the-margin" approach would adhere to legislated missions, existing professional skills, experience, and so forth, and would design options that fit around existing arrangements and propose marginal changes in the agencies. It is the least disruptive and quickest approach, though the one most likely to be compromised by agency momentum.

The Study Team has concluded that elements of each will be required: marginal change where agencies have demonstrated competence (e.g., efficacy and safety testing of drugs and devices; implementation of certain action mechanisms), and totally new development of such components as agenda-setting, monitoring and screening, review and synthesis, and technology transfer mechanisms.

This month-long Phase I study did not include independent assessments of agency performance or staff capabilities. To advance organizational change alternatives that attempt to overcome current agency deficiencies and, at the same time, take best advantage of existing capabilities would therefore overstep the Study Team's knowledge base. The Team believes it would be more appropriate to assign precisely this responsibility to a Phase II study as recommended in Section IX.

B. Management of the Proposed Technology System

Does the proposed system require oversight management or can its operation be left to the participating agencies? Departmental systems process requirements (like the evaluation agenda or the forward plan) typically assume a very low priority

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for agencies which are constantly trying to discharge major substantive responsibilities. In addition, institutional histories, fragmenting constituent pressures, interagency territoriality, etc. create centrifugal forces that tend to drive agencies apart and frustrate even such simple goals as information exchange. Where they do interact, their understandable jockeying for political advantage siphons energy away from the enterprise. For these reasons, the alternative option of leaving the management of the proposed technology system to a joint undertaking of the agencies is not presented for consideration.

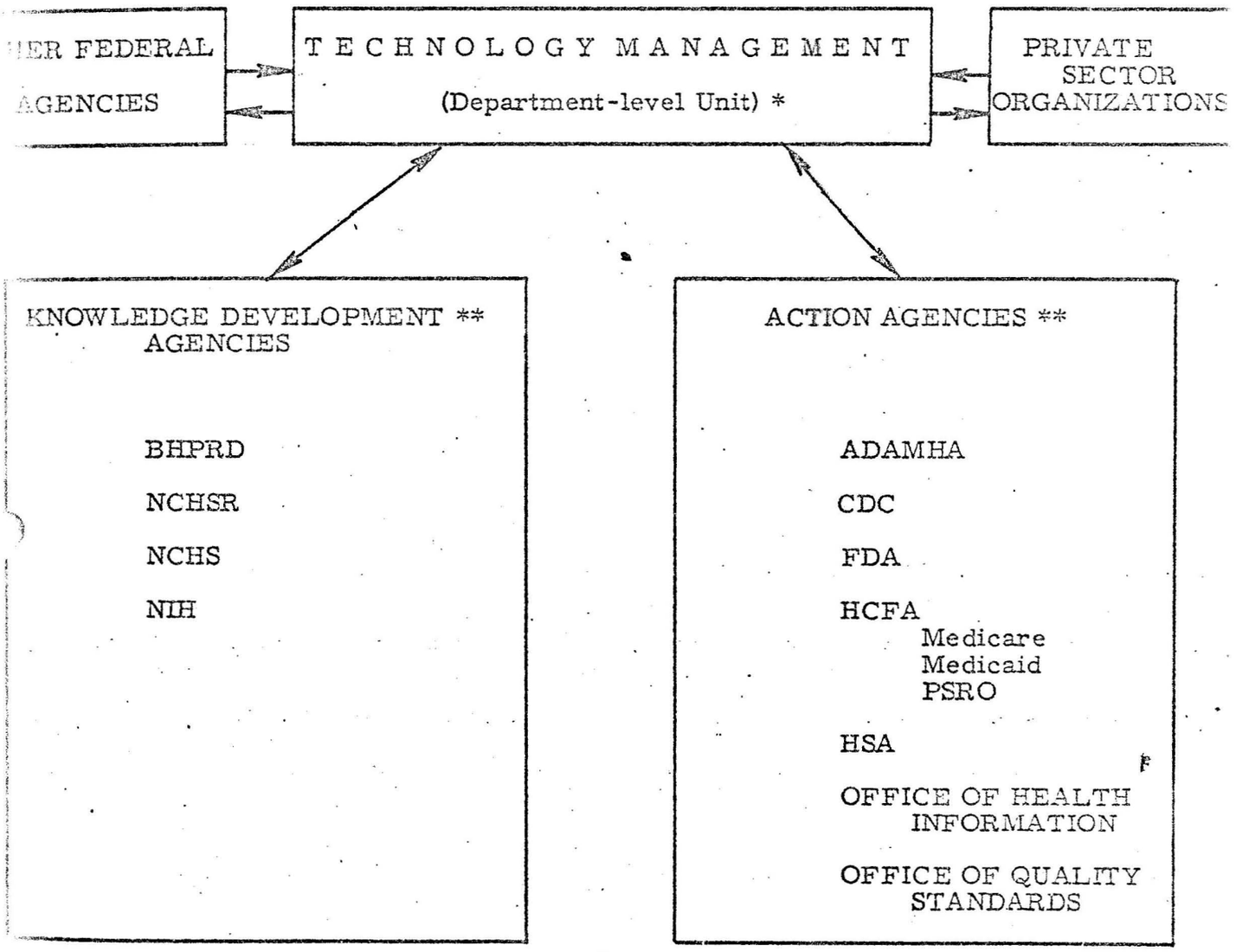
The Study Team concludes that the system will not operate effectively and mature without assignment of the responsibility for its management as a principal (not collateral) responsibility to a Department-level unit. This proposed new unit is depicted in Figure 3. Its responsibilities would include:

