of condensed matter at low temperatures. He earned his Ph.D. at Berkeley and has been on the faculty at Penn since 1960. He has been vice provost for graduate study and research since 1974.

Slaughter earned his Ph.D. in engineering physics from the University of California at San Diego. He worked at General Dynamics Astronautics in the late 1950's. From 1960 to 1975 he was at the Naval Electronics Laboratory Center in San Diego where he became head of the Information Systems Technology Department. Before going to NSF as assistant director in 1977, he was head of the applied physics laboratory at the University of Washington. He has been editor of the *International Journal of Computers and Electrical Engineering* since 1977.

NSF watchers will have noticed that both Slaughter and Langenberg have physics backgrounds and expertise in applied science. Do their appointments prefigure pressure on NSF to put greater emphasis on applied research and technology at the possible expense of basic research? Sources on both the NSB and in the White House discount the possibility. Breadth of background and relevant experience were the operative criteria for selection. But it is also true that creation of a national technology foundation is being mooted, and proposals to give more attention to engineering education are in the air. And when such discussions are in progress, and the chronic basic-versus-applied science argument is being rehashed, "It is not bad," as one NSB member observed of Slaughter, "to have a person with feet in both camps."—JOHN WALSH

Heart Transplants: To Pay or Not to Pay

Cardiac replacement pushes HHS into drafting policy about emerging medical technology

The reigning imperative of American medicine has been: *If it works, do it.* Or as many physicians might put it: *If it helps, how can it be withheld*? Up to now, the government has taken a similar stance, asking only three questions about a new medical technology before deciding whether to pay for it out of Medicare and Medicaid funds: Is it safe? Is it effective? Does it have wide acceptance in the medical community?

No longer. Using heart transplantation as a starting point, the government has embarked on a new and utterly uncharted course. Patricia Roberts Harris, Secretary of the Department of Health and Human Services (HHS), announced on 12 June that HHS will require new technologies to pass muster on the basis of their "social consequences" before "financing their wide distribution."

According to the secretary and top HHS officials, this assessment will be a sort of environmental impact statement for medical innovation, encompassing such boundless issues as a new procedure's cost-effectiveness and cost-benefit ratios, its ethical implications, and its "long-term effects on society." Voluminously detailed regulations embodying the requirement and setting forth its rationale are being drafted now. It will be the first time in the 15-year history of Medicare the government has attempted to define what is meant by the statutory requirement that the program pay only for "reasonable and necessary" medical care—including such controversy-fraught issues as "necessary for whom?" and "reasonable under what circumstances?"

As she announced plans for developing the all-encompassing new reimbursement tests, Harris declared that heart transplantation—a technology that holds symbolic first place in any ranking of therapies for aggressiveness, intensity, and derring-do—will be "the prototype" for such an assessment. Beginning in the fall, the department plans to launch an unprecedentedly broad assessment of the operation and its ramifications. Harris said the study will embrace "the patient selection process, the long-term social, economic, and ethical consequences of the procedure, and the potential for national expansion of the heart transplantation procedure." She put the cost of the study at $2 million "at the outside" and said it would take 2 years, but HHS staffers say it will probably cost more and take longer.

As part of its venture into technology assessment, HHS will examine closely the data on the 200 or so heart transplants that have taken place in the United States during the past 11 years. And it will look at data on patients who receive transplants during the next couple of years. Although HHS may decide ultimately not to pay for heart transplantation under Medicare, it will support certain qualified patients as part of the present study, which will, perforce, be centered at Stanford University Medical Center, the world's most active heart transplant unit. Other medical centers may also be part of the HHS study.

The study's legal foundation is an obscure provision of the original 1965 Medicare statute that had to be stretched in a new direction to enable the department to do what it wanted to: fund heart transplants only at a specific institution or two and for specified types of patients. According to HHS General Counsel Joan Z. Bernstein, there are no provisions in the law for selective reimbursement that would normally permit the department to pay for a procedure at one hospital but not another.

Harris, who says the study was her idea because "the deeper I got into this the larger the number of questions became," was nonetheless a bit hazy about the specific unknowns the study will address. "I cannot tell you the degree we will be going into the ethical and economic issues," she said in an interview. "It is not nearly as metaphysical as my [press conference] statement would suggest." For instance, she said, the department wants to know how much additional life a heart transplant buys, at what cost, but it also wants to analyze the quality of life posttransplantation.

