

~~all~~ Margaret Ross

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some recommendations

Background

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

STATEMENT OF

PHILIP R. LEE, M.D.
ASSISTANT SECRETARY FOR HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

DECEMBER 8, 1993

Mr. Chairman and Members of the Committee:

I am pleased to have this opportunity to discuss the Health Security Act (S1757) and how the National Institutes of Health is integral to the President's plan to improve the health of all Americans. I am very pleased, Mr. Chairman, that you are one of the Senate cosponsors on the Health Security Act.

The central role of NIH and the prevention research initiative becomes very clear when the objectives of reform are viewed from a health perspective, from a quality perspective, and from a cost containment perspective.

The Health Security Act (S.1757) is unique among the proposals before Congress to reform the health care system. It emphasizes prevention. It makes health plans accountable to achieve prevention and public health (population based health) objectives. It fosters a close working relationship between research, clinical care and public health.

Prevention research is the foundation for both clinical preventive services and the public health interventions included in the Health Security Act. Expanded prevention research will ensure the availability of effective preventive measures against existing diseases as well as new and emerging health threats. Progress in preventing disease will help to offset escalating acute health care costs and the disproportionate impact of disease and disability among women, minorities and the elderly.

Central to this approach is a restructuring of the personal health care system, enabling it- for the first time- to emphasize keeping people healthy by promoting health and preventing disease. The changes in the personal health care system will strengthen and foster the restructuring of the public health system, making both far more effective in protecting and promoting the health of all americans and reducing the disparities in the health status among different populations and individuals.

Mr. Chairman, I am particularly excited about the Health Security Act because the President, in developing this proposal, has clearly understood the importance of prevention and has included it in the Health Security Act in four ways:

- (1) by including a full range of clinical preventive services in the benefits package;
- (2) by making plans accountable for providing clinical preventive services;
- (3) by rewarding alliances and plans for keeping their populations healthy, and
- (4) by expanding prevention research at NIH and providing support to strengthen and expand state and local public health programs through the Centers for Disease Control and Prevention.

~~Health Care Reform~~ seeks to provide health security for all Americans by providing universal health insurance coverage with comprehensive benefits including clinical preventive services, containing the escalating costs of health care, improving the quality of care, providing consumer choice, simplifying the system and assuring responsibility. The broader purpose for the Health Security Act, as with all the health programs of the Department of Health and Human Services, is to increase the span of healthy life for all americans and reduce the health disparities among americans. Biomedical, behavioral and social science research, particularly in the area of prevention, is integral to our efforts to lessen the enormous personal, social, and economic toll exacted by disease in all its forms--prematurity and severe childhood illnesses, cancer, heart disease, independence-robbing disorders of the elderly, and unvanquished old and new infectious diseases.

Our national investment in biomedical, behavioral and social science research yields the knowledge and technology for health promotion and disease prevention for early diagnosis, treatment, rehabilitation and care. This research is translated into practical applications but all of the agencies of the U.S. Public Health Service, including NIH as well as by the medical, nursing and other health professions. The pharmaceutical industry, the biotechnology industry the medical device industry as well as the electronics

industry play a large role in the critical translation process.

The research conducted and supported by the NIH provides information needed to assist in adaption of health plan benefit coverage and the appropriate application of cost-effective methods for prevention and early intervention.

NIH Leadership Role in Science and Commitment to Basic Research

The National Institutes of Health is the premier biomedical research institution in the world and is dedicated to the pursuit of knowledge to improve the health of all Americans. As you are well aware, the NIH has long used the peer review system to evaluate research proposals in order to fund the highest quality, most meritorious research.

Scientific advances require the continued insight and understanding of the fundamental mechanisms of life, health and disease. Perhaps better than anyone, Dr. Harold Varmus, the new Director of the NIH, understands how basic research can and does lead to dramatic and many times unexpected discoveries which can effect the health of a few individuals or of millions of people. Dr. Varmus' own work in virology provides convincing evidence of the importance and value of basic biomedical research and I am confident he will be an effective champion of basic research.

The important and unanticipated pay-offs of basic research are illustrated by the announcement last week of the isolation of a gene associated with colon cancer. The function of this gene is relatively well understood as the result of past basic research on bacteria and yeast. The colon cancer gene turns out to be quite similar to genes in bacteria and yeast cells that function as DNA "editors". The gene product acts to ensure that mistakes in DNA replication are corrected. Defects in this editing function therefore result in errors, or "typos", in the genetic material. These errors result in disease.

An estimated 152,000 Americans will be diagnosed with colon and rectal cancer this year and 57,000 will die. While the recently discovered gene for colon cancer is not singularly responsible for all colon cancers, it is estimated to be the cause of about 10 percent of the cases. Clearly, understanding the basis of disease is the first and most critical step to developing measures to cure the defect and prevent disease, and when that is not possible, to screen and monitor individuals with the gene in order to intervene with measures such as a low fat diet and daily aspirin to reduce the likelihood of disease and to detect cancer early and cure the disease at that point. But who would have predicted that understanding bacterial DNA synthesis would be that first step in finding the means to understand and prevent colon cancer?

Basic genetic research provides the keys for locating defective genes causing many genetic diseases in addition to colon cancer. We have already identified and isolated the genes for a large number of diseases including duchenne muscular dystrophy, retinoblastoma, cystic fibrosis, fragile X syndrome, myotonic dystrophy, and Huntington's disease. Having these genes in hand will allow us to craft the tools necessary to greatly improve control, treatment and prevention of disease. These advances will provide benefits that will touch every American family.

Prevention Research and Health Care Reform: Reducing the Burdens and Cost of Disease

As you know, the President has included a Prevention Research Initiative in the Health Security Act (S.1757). More prevention research will generate knowledge that will help to generate such prevention tools as improved methods for early detection of disease and genetic susceptibility to disease; scientifically validated approaches for fostering adoption of dietary and other behavioral practices that protect health; and strategies for reducing or eliminating environmental factors that significantly increase disease risks. While offering returns that can be realized by all Americans, the Initiative gives special consideration to the health concerns of women, minorities, and other populations whose

particular health needs have received insufficient attention and study in the past.

Prevention research has four ultimate aims: (1) promoting health; (2) preventing the occurrence of disease; (3) preventing the occurrence of clinical illness in individuals who have physiological or biological evidence of abnormalities; and (4) preventing the progression of clinical disease. The Initiative spans a wide range of topics and objectives. Research in genetics, molecular and cell biology, immunology, and other fundamental sciences describes the biological basis of disease--what goes awry and why. This knowledge provides a sharp focus for efforts to devise preventive interventions, which can range from lifestyle changes to protect against damaging biological changes to molecular measures to correct or compensate for acquired or inherited genetic flaws.