- oversight, coordination, evaluation and improvement of agency and interagency technology-related activities;
- management of the analytic agenda process;
- oversight of the review and synthesis function;
- coordination of the decisionmaking process;
- development of policy recommendations for improvement of the technology management system; and
- liaison and clearinghouse functions between the Department's technology system and other governmental organizations (e.g., VA, DOD, NASA, NSF, OSTP), and the private sector (e.g., health insurers, providers, public and special interest groups, technology developers, academic institutions, medical specialty groups, Institute of Medicine).

technology system and other governmental organizations (e.g., VA, DOD, NASA, NSF, OSTP), and the private sector (e.g., health insurers, providers, public and special interest groups, technology developers, academic institutions, medical specialty groups, Institute of Medicine).

Figure 3

Functions and Relationships of Proposed Technology Management Unit



*PRIMARY FUNCTIONS
- -Management
- -Coordination
- -Policy
- -Oversight
- -Liaison
- -Evaluation
- -Clearinghouse

** Agencies are identified in terms of their primary mission vis-a-vis technology-based knowledge development or action

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** Agencies are identified in terms of their primary mission vis-a-vis technology-based knowledge development or action

Several alternatives for the organizational locus of such a management unit suggest themselves: OASH (given the health orientation of this initiative), OASPE (if considering extending the system to educational technology, telecommunications policy, etc.), or some direct staff arm of the Secretary or Undersecretary. Again, the scope of this study does not permit evaluation of these and other alternatives and recommendation of a best course of action. Instead, the follow-on Phase II study previously referred to should simultaneously prepare an evaluated set of options from which to select.

C. Recommended Approach

It is recommended that the Department adopt in principle both the technology system as outlined and the emplacement of an overall technology management unit, and that the Phase II study define alternatives and recommend organizational change actions.

IX. RECOMMENDED NEXT STEPS

This report has presented a strategy for managing medical techology at DHEW. It has described a comprehensive technology system and the management of that system. In addition, it has compared the technology-based activities of the Agencies within each component of the proposed technology system and has recommended initiatives needed to close the gaps and correct the deficiencies. Those component-by component recommendations are embodied in the following summary recommendations for next steps.

Recommended Step 1: endorsement in principle of 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.

Recommended Step 2: appointment of a Special Project Manager

(a) to prepare a decision memorandum within 45 days that examines alternatives and makes recommendations regarding the technology management unit (e.g., organizational location, authorities and responsibilities, staffing); and

(b) to promptly undertake a follow-up to this study to recommend those changes in Agencies' jurisdictions and responsibilities necessary to implement each component of the technology system and to develop an approach to Departmental collaboration with outside parties-at-interest. See Appendix tab 13 for outline of the Phase II study.

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Recommended Step 3: in addition to release of this report for broad circulation, transmission of a copy to Senator Kennedy in light of his particular interest in the subject.

Recommended Step 4: following completion of the Decision Memorandum described in Step 2 (a), establishment of the technology management unit, and transfer to it of activities begun under the Special Project Manager.

Note. On one issue related to Step 2 (b), the Study Team did not reach consensus. One opinion held that if the Department committed substantial resources to the Phase II Study, organizational change decisions could be made in six months. Consequently, the NIH and NCHSR proposals should be considered in the context of the Phase II Study, and not advanced for a separate Secretarial decision at this time. The contrary opinion held that the Phase II Study and decisionmaking process would take a full year; and that, while they might need to be altered in light of Phase II results, the NIH and NCHSR proposals should be advanced at once, recognizing that their approval would provide needed capability more quickly.

APPENDIX 1: GLOSSARY

MEDICAL TECHNOLOGIES: The drugs, devices, medical and surgical procedures used in medical care. Some definitions of this term include the organizational and supportive systems within which such care is delivered. For this study, however, only the former definition is used.

KNOWLEDGE-DEVELOPMENT AGENCIES: Those agencies in the Department whose primary mission is the development of knowledge relating to health or health care. These agencies conduct or sponsor analysis and testing activities. While their primary mission is knowledge development, they may have some significant action functions.