Other "unanswered questions" that are likely to be reflected in the study design, according to several HHS officials, include:

▶ Characteristics of patients who have been selected for transplantation to see if there is any implicit discrimination by social class, education, economic resources, or age.

▶ What resources are necessary to perform heart transplants well, and

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whether the operation should be regionalized, which would be unprecedented;

▶ Prospects for advances in immunosuppression, preservation of donor hearts, and the artificial heart as a substitute for or stopgap measure for end-stage heart patients—any of which could drastically alter the demand and cost sides of the equation;

▶ The all-inclusive costs of heart transplantation, including but not limited to medical expenses. One controversial HHS staff analysis by John B. Reiss, Fred Hellinger, and John Burckhardt of the Health Care Financing Administration (HCFA), recently estimated the total first-year cost of a national heart transplantation program at $212.2 million to $3.2 billion, depending on whether 2,000 or 30,000 transplants were done.

▶ The potential trade-offs. For instance, how does heart transplantation compare with other heroic medical care in terms of costs and benefits? Does transplantation imply diverting funds from other programs, such as immunization of the elderly against pneumonia?

Obviously an ambitious if not hopelessly broad undertaking, the study reflects a once-burned-twice-shy attitude traceable to Medicare's 8-year-old End-Stage Renal Disease program, which was launched without serious consideration of questions such as these (*Science*, 2 May 1980).

The focus on heart transplantation as HHS's premier real-world attempt to regulate technology diffusion is by necessity, not choice. "We were going to start with percutaneous transluminal coronary angioplasty," said Ruth Hanft, deputy assistant secretary for health research, statistics, and technology, referring to a new artery-reaming technique that some feel might replace coronary artery bypass surgery. But heart transplantation couldn't wait. The reasons why are instructive.

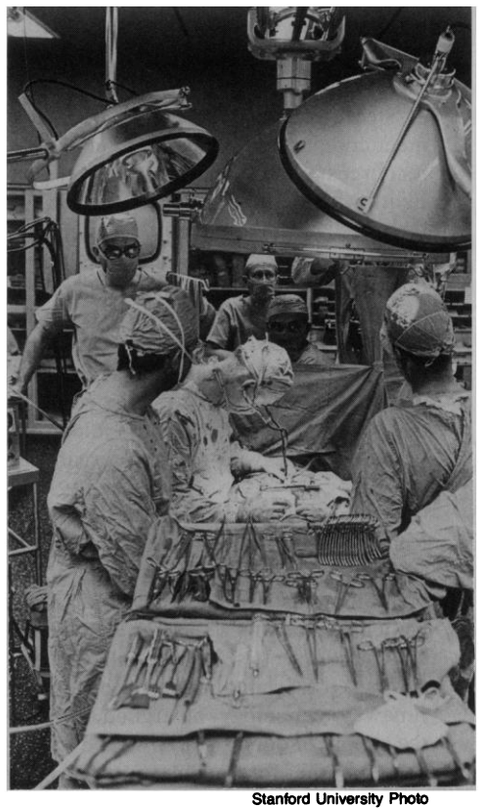
Ever since South African surgeon Christiaan Barnard sewed the heart of a 25-year-old woman into 53-year-old Louis Washkansky in December 1967, transplantation of the human heart has never been just another operation. Pressures have been building in the past 2 years, however, to put it into that category. Those pressures emanate mainly from Stanford University Medical Center, where Norman E. Shumway (who trained Barnard) quietly nursed the controversial operation through its nadir in the early 1970's and gradually improved its dismal early success rates through rigorous patient selection, better diagnosis of the early signs of rejection, and fine-tuning of immunosuppression.

Today the two dozen end-of-the-road patients who receive new hearts at Stanford annually have a 65 percent chance of living at least a year after the operation—versus a 100 percent chance of dying within about 6 months otherwise. One Stanford patient is doing well 11 years posttransplant; a few survivors have had two and three new hearts. Actuarial projections put overall 5-year survival currently at somewhat better than 50 percent.

Such relative success with such hopeless patients, of whom there may be 30,000 to 75,000 a year,* has long since convinced Shumway and heart surgeons across the nation that the time has come to disseminate this bold technology—at a measured rate.

That, in fact, is the rub. There has never been a mechanism in this country to regulate the diffusion rate of new medical technology once past the strictly investigational stage, other than the skepticism or enthusiasm of the doctors involved. Thus, the last decade has seen a lot of post hoc hand-wringing over kidney dialysis, coronary artery surgery, and computerized tomography. About a year ago, Congress set up a National Center for Health Care Technology (NCHCT) to serve as an early warning system for new medical technologies, but gave it only $3.2 million to do its mammoth task and provided no way to link its recommendations to the all-important reimbursement mechanism.