~~The social and behavioral sciences~~ comprise a complementing research area, investigating disease and health in the context of personal choices, social and economic conditions, community and cultural influences, and psychological and environmental factors. We know from social and behavioral sciences research in the past decade, for example, that social class or socio-economic status is a major determinant of health status--particularly how long we live and how healthy we are during our lifetime. Knowledge gained from this research also yields fundamental insights into methods to prevent and control disease. Fundamental research in behavioral sciences is vitally needed to understand both healthy and unhealthy behaviors.

While NIH has long invested in prevention research, and tracked expenditures for prevention research since the 1980s, it was felt that an increased investment in NIH research will translate into advances in knowledge that will promote health, prevent disease and reduce the nation's expenditures for treatment of preventable illness and injury. Expanded prevention research will help ensure the future availability of effective preventive measures against existing disease, as well as new and emerging health threats. Prevention of disease before its onset can be significantly less expensive than treating symptomatic disease.

The initiative will focus on the solutions research can provide to critical preventable health problems in:

Child and adolescent health

Reproductive health

Mental Health

Substance Abuse .

Infectious diseases,

Health and Wellness Promotion (including fitness/nutrition)

Environmental Health

Chronic and Recurrent Health Conditions

~~Elderly Health~~

Resource Development

The President's Health Security Act would authorize appropriations of \$400 million in FY 1995 and a total of \$2.9 billion over six years for NIH prevention research expansion. These authorizations are in addition to the \$2.6 billion NIH is spending on prevention research in FY 1994. Increases in the NIH prevention appropriations would be subject to the discretionary spending cap.

Our national investment in biomedical and behavioral research and particularly prevention research has important impact on the long term health and health costs. I would like to highlight several specific examples of the ways in which biomedical and behavioral research has already impacted on the burden of disease and the cost of health care.

Vaccines

Vaccines provide convincing examples of the successes and cost savings that are achievable through prevention research. It is widely acknowledged, in fact, that immunization represents by far the single most cost-effective procedure in medicine.

Universal immunization programs are responsible for much of the increase in life expectancy in the last half-century. In the United States, the use of vaccines virtually eliminated diseases such as diphtheria, tetanus, mumps, and poliomyelitis. In the last decade alone, nine new or improved vaccines have become available. Biomedical research has greatly expanded the possibility for creating new safer and more effective vaccines. In this effort, Government, industry, and universities all play vital roles.

Vaccine development is dependent on advances in basic research, often by discoveries that were unanticipated. In the recent Institute of Medicine report on Childhood Vaccines it was noted;

~~Basic research relevant to vaccine development includes such things as the~~ identification and isolation of the protective antigens of a specific pathogen, methods of DNA cloning, the creation of new vector systems, and the development and immunologic evaluation of new adjuvant systems (p 111).

NIH support for vaccine research and development includes basic research as well as clinical trials to assess the safety and efficacy of vaccines. Important recent developments indicate that it may soon be possible to splice as many as 5 to 10 protective antigens into a single virus and bacterium, thus providing protection against many diseases with a single administration. Research involving microcapsules which gradually dissolve after administration offer new prospects for single inoculations of some protective agents which now require 3 or 4 inoculations. Moreover, recent progress in cellular biology, immunology, and biotechnology presents solid opportunities to pursue a new class of vaccines for preventing and treating cancer and other non-infectious chronic diseases.

During the past year, the rapid development of improved vaccines for hepatitis B and for Haemophilus influenza type b (Hib), an important cause of meningitis in children, led to recommendations that both be included in universal childhood immunization programs.

NIH funded research played a key role in developing vaccines for these two serious diseases.

Hepatitis B virus causes acute liver disease sometimes with severe, life-threatening manifestations. However, on both an individual basis and an overall economic one, its major impact occurs when an individual does not recover, i.e. becomes a chronic carrier at risk of long-term consequences such as chronic liver disease and liver cancer. Immunization with hepatitis B vaccine is the most effective way to prevent infection and its consequences, and could lead to an estimated annual savings of between \$74 and \$147 million.

~~Haemophilus influenza~~ type b (Hib) was a leading cause of mental retardation and deafness in children before the introduction of effective vaccines. One in 200 children in the United States developed invasive disease by the age of five years. Recent reports indicate that since the introduction of the new conjugate Hib vaccines, the incidence of Hib infections in the United States has fallen by as much as 90 percent, preventing an estimated 10,000 to 16,000 cases of Hib disease each year. Universal immunization has the potential to virtually eliminate Hib meningitis in children. The cost savings resulting from the use of the Hib vaccines is considerable. NIH's cost of research towards the development of the Hib vaccines was \$20 million; widespread use of the vaccine can save approximately \$400 per year.

Cardiovascular Disease

The return on investment in prevention research is well demonstrated by the dramatic decline in the death rate for cardiovascular disease. Heart disease mortality has declined 57 percent from its peak in 1963, resulting in more than half a million american lives saved annually. Over the same period, stroke mortality declined 66 percent, so that, in 1992, 260,000 lives were saved. This impressive success story is due both to advances in basic, clinical and population-based research and to innovative programs that transfer scientific results to health professionals and the public. The major modifiable risk

factors for cardiovascular disease are high blood pressure, high blood cholesterol and cigarette smoking. Research in all of these areas by NIH has been a major factor in the understanding of these risk factors and the development of effective clinical and public health interventions.

Diabetes

The recently concluded diabetes complications and control trial demonstrated conclusively the value of strict control of blood sugar in the prevention of complications in Type I (insulin dependent) diabetes. We are now working with NIH, CDC, AHCPR, IHS and HRSA to disseminate this information to practitioners and public health officials.

Alzheimer's and HIV provide examples of the potential reductions in health care costs as the result of continued investments in biomedical research.

Alzheimer's

Alzheimer's disease affects more than four million Americans and cost the Nation an estimated \$90 billion annually. At present, there is no effective therapy to prevent or delay the onset of Alzheimer's. However, recently NIH-sponsored research identified a gene, ApoE, that is directly related to late-onset Alzheimer's. One form of the gene can predict the likelihood of late-onset Alzheimer's with nearly 91 percent accuracy. Even a partial victory against this devastating neurological disorder would yield tremendous personal, social, and economic dividends.

HIV

The cumulative cost of treating persons infected with HIV is forecast to increase by 48 percent over the next three years. The cost for providing medical care for an HIV infected person from time of infection till death is approximately \$120,000. As the basic biology of the HIV virus is understood, as the pathogenesis of the disease is elucidated, effective preventive strategies can be developed to control the epidemic and effective

treatments can be developed. In addition, as research advances related to the opportunistic infections that kill most person with HIV/AIDS, it should be possible to develop more safe and effective treatments for these diseases.

Diffusion of Research Findings into Clinical Practice

The President's plan promotes the diffusion of research findings into clinical practice and the public health. It facilitates close cooperation among clinicians and public health practitioners and it would strengthen the role of public health agencies in protecting and promoting the health of all Americans.