ACTION AGENCIES: Those agencies in the Department whose primary mission is the administration of programs which can affect the development, diffusion, or utilization of medical technologies. These agencies manage the Intervention Mechanisms. They may however, have some knowledge-development capabilities and functions.

EFFICACY: Potential benefit from a medical technology applied for a given medical problem to individuals in a defined population. Efficacy is sometimes used to refer to benefit under ideal conditions of care to differentiate it from effectiveness, which would then be benefit under average conditions of care. We have not made that distinction here; instead, we regard benefit under ideal conditions as a special class of efficacy.

SAFETY: The probability that a medical technology applied for a given medical condition to individuals in a defined population will not cause disease, injury, or harm.

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SAFETY: The probability that a medical technology applied for a given medical condition to individuals in a defined population will not cause disease, injury, or harm.

COST-BENEFIT ANALYSIS: Analysis which compares the monetary value (usually in present value terms) of future benefits with the monetary value of all immediate and future costs (usually in present value terms).

COST-EFFECTIVENESS ANALYSIS: Analysis which relates resource costs to the levels of effectiveness of alternative technologies under study. Their goal is to identify: 1) the alternative that maximizes effectiveness for a given resource cost, or 2) the alternative that involves the least resource cost to attain a specified level of effectiveness.

TECHNOLOGY ASSESSMENT: A relatively new approach to comprehensive policy studies which has a relatively defined set of conceptual parameters. The most commonly accepted definition of technology assesment (TA) is:

> "TA is a class of policy studies which systematically examines the effects on society that may occur when a technology is introduced, extended, or modified with special emphasis on those consequences that are unintended, indirect, or delayed..." (J. Coates)

This term is increasingly being used to refer to any technology-based policy analysis or planning. We have restricted our use of the term to the first sense because the term was coined explicitly by the Congressional Office of Technology Assessment to distinguish comprehensive technology assessment from other technology-based studies which examine such discrete aspects as efficacy, cost-benefit, or cost-effectiveness.

Outline of Analyses to be Included in Phase II Study

-- evaluation of Agencies' institutional and professional staff capabilities for conducting the types of technical studies described, and recommendation of appropriate distribution of technical analytical skills and responsibilities (both mandate and staff) among the Agencies.

-- evaluation of alternatives and recommendation of an approach for establishing one or several locations within the Department to routinely monitor, collect, synthesize, store and report on emerging and existing technologies. Also, recommend assignment of responsibility for development of the "rough screening" criteria by which candidate high-priority technologies are identified, and for periodic application of those criteria as part of the Annual Technology Analysis Agenda process.

-- development of a process outline for development of the Annual Technology Analysis Agenda.

-- identification of institutional roles and processes for synthesizing the results of technical studies of technologies (both Departmental and extra-Departmental) and expert opinion, and preparation of the results for decisionmaking by Department-level or agency-level officials or non-Departmental organizations.

-- recommendation of processes and structures for the making of decisions to promote or restrict technologies, and the linkage of those decisions with a coordinated array of intervention mechanisms.

-- evaluation of agencies' institutional and professional capabilities for employing existing intervention mechanisms to affect development or use of technologies, and evaluation of alternative approaches including new mechanisms that might be adopted with or without new legislation.

-- assessment of the approach of other Federal agencies to technology management, particularly VA, DOD, NASA, Commerce and NSF.

-- assessment of collaborative efforts that the Department might undertake with outside groups both to improve our own technology management capability and to enhance the possibility of collaborative efforts. Such groups include the Institute of Medicine, private insurers, academic health science centers, manufacturers, medical specialty groups, labor unions, providers, consumer and public interest groups.

-- evaluation of approaches to including in the technology management system those health technologies excluded from the present study such as disease prevention, systems management, mental health, prosthetic devices for the physically handicapped, and environmental technologies.

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Sharman Stephens	BHSQ	443-4670
Gerri Ellis	BHSQ	443-4654

Public Health Service

Ruth Hanft	DASPRS, OASH	245-1824
William Munier	OQS, OASH	245-6611
James Kleeman	OQS, OASH	443-4990
Daniel Zwick	OPEL, HRA	436-7270
Thomas Hodgson	NCHS, OASH	436-7026
Terry Shannon	BHPRD, HRA	436-6852
Donald Goldstone	NCHSR, OASH	436-8915
Sherry Arnstein	NCHSR, OASH	436-8963
Seymour Perry	OD, NIH	496-2500
Bruce Carson	OD, NIH	496-3152
Robert Kennedy	BMDDP, FDA	427-7900
Marion Finkel	BD, FDA	443-4330
Anthony Bruno	BCHS, HSA	443-1994
Dennis Tolsma	OPPE, CDC	8-236-3243
David Kefauver	OA, ADAMHA	443-4266
Howard Davis	NIMH, ADAMHA	443-6165

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