Meanwhile, the looseness of the Medicare reimbursement system, in which it is up to nongovernmental regional intermediaries to ask Baltimore headquarters whether a new procedure is "reasonable and necessary" and thus covered by the program, nearly gave the whole heart transplant show away by inadvertence. A year ago HHS officials discovered that Blue Cross of Northern California, the regional Medicare intermediary, had paid for 23 transplants and 21 posttransplant cases at Stanford since 1973 under the assumption that the procedure was approved—that is, no longer experimental. The department clumsily tried to shut off reimbursement, but soon an uninsured dying patient appeared at Stanford's door. The university hospital's trustees, beset with other financial headaches, decided they could not subsidize the operation. A Stanford attorney told the Los Angeles *Herald-Examiner* that the man "may be the patient to force the issue."



Stanford University Photo

Norman Shumway at work.

The department succumbed to the adverse publicity and political pressures from California Senator S. I. Hayakawa and said Medicare would pay for this patient and for others for heart transplants on a "tentative" and temporary basis at Stanford, saying it would have a final decision in early 1980.

As it turned out, last November's decision to think twice about heart transplantation led to 7 months of wide-ranging and often sharp debate within HHS in which the secretary became engrossed to an extraordinary degree. The first thing Harris wanted, naturally, was advice from the medical experts. She got it, and pretty quickly as these things go, but from her perspective it wasn't very helpful.

The experts, an ad hoc panel of 18 cardiologists and cardiac and transplant surgeons, assembled by the National Heart, Lung, and Blood Institute (NHLBI) at the behest of the National Center for Health Care Technology, concluded they could make no "generalized or unqualified statement" about the safety, efficacy, and reasonableness of heart transplantation. The procedure is safe, effective, and reasonable at Stanford, they concluded, for the carefully culled population defined by Shumway's group.

In a 21 January consensus memo written by NHLBI Deputy Director Peter

*A 1979 Ad Hoc Task Force on Cardiac Replacement estimated that there were about 32,000 candidates for a heart transplant in 1979. A member of the Stanford team, cardiologist John Speer Schroeder, estimated in an article in the *Journal of the American Medical Association* (11 May 1979) that there are 75,000 patients a year "who might be suitable candidates for cardiac transplantation."

Frommer, the committee recommended that Medicare pay for heart transplants at Stanford and other U.S. centers that meet comparable standards of expertise, resources, and commitment, and for patients who fit the Stanford selection criteria or "acceptable equivalents." They also identified "several dangers which must be forcefully resisted or carefully avoided," though they didn't say how. These included proliferation of other centers not as well-equipped as Stanford and loosening of patient selection criteria (for example, to encompass older patients or those with multiple organ failure).

Frommer who, like NHLBI director Robert I. Levy, is an advocate of controlled expansion of heart transplantation, also tried to allay some of the anxieties he was hearing from HHS headquarters. It's highly unlikely that cardiac transplantation will become a runaway technology, he argued, because the supply of donor hearts will be so limited for the foreseeable future. Only about 1000 usable donor hearts might be "harvested" annually, Frommer estimated. Because of this foreseen shortage and the probability that many U.S. hospitals with the capacity to transplant hearts probably won't want to (see box), Frommer predicted there would be no more than 10 to 20 groups taking up the technique "for at least the next 5 years." If all these centers eventually geared up to Stanford's arduous two-a-month rate, that would still mean only 250 to 500 heart transplants a year.

Frommer's report, passed on to HCFA as the recommendation of the NCHCT, got mixed reviews at HHS headquarters. Hanft told the center's advisory board that the issue was being addressed too narrowly: "We'll have to face the same series of questions" for all transplants, she said, including liver (about which Medicare has already had a reimbursement query), bone, pancreas, lung, and heart-and-lungs together, which is within about 2 years of clinical trial at Stanford.

Harris was unsatisfied with the NHBLI-NCHCT report too. "The experts kept saying, 'Fund these, fund these at Stanford,' and I kept asking more questions to which there were no answers," she said recently.

As the debate progressed, a special point of contention was the way the NHLBI-NCHCT recommendation brushed over ethical questions about how to choose the lucky 250 or 500 or 1000 or 2000 recipients from a potential candidate pool of 15 to 120 times that size.