~~The Health Security Act~~ provides for the innovative approaches to the dissemination and application of technology. In addition, the NIH's National Library of Medicine has assumed a leadership position in encouraging access to data bases for physician in practice around the country through its Rural Outreach Program. NLM's National Network of Libraries of Medicine consists of eight regional medical libraries, 135 resource libraries, and 3,600 member institutions. Since 1989, NLM has funded over 139 institutions and groups to introduce "grateful Med to rural health professionals to provide them access to the enormous data resources of the National Library of Medicine.

The telemedicine initiative of the NLM have been greatly expanded in recent years. In Iowa, for example, a group of over 20 hospitals have joined in a network known as the Midwest Rural Telemedicine Consortium. This project seeks to ensure the viability of rural images from CT scans, ultrasound, and MRI; interactive video communications for consultation and education; and administrative information to streamline payment processes and enhance communications capabilities.

outlined.

The Health Security Act increases funding for health services research at the Agency for Health Care Policy and Research and the Health Care Financing Administration.

Health services research plays a critical role in evaluating the application of new clinical and public health interventions in the field to assure that their projected efficacy is realized in all settings and for all populations. Thus, health services research serves as an important bridge between the controlled setting of a clinical research trial to the world of patients seeking care in diverse health care settings. Health services research also provides the information on how to best organize, structure, and deliver cost effective services. Further, health services research makes this information readily available to consumers, health care providers and decision makers at the plan, alliance, state, and national level.

The Health Security Act will enhance the use of clinical research in health care delivery through the development of practice guidelines through the National Quality Management Program. The National Quality Management Council will direct AHCPR to develop, disseminate, and evaluate clinical practice guidelines. These guidelines will be based on the best available research and professional judgment regarding the effectiveness and appropriateness of health care services and procedures. The recent practice guidelines on clinical depression in primary care and on cataracts illustrates both the process and the potential benefit of guidelines. As part of any guideline development, all relevant clinical research, including clinical trials, is reviewed and evaluated to create an updated summary of the state of our knowledge for that condition. These practice guidelines will play an important role in educating practitioners on the appropriate use of the latest clinical management options available to them.

Clinical research findings will also be used in the development of performance indicators for the quality report cards which will measure plan and provider performance and are to be developed by the National Quality Management Program. These indicators will take into account the best available scientific evidence about the impact of care on

particular health outcomes.

In addition, the Act provides coverage for routine care costs associated with participation in clinical trials. This expansion of coverage should increase the access to experimental treatments for those who are now uninsured or those without such coverage.

Another provision in the Health Security Act to assure the application and dissemination of research findings is the establishment of Regional Professional Foundations. These Foundations will be established by the National Health Board and will have as part of their charge the dissemination of information about health care quality improvement approaches and research findings. They will also be eligible to apply to AHCPR for ~~funds to support research on health care quality.~~

The President's plan will further promote the diffusion of research and technology by assuring that Academic Health Centers are integrated into the reformed health care system. Academic Health Centers are where much of clinical research is carried out and first applied. Health plans will be required to contract with a sufficient number of Academic Health Centers to assure that all of their enrollees have access to their specialized services.

Finally, title III, subtitle D, of the Health Security Act includes competitive grants to State health agencies to improve their ability to carry out core public health functions at the state and local level. These core functions include:

- surveillance of communicable and chronic diseases, and investigation of community health problems;
- control of communicable diseases and injuries;
- environmental health (water, food, housing);
- community health education; and
- laboratory services.

These grants also foster greater accountability to the federal government for the definition and reporting of progress in achieving public health objectives.

A second provision in Subtitle D provides grants to public and private non-profit agencies to address preventable priority health problems. Many of these problems do not affect the population of the country uniformly and call for tailored, community based prevention programs. For example, in some areas of the country, diabetes mellitus is a major problem; in other areas, priority may be accorded to programs that deal with cigarette smoking; while in still other areas, violence is an issue of great concern.

Mr. Chairman, this concludes my statement today. I would be pleased to answer any questions you might have.

Q&A

Senator Harkin: What do you think of the idea I have been suggesting for some time now, that of a Federal trust fund for supporting biomedical research?

Dr. Phil Lee: The Health Security Act authorizes sizeable sums for biomedical research on prevention, which has long been one of your priorities. As to your proposal for a dedicated financing mechanism for biomedical research, the President's proposal does not contain such a fund, and I would defer evaluation of such a proposal to those with particular expertise in the financing of trust funds.

Health Research: Improving the Knowledge Base

THE HEALTH SECURITY ACT OF 1993

IMPROVING THE KNOWLEDGE BASE & INFORMATION SYSTEMS

- Prevention research to learn how to promote health and prevent disease more effectively
- Health services research to treat the population more effectively and efficiently
- Improved information systems to help all participants in the system assess, improve, and make choices about care.

THE HEALTH SECURITY ACT OF 1993

PREVENTION RESEARCH

- Foundation for clinical preventive services and public health interventions
- Ensures availability of effective preventive measures against existing diseases and new/emerging health threats.
- Enables research to target populations that are disproportionately affected (eg. Alzheimer's disease, children's health, breast cancer, reproductive health).
- Preventing onset or progression of disease saves money

THE HEALTH SECURITY ACT OF 1993

HEALTH SERVICES RESEARCH

- Translate scientific advancements into the health delivery system to help control costs and improve the quality of life
- Identify what works best in medical care and how to provide care most efficiently and effectively.
- Develop accurate measures to assess the performance of alliances and health plans
- Identify how public health programs and personal health services can best be integrated

THE HEALTH SECURITY ACT OF 1993

HEALTH SERVICES RESEARCH

- Develop practice guidelines to improve health care
- Develop and validate approaches to risk adjust payments to health plans and providers
- Develop better analyses of economic and financial performance of plans and providers

THE HEALTH SECURITY ACT OF 1993



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

M E M O R A N D U M

To: Melanne Verveer
Nicole Rabner

From: Richard Soriano *RS*

Subject: Draft of First Lady's Remarks at NIH

Date: 2/14/94

Attached are the draft remarks for the First Lady's 2/17 visit to N.I.H. They have been reviewed by Dr. Philip Lee, Assistant Secretary for Health, and by Dr. Harold Varmus, NIH Director.

Please let me know if you would like me to make revisions to this text or if I can be of further assistance in any other way. I can be reached at (202) 401-5920 or by Fax at 690-7318.

Thanks again for the opportunity.

Remarks of
Hillary Rodham Clinton

at

The National Institutes of Health

February 17, 1994

GOOD MORNING:

It is, indeed, an honor and a privilege to join you here today at the seat of our nation's vital biomedical research effort.

My thanks to Secretary Shalala for that warm introduction. As you know, Donna and I go way back in our efforts to fight for the health of children in this country. She's doing a marvelous job at H.H.S. advancing our domestic agenda. My thanks, too, to your director, Dr. Harold Varmus, and to Assistant Secretary for Health Dr. Phil Lee, two of the sharpest minds in medicine and science who

have joined forces to give our government the best advice available to us.