Noting that these issues have been discussed extensively in the past, Frommer said that to say that no one should benefit from a technology so scarce and expensive that it can be extended to only a fraction of those who might benefit "is analogous to arguing that if not everyone can fit into the only lifeboat from a sinking ship, it is unethical for anyone to get in."

This argument does not satisfy some within HHS who are troubled by Stanford's screening criteria, which require:

- A stable, rewarding family and/or vocational environment to return to posttransplant;
- A spouse, family member, or companion able and willing to make a long-term commitment to provide emotional support before and after the transplant;
- Financial resources to support travel to and from the transplant center accompanied by a family member for final evaluation; living expenses near the center before, during, and after the transplant (a period of up to 10 months); and all pretransplant medical care, which can run more than $8000. Contraindications at Stanford are a history of alcoholism, job instability, antisocial behavior, or psychiatric illness.

Hanft told the NCHCT advisory board that the Stanford criteria "raise questions of distributive justice." One HCFA official added recently: "If it turns out that all these patients are white middle-class males under the age of 50, that isn't the population that the department is concerned about."

Lois K. Christopherson, the Stanford social worker who does the initial screening of heart transplant patients, defends the criteria and says that in reality they produce candidates with a wide spectrum of socioeconomic and educational characteristics—though this has never been analyzed systematically in the nearly dozen years of the transplant program. The point, Christopherson says, is to find patients with a fierce will to live and strong coping skills, since having a heart transplant is an arduous lifelong process. "The coping skills to deal with financial problems are the same coping skills that make for long-term survival."

At least one Stanford observer, however, acknowledges the potential for selection of heart recipients based on unstated grounds of "social worth." Stanford Medical Center Chaplain Ernle Young, whose office is decorated with smiling pictures of successful heart transplant recipients and their families, worries about "a subtle temptation for

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Debate Continues on the Bomb That Wasn't

"A lot of people remain convinced that this was a nuclear explosion," said a White House briefer as he released a sanitized report on the "event in the South Atlantic" seen on 22 September by the Vela surveillance satellite. The paper, given out on 15 July, summarized the findings of a group of independent experts brought together by the President's science adviser in an attempt to settle a technical dispute within the Administration (see *Science*, 1 February). It concluded that the Vela probably did not see a nuclear explosion, but may have seen sun glinting off some debris chipped loose from the satellite.

The technical dispute was in plain view last week. Just before the White House released its study, the word had gone out that the Defense Intelligence Agency (DIA) had finished its own classified paper concluding that the satellite had, in fact, seen a nuclear blast. The White House official would not discuss the contents of the DIA report. It was a coincidence, he said, that the two papers came to light in the same week.

Jack Ruina, chairman of the White House review panel and a professor of electrical engineering at the Massachusetts Institute of Technology, said that his group had started its task assuming that it would confirm that there had been an explosion. But by the end of the exercise in early April, the consensus was that the 22 September signal was too different from known blast signals to be taken as the sole confirmation of a blast. As one member of the panel put it, "On the first day we were betting four-to-one that it was an explosion, and at the end we were betting four-to-one that it was not."

Some physical data seemed to confirm that there had been a blast, but none of it persuaded the committee. One acoustic signal picked up at the right time in the Northern Hemisphere seemed to be contradicted by the absence of similar signals in the Southern Hemisphere. Some weak hydroacoustic signals were detected as well, but a study of them done by the Naval Research Laboratory was judged "too incomplete to apply to the event" because it contained ambigui-

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Mass. General: No Heart Transplants Here

The Department of Health and Human Services (HHS) is not the only place where some policy-makers have been having qualms about heart transplantation. On 1 February, the 12 lay trustees of the Massachusetts General Hospital (MGH) voted not to permit heart transplants at that institution "at the present time."

"To turn away even one potential cardiac transplantation patient is a very trying course to follow," the trustees said in an explanatory statement. "Yet in an age where technology so pervades the medical community, there is a clear responsibility to evaluate new procedures in terms of the greatest good for the greatest number."

The vote was the unexpected culmination of nearly 2 years of in-hospital discussion and debate over the proposal of MGH Chief of Surgical Services W. Gerald Austen and his colleagues to launch a "limited" cardiac transplant program—no more than six cases a year initially. "I don't look at this as a big program," Austen said in an interview in July 1978, as the campaign was getting under way. "I look at it as a program which, if properly done, would move the field forward."

The trustees' decision came as a shock to many at the venerable hospital, not the least because it set a striking new precedent for lay control over clinical decisions that have previously been the doctor's province. Austen and transplant surgeons Paul S. Russell and A. Benedict Cosimi had carefully steered their proposal through the hospital's General Executive Committee, made up of clinical chiefs, with only one dissenting vote—Chief of Medical Services Alexander Leaf. The physician in chief argued adamantly that with 4 million Americans suffering from atherosclerotic heart disease, heart transplantation "doesn't make much of a dent."

Leaf later wrote approvingly in the *New England Journal of Medicine* that the trustees' decision "demonstrates . . . that physicians may not make independent decisions regarding what professional services they provide. If one considers that the medical profession has historically been fostered and supported to serve a societal need and not to supply physicians with a privileged status," he added in a comment that rankled the surgeons, "one can find little argument with the course that the MGH trustees thoughtfully and responsibly followed."

Norman E. Shumway, the Stanford University heart surgeon who has been urging the dissemination of cardiac transplantation for the past 2 years, had a rather different interpretation of the MGH outcome. "Maybe it has to be considered—perish the thought—that the MGH isn't the leading institution it used to be," Shumway suggested when he heard the news. "Apparently somebody feels they just don't have the horses."

In one sense Shumway is right. Though there is wide agreement that the MGH has the talent and facilities to do heart transplants if anyplace does, the MGH trustees clearly decided not to hitch their horses to that particular wagon. One argument that weighed heavily with the trustees, one of them said afterward, was that each heart transplant would consume the resources of six to eight routine open-heart surgery cases.

Austen promised that none of these valve replacement and coronary bypass cases would be turned away. He also argued that the MGH expends resources extravagantly on some patients, such as terminal cancer victims and those suffering ruptured abdominal aneurysm with kidney failure, who have far less chance of survival than a good heart transplant recipient currently does. But the trustees were unwilling to make the trade-off.

The trustees also worried whether the program could be kept within the six-patients-a-year limit the surgeons had set. "That was bound to be a worry," trustee Francis H. Burr said. "Suppose you do six and the perfect case comes up. What are you going to do? I guess I know: we would do the seventh."

Finally, the trustees were told that a clinical heart transplant effort was unlikely to generate much in the way of new knowledge, either of the rejection phenomenon that is the paramount obstacle or of heart disease and cardiac function. Austen and his colleagues had asserted research benefit as a primary justification for undertaking clinical heart transplantation at the MGH. The trustees ordered a closer look at this rationale, and a subcommittee of the hospital's Committee on Research concluded that while predicting research benefits is hazardous, the main rationale for doing human heart transplants should be its therapeutic effectiveness and not its research payoffs.

Jerome Gross, chairman of the Committee on Research, believes it was "a mistake, a tactical blunder" for the proponents of heart transplants to put forward the research argument. "It's really a therapeutic problem and the emphasis should be on that and whether the hospital could afford it," said Gross. "The scientific aspects of it were going to wind up iffy."

The impact of the MGH decision—if any—on other institutions remains speculative. One other Boston heart surgeon, who is not enthusiastic about heart transplants, confided that he was feeling pressure from his trustees to jump into the breach. Two other local hospitals were actively exploring heart transplantation before the government's recent decision, but now the issue may have been moved to a back burner.

In Washington, HHS officials said that the MGH outcome did not influence their thinking. On the other hand, HHS Secretary Patricia Roberts Harris seemed to go out of her way to compliment the Boston hospital on its decision. "The MGH is to be applauded for making a very rational and wise decision with respect to the allocation of very sparse resources of both dollars and personnel," she said at a 12 June press conference. Privately she added that the Boston hospital's choice lent support to her position.

Meanwhile back in Boston, the MGH surgeons have not folded their tents. Asked recently if the MGH might submit a response to the government's upcoming invitation to participate in the heart transplant study that Harris announced, MGH surgeon Paul Russell replied: "I don't see any reason why we shouldn't have another look at it. It has been explicit all along that the hospital's trustees would be willing to look at it again if circumstances had changed enough."—R.A.K.

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the transplant team to select recipients on the basis of other than the publicly stated medical and sociopsychological criteria."

Addressing such sensitivities, nine of NHLBI's heart transplant experts decided at a meeting on 27 May that these thorny patient selection questions might be sidestepped if the criteria were stated in more explicitly medical language. "For the purposes of HCFA," says a memo summarizing the discussion, "these criteria must be stated more generally and exclusively in terms of enhancing the likelihood of successful medical outcome."