I have enjoyed my time here today immensely. For more than a century, N.I.H. has led our nation toward the future, provided our people with better health, and afforded the world with scientific advances that guarantee us all a better quality of life. Today, N.I.H. stands as a beacon for scientists all over the world, who come seeking knowledge that can improve the lives of their people back home.

The accomplishments of this great research venture are truly impressive. Thirty-five thousand scientists in every state of our nation and in countries around the globe draw sustenance from N.I.H. Over its history, N.I.H. has supported the work of eighty-three scientists who have gone on to win a Nobel Prize for that work. Four of those scientists worked right here in N.I.H. laboratories.

The results of this work have been remarkable.

Mortality from heart disease, our number one killer, has declined 41 percent between 1971 and 1991.

Death rates from stroke dropped 59 percent in that same time period.

Improved detection and treatment have raised the five-year survival rate for people with cancer to 52 percent. That translates into 80,000 people surviving a disease that used to be considered a swift and sure killer.

New medications discovered here at N.I.H. have eased the pain of schizophrenia and reduced the tragic suicide rates among those who suffer that disease.

But you know as well as I that these accomplishments do not mean that your work here is done. And I'm here today to tell you that you and your colleagues around the country will have the full support of this Administration in carrying out the important work you do.

N.I.H. wasn't born out of whole cloth. It didn't suddenly spring up from the ground here in Bethesda, full-grown and fully matured. It was nurtured by the government and the people of this country, nourished by a consistent flow of funding and new minds to challenge the old precepts and stretch the bounds of science.

In 1945, in his landmark report, Dr. Vannevar Bush told us:

"Progress in the war against disease depends upon a flow of new scientific knowledge. New products, new industries, and more jobs require continuous additions to knowledge of the laws of nature, and the application of that knowledge to practical purposes."

That remarkably prescient counsel has guided our national science policies in the post-World War II era. Now, as we adjust to the post-Cold War period, Dr. Bush's words ring just as true.

Just last week, the scientific community lost one of its great leaders. Dr. Howard Temin, whose dogged pursuit of the enzyme, reverse transcriptase, won him a Nobel Prize in medicine, is one of the best examples of the importance of basic research.

No one would have called Dr. Temin an AIDS researcher, yet his work led directly to the quick identification of the AIDS virus. No one would have called him a bio-engineer, yet his work led to the birth of the biotechnology industry. What his colleagues did call him was a bench scientist -- words of high praise -- whose work opened doors and saved lives. Dr. Temin's death robs us of one of our best scientists and one of our best teachers.

The Clinton Administration believes very strongly in the wisdom of investment in basic science and in biomedical research. And we believe that biomedical research has been neglected for much of the past decade. We have underfunded research and we're trying to fix that.

Since taking office last January, the President has provided new leadership and new resources for the research enterprise here at N.I.H. In fiscal 1994, the President increased the N.I.H. budget by 631 million dollars over fiscal 1993. And this year, in the face of hard and fast spending restraints agreed to with the Congress, the President has proposed another 517 million dollar increase for fiscal 1995.

Money alone is not the entire answer. Leadership is important, too. That's why we were so glad that Harold Varmus agreed to come back to N.I.H. to take the helm. The first Nobel Prize winner to

head this distinguished agency, Dr. Varmus has an international reputation that raises the profile and the prestige of N.I.H. simply by his presence.

We have also established priorities for our national research effort that will provide direction without tying the hands of our creative research minds. There are significant new funds for AIDS research -- 21 percent more last year and another 6 percent increase this year. Today, one American dies of AIDS every nine minutes. By the end of this year, more than 348,000 Americans will have died of this disease in slightly more than a decade. We must continue to invest in AIDS research until we can talk about this epidemic in the past tense.

Between 1980 and 1990, the incidence of breast cancer rose 27 percent. Today, breast cancer is the leading cause of cancer in women in this country and, in this decade alone, more than 500,000 women

will die of this disease. Over the last two years, we have increased our commitment to breast cancer research by 84 percent, funding hundreds of new research projects in this area.

The Human Genome Project holds the promise of unlocking a myriad of mysteries about human life and disease. Already, it has identified 27 inherited disease genes, including 12 in 1993 alone. In the fiscal 1995 budget, the Genome Project receives an 18 percent increase to continue that important work.

Promising research is underway to identify the gene that causes inherited, early onset familial breast cancer, a discovery that could quickly lead to a simple test to identify those who are at risk. Just imagine the peace of mind or the sense of purpose that such knowledge will provide to women and their families.

Earlier today, I met with Dr. Francis Collins, the director of the Genome Project. I'm sure many of you know that one of Dr. Collins' pastimes is motorcycle riding. But I bet you don't know that every time the Genome Project identifies a new gene, Dr. Collins puts a Double Helix on his helmet -- sort of like a World War II fighter pilot. In the months and years ahead, we want to make sure that Dr. Collins will have a lot more opportunities to add to his collection. In fact, I think he'll have to start on a second helmet.

The President and I know, that the truest course to scientific advance is through basic research. A 1965 White House report on the N.I.H. included advice that is as important today as it was then. In advising the government to continue to invest in basic research, the authors said: *"the long way around is often the best and shortest path to useful results."*

Today, I saw first hand the evidence of how right that advice was. Sitting with us here today is a little girl named Ashanti DeSilva (Ah-Shahn-tee Di Sil-vah). Nearly three and a half years ago, Ashanti was in this very hospital to receive the world's first gene therapy to treat her ADA deficiency, a genetic defect that destroys the immune system and leaves a person vulnerable to countless infections. Before her treatment, Ashanti's life was one of confinement and fear. Today, she is healthy and living a full life.

Ashanti's successful treatment is only a chapter of a story that stretches back over nearly 30 years of basic biomedical research. From the discovery in 1944 that genes are made of DNA to the breaking of the DNA code in 1961 to the explanation of retroviruses in 1970 and the cloning of DNA in 1983, scientists here at N.I.H. put the pieces together that allowed Ashanti's treatment to become a reality.

Today, scientists are hard at work trying to apply the success with ADA Deficiency to such conditions as Cystic Fibrosis and AIDS.

We must build on these successes so that humankind can continue to benefit from our knowledge and our skill. That's why the President and his Administration have spent much of the last year developing a comprehensive plan to reform our nation's health care system. The President's Health Security Act builds upon the success of N.I.H. and shares the benefits of these achievements with all of our citizens.

First, and foremost, we must ensure that all Americans have the kind of private health coverage that those of us in Washington enjoy. When we hear the stories of families who have been shut out of our health insurance system we realize how valuable the security of health coverage really is. However, under our current financing system, no

American has true security. Each of us is one pink slip, one serious illness away from losing our coverage.

Those of you in the medical profession know too well the impact that a chronic illness can have on a family's well-being and on its income. When a family is locked out of the health care system by the refusal of an insurance company to provide them coverage, the remarkable breakthroughs you achieve here at N.I.H. become nothing more than a cruel hoax. Like a child pressed to the glass of a candy store window, these families can only look in and dream about what health care security would mean for them.