While the memos were flying and the HHS legal department was vacillating about selective reimbursement, an event in Arizona this spring nearly toppled all the resource allocation arguments that some were trying to pile up against the reimbursement gate.

In early March, Administrative Law Judge Walter McCormies of the Social Security Administration ruled that Medicare must pay a $30,533.68 claim for the heart transplant of Norman E. "Dutch" Tarr, a 50-year-old retired Air Force master sergeant who lives in Tucson. Tarr was one of the first patients in the heart transplant program set up at the University of Arizona Health Sciences Center by Jack Copeland, a Shumway trainee.

Blue Cross of Arizona, the Medicare intermediary locally, denied the University of Arizona's claim for Tarr's transplant because the operation "is considered experimental or investigational."

Charles E. Buri of the Arizona Attorney General's office countered successfully before Judge McCormies that "experimental" had nothing to do with it. The only test, Buri asserted, was whether a heart transplant was "reasonable and necessary" treatment for Tarr. It didn't hurt Buri's case to have Tarr at the hearing, looking fit nearly a year after his transplant—living proof that the operation was at least "necessary" for him.

Norman Tarr's case, which was supported by Arizona Senators Barry Goldwater and Dennis DeConcini and by Congressman Morris K. Udall, exactly illustrates the dilemma the government faces as it tackles heart transplantation and other potentially lifesaving but very expensive technologies. Confronted with a dying patient, resource allocation arguments tend to appear bureaucratic, if not academic, to politicians and perhaps to some nonpoliticians as well.

To prevent more Norman Tarrs from determining the outcome of the process that Harris has set in motion, HHS has declared that any potential Medicare beneficiary now in the heart transplant selection "pipeline" will be covered retroactively as participants in the study. (So far HHS officials can identify only one such patient.)

A larger question remains. The government has no power to prevent any doctor or hospital from doing a heart transplant. In fact, the Mayo Clinic plans to begin doing heart transplants this fall despite the recent government decision, and whether or not it receives patient care funds under the study.

Moreover, government funds are not the only funds available for heart transplants. Some private insurance companies pay for the operation, as do some but by no means all Blue Cross plans. And HHS can do nothing about entire towns raising the money to pay for some patient's new heart, just as they used to pay for dialysis in the days before Congress placed that burden on the Medicare trust funds.—RICHARD A. KNOX

The author is a medical writer for the Boston Globe.

Global 2000 Report: Vision of a Gloomy World

Projections in CEQ–Department of State study show trouble ahead unless the international community takes strong corrective action

The *Global 2000 Report* issued by the Carter Administration on 24 July indicates that, unless the nations of the world act decisively to alter current trends, life for most people will be increasingly precarious.

"If present trends continue, the world in 2000 will be more crowded, more polluted, less stable ecologically, and more vulnerable to disruption than the world we live in now," says the report.* "Despite greater material output, the world's people will be poorer in many ways than they are today."

Work on the report began in 1977 after President Carter called for it in his first environmental message. Although some 11 agencies participated in its preparation, the report has been issued only in the name of its two sponsoring agencies, the Council on Environmental Quality (CEQ) and the Department of State. Gerald O. Barney, a consultant to these agencies, was the study director.

The chairman of CEQ, Gus Speth—who, together with Assistant Secretary of State Thomas R. Pickering, headed the study—has now been asked by the President to chair a interagency task force on global resources and environment. Other members of this task force will include the directors of the Office of Management and Budget and the Office of Science and Technology Policy, the head of the White House domestic policy staff, and the Secretary of State. The President said that "the projected deterioration of the global environmental and resource base" was among the world's "most urgent and complex challenges," and he called on the task force to give high priority attention to the global resource, population, and environmental problems and seek ways to improve the government's capability for analyzing global trends. The task force will in effect develop policy recommendations to go with the report, which, as it stands, contains none.

Speth told *Science* that carrying out this assignment will be his highest priority. As an example of the kind of initiatives that may be proposed, Speth pointed to the U.S. strategy for the conservation of the world's tropical forests, which has been developed by an interagency task force cochaired by officials from the State Department and the Department of Agriculture. This policy calls for U.S. government agencies to promote wise use of tropical forests

**The Global 2000 Report to the President*. For sale by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402; $3.50 for volume I (the summary); $13 for volume II (the technical report); and $8 for volume III (describes the government's global model).

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