When an uninsured man with chronic heart disease reads about a new bypass technique his reaction is not one of joy, as we might expect. Instead, he believes that only others will benefit while he continues to suffer.

When an uninsured young couple hears about an N.I.H. breakthrough on infertility, they are not cheered. It's just one more disappointment for them.

And, when an uninsured woman with a history of breast cancer in her family reads about that momentous day when N.I.H. isolates the breast cancer gene, her anguish will stand in stark contrast to the elation felt by so many other Americans.

These are not simply moral or ethical conundrums. There are basic, practical reasons to ensure that all Americans have private coverage.

First, if we don't cover everyone, there is just no way that we can get a handle on these costs. We will spend more than a trillion dollars on health care this year and much of that will go for sick care, not health care. Despite the remarkable work done here at N.I.H. on

behavioral research, we spend billions to treat the symptoms of disease and comparatively little to prevent it.

Second, if all Americans don't have coverage, we won't share the benefits of our research advances with all of the people who work hard to pay the cost of that research.

And, third, if we don't change our insurance rules millions of Americans will be squeezed out of the system. Scientists here at N.I.H. are successfully developing better methods to identify early signs of hereditary illness. At the same time, insurance companies are finding more and more sophisticated ways to exclude those who are susceptible to disease from coverage. If this is allowed to continue, there will be no incentive for people to learn their status to protect their health.

Health reform isn't only about coverage and security. If we just hand every American a health security card the job of health reform is not done. Not by a long shot.

There hasn't been a great deal of attention paid to Title III of the Health Security Act, known as the Public Health Initiative. This critical part of the overall plan maps out a plan of investment in public health and biomedical research that will ensure that all Americans have access to the kind of top-quality medical care that N.I.H. research makes possible.

People with insurance cards have to have someplace to go to get their care. That's why we will make a huge investment in our public health infrastructure.

People with insurance cards need a physician to go to. That's why we will increase our investment in the training of health

professionals and provide an important new emphasis on primary care and prevention in the education of the next generation of physicians.

And people with insurance cards have to have access to the newest forms of treatment. That's why the Health Security Act makes an important new investment in biomedical research.

Together, these proposals create a new direction in health care that emphasizes prevention and primary care. And, for the first time, the public health system will be working with the personal health system to increase the healthy life span and reduce health disparities.

All across our country there are people who wake up every day, go to work, and come home to take care of their family yet they can't get basic health insurance. For more than forty years, we've tried to come to grips with this problem. This year we must be successful.

When we are, we will pave the way for a generation of Americans who are not only more secure but healthier too.

After all, that is what America is all about. We are a people who keep one eye on the past -- so that we can learn from our mistakes -- and the other on the future -- so that we can make sure to leave our children a better world than we inherited from our parents.

That's what this great debate is about. Leaving this world better than we found it. Giving our children better health and better lives. And allowing our parents and our grandparents to leave this life with more dignity and more comfort. I believe we can do this. I know we must do this.

Thank you very much.

cine has been available for more than a decade but remains greatly underused. Broad-scale vaccination today would be the most effective way to resolve many of the problems related to liver transplantation in generations to come.

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SOUNDING BOARD

CARDIOLOGY — DIVISION OR DEPARTMENT?

UNTIL the beginning of the 20th century, the organization of medical schools and hospitals was simple. There were usually four clinical departments representing the traditional disciplines — medicine, surgery, obstetrics and gynecology, and pathology. As various specialties developed, with their own training programs, a number of new departments evolved from these ancestral departments. From medicine came radiology, pediatrics, psychiatry, neurology, and dermatology, and from surgery came anesthesiology, orthopedics, ophthalmology, and otolaryngology.

As we approach the 21st century, the movement to subdivide medicine and surgery is continuing. In many institutions, divisions of neurosurgery and urology are seeking departmental status (and in some cases they have achieved it). It is in this context that the pressure exerted by some cardiology divisions to become free-standing cardiology departments should be viewed. This secessionist movement is controversial and is creating consternation for reasons that are easy to understand. Cardiology is by far the largest of the subspecialty divisions within departments of medicine. Because a cardiology division is often responsi-

ble for more than one third of a department's clinical activities and an even greater share of its clinical revenues, it is considered vital to both the teaching programs and the financial well-being of a department of medicine.

The drive by cardiology divisions for departmental status is being felt in both teaching and nonteaching hospitals. In nonteaching hospitals, where the principal mission is the efficient delivery of high-quality care, cardiology "services," including designated cardiac beds distinct from the rest of the medical beds, are becoming commonplace. Larger community hospitals have recognized that it is more efficient to segregate patients with cardiac diseases in cardiac intensive care units, step-down (telemetry) units, and cardiac nursing units, where specially trained personnel and appropriate equipment can both ensure optimal care and reduce the length of stay. In these institutions, the administrative separation of cardiology from medicine may not be perceived as a grave threat to the department of medicine. The situation is quite different in academic medical centers, however, where chairpersons of departments of medicine view the secession of their divisions of cardiology as the mayor of New York City might view the secession of Manhattan.

CONTENTIOUS ISSUES

Although several factors have led to the growing desire of members of cardiology divisions for independence, the most contentious issue, according to a

survey of chiefs of academic cardiology divisions, is financial, as reported by Barry Zaret, past president of the Association of Professors of Cardiology.¹ Revenues generated by cardiology divisions have been essential to departments of medicine for many years. With financial support from all sources dwindling, however, many cardiologists feel that a disproportionately large percentage of their clinical income is being used to subsidize other divisions within the department of medicine whose clinical services are in less demand and whose revenues often fail to match their expenses. Chiefs of cardiology in academic medical centers have had to stand by and watch some of their most respected clinicians move into the private sector, where they have been lured by lucrative offers. In addition, chiefs of cardiology also complain that limitations on their control over the resources generated by their divisions interfere seriously with their ability to direct large, complex programs and that their participation in decisions about institutional and departmental policies is inadequate, particularly when these decisions affect cardiology programs.^{1,2}

Academic cardiologists complain further that their colleagues in other divisions of the department of medicine, whom they subsidize — particularly those whose research involves molecular biology — regard research in cardiology as superficial, perhaps because it often involves relatively simple physiologic measurements such as volumes, shapes, pressures, flows, and wave forms. Cardiologists argue that if their division is to be the clinical workhorse of the department, the revenue it generates should at least be used for the academic enrichment of the division. In this manner it could provide much-needed support for basic research, so that research in cardiology would come to be as highly regarded within the academic community as that performed by, for example, endocrinologists or virologists in departments of medicine.

These sources of dissatisfaction need to be taken very seriously. In a recent survey, the majority of chiefs of cardiology in American medical schools favored departmental status for their divisions.³

THE THREE MISSIONS OF ACADEMIC CARDIOLOGY

It may be useful to view this controversy in terms of the three pillars of the academic medical center: research, education, and clinical care. Is cardiology more likely to accomplish its mission in these areas as a division within the department of medicine or as a free-standing department?

Research

The research mission of cardiology during the next few years will have three broad goals. The first is to continue to refine the current state of the art. Improvements in imaging procedures, invasive cardiology, and cardiovascular drugs will involve collaboration with other cardiovascular specialists, particularly radiologists and surgeons, and can probably best be

achieved in the setting of multidisciplinary cardiovascular units (which I shall discuss later).

The second goal is to assess new technology, diagnostic techniques, and therapeutic interventions and develop practice guidelines. This task involves research in epidemiology and health services, observational studies, and clinical trials. Strong divisions of general internal medicine and clinical epidemiology within departments of medicine usually include biostatisticians and experts in the design of clinical trials, assessment of outcomes, and analysis of the cost effectiveness of different management strategies. By functioning within departments of medicine and therefore benefiting from these departmental capabilities, cardiology divisions are likely to be more successful in achieving this objective than they would as free-standing departments.⁴

The third goal — and the one with the greatest potential for preventing disease, prolonging life, and reducing morbidity — is to apply the knowledge and techniques of modern biology to the understanding and treatment of cardiovascular disease.⁵ Perhaps because cardiology is rooted in hemodynamics and electrophysiology and has focused so strongly on these subjects, it has lagged behind other medical subspecialties in applying the principles of cell and molecular biology in the prevention, study, and control of disease. As we now know, the molecular processes underlying diseases of all organ systems are closely related. Therefore, research in any subspecialty of medicine should not be confined within the relatively narrow boundaries of the organ-oriented discipline.

Cardiovascular scientists have much to learn from working closely with virologists, immunologists, geneticists, hematologists, and endocrinologists. Strengthening, rather than weakening, the links between cardiology and other subspecialties in the department of medicine is likely to lead to important discoveries.⁶ Since many departments of medicine are now committed to research using the techniques of modern biology, cardiovascular scientists could incorporate these techniques more readily into their own research efforts if they were functioning within departments that already had a critical mass of scientists, technological expertise, facilities, and equipment.

Education

Reform of the health care system, with its emphasis on cost containment, will change the way that care is delivered in this country. Although many details are not yet clear, there is no doubt that the role of primary care physicians will be greatly expanded, whereas that of specialists will be curtailed. As the already enormous human and financial costs of cardiovascular disease continue to grow with the aging of the population, caring for patients with the most common chronic cardiovascular conditions — hypertension, coronary heart disease, and heart failure — will necessarily be the principal responsibility of primary care

physicians, who are believed to deliver care less expensively than cardiologists. Acting principally as consultants called in by primary care physicians, cardiologists will be involved only at certain stages in a patient's illness, evaluating complicated diagnostic problems, managing an acute event, or recommending catheterization, angioplasty, or surgery when indicated. They will continue to interpret the results of specialized tests and perform invasive procedures, but they will participate far less in the routine care of patients.

In the United States, there is 1 cardiologist for approximately every 13,000 people; in the United Kingdom, in contrast, with its emphasis on primary care, this ratio is about 1 per million. Although the imminent reform of the U.S. health care system will not transform the American system into the British one, we are likely to have a plethora of clinical cardiologists, whereas the need for primary care physicians who are competent to care for the great majority of patients with cardiovascular disease will increase.

Thus, the educational mission of cardiology divisions is likely to change substantially over the next few years. The emphasis will shift from the preparation of fellows for the practice of clinical cardiology to the training and continuing education of primary care physicians in the skills needed to deliver high-quality care to patients with cardiovascular disease, generally on an outpatient basis. Cardiologists will need to become more actively involved in the development of the curriculum in cardiovascular medicine for noncardiologists at both the undergraduate and graduate levels. Since the general medical training of students and the preparation of primary care physicians are important responsibilities of departments of medicine, this modified educational mission can, in my view, be carried out more effectively and responsibly by cardiology divisions functioning within departments of medicine than by free-standing departments of cardiology. The diagnosis and management of cardiovascular problems are so central to general medical care that it seems unwise to separate training in cardiology from that in general internal medicine, as is likely to occur if cardiology divisions assume departmental status.

I believe that departmental status for cardiology would also hinder the recruitment of the most promising young physicians into this subspecialty. Even with a reduction in the size of fellowship programs in cardiology, the field will still be forced to continue to compete against other specialties for the trainees who are most creative in research. To compete successfully, cardiology divisions must offer training in fields as diverse as molecular biology and clinical epidemiology. The most promising candidates for academic research careers are no longer as attracted to technology-based specialties as they are to using the tools of modern biology to understand and treat disease. They

are more likely to opt for a career in academic cardiology divisions where cardiology is perceived as part of the fabric of internal medicine.

Clinical Care

Patients hospitalized with primary cardiac illnesses — such as life-threatening arrhythmias, acute ischemic syndromes, and refractory congestive heart failure — will, of course, continue to require the services of cardiologists. An expanding array of conditions, ranging from stable angina to a variety of cardiac arrhythmias, can be managed effectively by cardiologists with training and experience in interventional or electrophysiologic techniques. In teaching hospitals, as in the larger community hospitals, these services can generally be provided more effectively in specifically designated cardiac beds, with medical and surgical patients with cardiac disorders occupying the same or adjacent facilities.⁴ From the perspective of the delivery of specialized high-technology clinical care, an argument can be made for the creation of multidisciplinary cardiovascular units.

ROUTES TO RESOLUTION OF THE CONFLICT

If the evolving missions of cardiology are to continue to be carried out effectively within the department of medicine, both the department and the division will need to make some concessions. Chairpersons of departments of medicine will have to cede more financial autonomy, control of clinical services, and departmental policy decisions to their chiefs of cardiology; sometimes this may be accomplished by appointing the chief of cardiology as vice-chairperson of the department. Chairpersons of medicine will also need to recognize the unique pressures faced by the members of cardiology divisions. For example, if cardiologists are devoting more time to acquiring and maintaining the high degree of technical expertise necessary in this specialty, they may find it harder to produce the scholarly work required for their academic advancement. Therefore, the chairperson of a department of medicine needs to nurture junior faculty members in the cardiology division and work with the division chief to develop fulfilling career paths for them within the academic institution. If the clinical income of cardiology divisions declines, cardiology will have to become fully eligible for the discretionary funds available to the department. Such measures should reduce the pressure for secession.

At the same time, chiefs of cardiology must recognize that the secession of cardiology divisions would seriously threaten the integrity of departments of medicine, since it would probably encourage other major subspecialty divisions to seek departmental status as well. The resulting balkanization could jeopardize the research and teaching goals that have been and remain the chief responsibilities of integrated departments of medicine as we know them — a heavy price to pay for some limited short-term gains for

the cardiology divisions.⁷ If the largest division of the department of medicine seceded, it would become much more difficult for that department to meet its educational responsibilities to medical students and house staff. The current difficulty of attracting medical students into training programs in internal medicine would be greatly intensified if students perceived that dealing with cardiovascular diseases was not a central responsibility of the internist.

Ironically, the greatest source of friction between divisions of cardiology and departments of medicine — the redistribution of clinical revenues — is likely to decline in importance, because the revenues generated by cardiology are themselves shrinking. The relative affluence of cardiology divisions has been a peculiarity of the fee-for-service reimbursement system, in which the reward for performing procedures and interpreting the results of specialized tests is disproportionate to that for the so-called cognitive aspects of care. This system is being replaced by contracted care and capitated reimbursement, in which the primary care physicians decide when the services of cardiologists (and other specialists) are required. The need for cardiologists, as well as payments for their services, will be reduced. Simply put, there will soon be far less revenue derived from clinical cardiology services to redistribute to other divisions.

RECOMMENDATIONS

We need to reconfigure our teaching hospitals in order to apply recent technological advances and our vastly enhanced understanding of human biology to patient care, rapidly and in a cost-effective manner. This task will demand the creation of strong, multidisciplinary subspecialty units, including cardiology units. A useful framework might be one in which the traditional clinical departments (medicine, surgery, radiology, anesthesiology, and so on) serve as the "vertical" components of a matrix and the multidisciplinary subspecialty groups (cardiology, oncology, neurology, and so on) form the "horizontal" components. In the case of cardiology, the members of such a unit would be cardiologists (treating adults and children), cardiovascular surgeons, cardiovascular anesthesiologists, cardiovascular pathologists, cardiovascular nurse specialists, and specialized support staff. According to this scheme, both the vertical and the horizontal components of the matrix would have important, albeit complementary, roles. Departments of medicine, which would be important vertical components in all teaching hospitals, would be responsible for the nonspecialty care of both inpatients and outpatients and for the education of medical students and primary care physicians, as well as for training medical subspecialists in internal medicine. The training of students and residents in cardiology and much of the most important research in cardiology, especially that using the tools of molecular

biology and clinical epidemiology, would be carried out within departments of medicine.

Traditional departmental boundaries must not be allowed to stand in the way of efficient patient care, however, and the horizontal multidisciplinary units, such as that focused on cardiology, would have increasingly important roles in clinical care, clinical research, and the training of subspecialists. For example, in such units cardiologists would learn more about the complexities of surgical care and cardiac surgeons would gain a deeper understanding of medical cardiology. Multidisciplinary cardiology units could be expected to provide better-coordinated, more comprehensive, and less fragmented care throughout the continuum of disease, from prevention to diagnosis, medical treatment, invasive cardiologic procedures, and surgical interventions.

In short, clinical cardiologists and cardiovascular scientists could best carry out certain important activities within departments of medicine, the vertical component of the matrix, and other, equally important activities within multidisciplinary cardiovascular units, the horizontal component. Thus, every cardiologist treating adult patients would be a member, simultaneously, of the department of medicine and of the multidisciplinary cardiovascular unit. (Similar multidisciplinary units could be established to deal with patients with cancer and patients with neurologic and musculoskeletal disorders.) Many knotty issues remain to be resolved, including the relative roles of the department and the multidisciplinary specialty unit in the allocation of space, salaries, and other resources — the usual problems that arise in situations of divided loyalty. But our academic medical centers must be flexible enough to allow for organizational innovation.

The medical profession is at a new and critical juncture. At no other time have the scientific underpinnings of clinical medicine been so powerful and the potential for applying them to the improvement of health care so strong. Yet at no other time has the profession been under greater scrutiny. Our leadership skills are being tested as never before. Internal struggles must not be allowed to divert us from the many important tasks at hand.

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BIOMEDICAL SCIENCE AND ITS ADMINISTRATION

A Study of The National Institutes of Health



THE WHITE HOUSE
WASHINGTON, D.C.
FEBRUARY 1965

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The Principal Findings

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The first and probably the most important general conclusion of the study is that the activities of the National Institutes of Health are essentially sound and that its budget of approximately one billion dollars a year is, on the whole, being spent wisely and well in the public interest.

The second general conclusion of the study is that, despite the significant past accomplishments and the high quality of the current effort, substantial problems will arise in the future unless changes are made in the *organization* and *procedures* of NIH.

The most important *organizational* need of NIH is the strengthening of its capacity for long-range planning, for determining the optimum utilization of its funds, and for ensuring that its activities and policies have the continued understanding and approval of the scientific and lay public. To help accomplish this strengthening, the Committee recommends the establishment of a new advisory group, referred to herein as the Policy and Planning Council, to operate at the level of the Director of the National Institutes of Health. Concurrent with the establishment of the Policy and Planning Council, the autonomy of the separate Institutes and Institute Councils should be diminished and the authority of the Director of the National Institutes of Health should be increased. Such change in the balance of authority should occur both with respect to the various elements of the NIH organization and with respect to the access of the Director to the higher councils of the Department of Health, Education and Welfare.

With respect to *procedures*, the most important NIH need is for changes to enhance the responsibility and authority of the university executives for the work conducted in their institutions. Accompanying their assumption of more responsibility for the NIH-supported work, the well-managed institutions should be made eligible for more funding of institutional grants (such as program projects and general research support grants). Authority should also be assigned to institutional executives to make a variety of project-related decisions presently reserved for central NIH determination. If proper changes are made a decrease in the red tape harassments that currently annoy many scientific investigators, along with an increase in the quality of institutional accountability for government funds, should be simultaneously achievable.

Current Quality and Cumulative Impact of NIH Activities

* *The NIH mission.*—Its broad mission of improvement of virtually all aspects of the Nation's health requires NIH to concentrate most of its effort on basic research, leaving for directed, developmental effort only those research discoveries which appear to be susceptible of exploitation. The "disease category" nature of the NIH organizational structure makes the task more difficult, but not impossible.

* The activities and accomplishments of the National Institutes of Health, like those of any other organization, must be judged in terms of its mission. In general terms, the public funds that support NIH activities are intended to "buy" for the American people a commensurate degree of relief from suffering and improvement of health. To achieve this goal, NIH devotes its principal effort to a broad program of investigation of life processes, rather than to a search for direct cure or prevention of specific diseases. It employs this approach for a simple and valid reason: life science is so complex, and what is known about fundamental biological processes is so little, that the "head-on" attack is today frequently the slowest and most expensive path to the cure and prevention of disease. When a goal is as broad as that of a national health program covering a wide range of human illness and suffering there is adequate justification from the past history of science for an emphasis on basic research, supplemented of course by a sharp watch for and exploitation of those findings which are capable of leading to treatments, cures and preventives. The "long way around" is in this case likely to be the shortest path to useful results.

The non-directed research orientation of most of the NIH programs deserves mention, we believe, because it may not be universally understood. cursory reading of the various legislative acts that establish NIH powers and responsibilities would not make this point clear. Similarly, the employment of such labels as "heart," "cancer," "neurological diseases and blindness," and the like, in the titles of the major organizational units of NIH, suggests more of an orientation to specific diseases than actually exists. Although there are practical reasons for such an over-emphasis on disease categories in the organizational structure, it is not ideally suited to the kind of research programs which must actually be carried out. One of the accomplishments of the NIH management

has been that of making a scientifically inappropriate organizational structure an effective arrangement for performing its real mission. The fact that responsibility for certain projects has been assigned to the Heart Institute has not prevented the results of such projects from finding their most extensive application in the alleviation of arthritic suffering. Similarly, outstanding investigators working in basic areas of broad application such as biochemistry and genetics have been supported by, and in turn have technically supported, the scientific work of more than one Institute. Because of the number of different Institutes, there is room for the assignment to one or the other of substantially all of the special disciplines that comprise the life sciences. In this way the necessary broad coverage is secured.

Thus, we may say that the primary *de facto* mission of NIH is the stimulation and support of a very broad range of health-related or biomedical research.

* *Quality of current work.*—The opinion of the Committee, based on the extensive investigations of its consultants, is that the large majority of the intramural and extramural research supported by NIH is of high quality. We strongly approve the peer evaluation method of selecting recipients of extramural grants.

One of the principal purposes of this study was to evaluate the quality of the research currently supported by the National Institutes of Health. Because of the competence and distinction of the consultants who performed the survey for use, as well as the extensiveness of the survey itself, we have considerable confidence in the validity of our conclusions regarding the general quality of the NIH activities.

1. The non-directed* research supported by NIH, both through extramural grants to scientists in non-government institutions and through its own intramural activities, is typically of high quality. Out of the 240 "traditional" extramural research grants investigated, the panel teams expressed serious reservations about 9 projects and adjudged an additional 7 to be unworthy of support. In scientific research, such a ratio of ill-advised projects, when judged after the fact, is impressively low. Much more frequently, NIH-supported work was found to set the national or international standard of excellence in its field.

2. Despite the tenfold increase in NIH support of research during the last eight years, there is no evidence of over-all degradation in quality of the work supported. On the contrary, there is good evidence that the average quality is steadily improving. This appears to be a consequence

*The large, centrally managed Collaborative Research programs are not referred to here.

of a rate of increase in the production of competent biological research scientists matching the over-all rate of increase in research support.

3. The NIH funds and equipment allocated to a project are ordinarily well related to the task to be accomplished, and the funds are expended with care and probity by the investigator.

4. The NIH method of selecting recipients of its extramural grants, which account for more than 70 percent of the entire NIH expenditures, is an exceedingly good one. The selection method incorporates reviews of both the scientific merit of an individual proposal and of its relevance to the over-all program of the NIH. The most important characteristic of these reviews is that they are accomplished almost entirely through peer judgments of non-government research scientists. In science, we know of no valid method of estimating the probable pay-off of a proposed project except that of exposing it to such an appraisal by distinterested and expert scientists. In the NIH program, we believe there is correlation between the generally high quality of the scientific work supported and the utilization of scientific peer judgments prior to initial award or grant renewal. The many advisory groups that perform the difficult chore of evaluating the relative merits of thousands of applications are deserving, we think, of the admiration they receive for the distinction and dedication of their membership, and for the competence and fairness of their decisions. The investigators were impressed by their discovery that such admiration was almost as widespread among those whose applications had been rejected as among those who had succeeded in getting support.

5. The only major category of NIH activity in which the over-all level of performance was not judged to be high consisted of the large Collaborative Programs. These Programs are characterized by special technical management problems. The special problems associated with Collaborative Programs are treated in a later section of this report.

* Cumulative impact of NIH activities.—The NIH activities of recent years have greatly improved the quality and quantity of both research and teaching in our biomedical institutions. In the process, the Federal Government has established an important precedent of financial assistance; withdrawal or substantial curtailment of its support would be disastrous to this important segment of science and education.

The principal locale of health research has always been, and remains today, the universities and medical schools. Therefore this is where NIH employs the majority of its funds: more than three-quarters of its entire budget, in fact. In universities and medical schools the performance of research is inextricably interwoven with the teaching of stu-

dents. Such interrelationship is not only an undeniable fact of academic life; it is, we think, a very desirable fact of academic life. Scientific research and higher education should not and cannot be dissociated. Current biological discoveries constitute the useful immediate products of the NIH-supported research projects; future discoveries will largely depend on the effectiveness of today's scientist/teachers, frequently aided by NIH training grants, in instructing and inspiring the next generation of health research scientists.

Therefore, if we are to appraise the major effects to date of the NIH program, we must seek an answer to the question: "What contribution has NIH made to the capability of the universities and medical schools to perform productive health research now, and to maintain a flow of trained scientists to perform the health research of the future?"

One of the assignments of our visiting teams was to determine the opinions of the scientists and administrators of each institution visited relative to this issue. On the basic question there was complete unanimity in the opinions expressed, as well as in the supporting judgments of our own panel members: the NIH programs have been of enormous benefit to the universities and medical schools. In case after case we learned that institutions had, because of NIH support, been able to build up their health research activities to a much higher level of quality and quantity than would otherwise have been possible; and through the NIH training grants serious deficiencies in research talent available for exploitation of important fields of life science had been systematically ameliorated (see, for example, the reports of the Panels on Pathology, Biochemistry, Biophysics, and Behavioral Sciences). Despite the preponderance of funding for research rather than training, the quality of instruction in the medical schools and life sciences departments has been much improved as a consequence of the Federal program. To quote the Behavioral Sciences Panel, "The availability of stimulating researcher-teachers, and the new areas of interest and inquiry which they bring to their instruction, arouse greater interest in students than did the exclusively clinical doctrinaire instruction which is steadily being supplanted."

To be sure, a price has been paid for these results, in terms of a new and extensive dependence of our educational institutions on Federal funding. Many of the medical schools, and some of the biology departments in the institutions in our survey, now receive more than half of their total budget from NIH. By extrapolation it is probably safe to say that nearly all important medical schools in the country, and many departments of life science, are now critically dependent on Federal funding. Fortunately, NIH has administered its programs with such restraint that there is almost no serious suggestion that government funding has been accompanied by undesirable Federal control of educational

policy. Nevertheless, financial dependence on the government is now an established fact of scientific academic life. We see no prospect that this will change in the future. Congress will presumably use its powers to ensure that the NIH programs remain responsive to the health needs of the nation. However, withdrawal or substantial curtailment of Federal support would be disastrous to this important segment of science and education. Indeed, continued growth appears to be imperative.

✕ *Economic appraisal of the NIH program.*—The Committee believes that the current billion dollar budget of NIH is not too high, and that it constitutes a sound investment for the American people.

In FY 1965 the NIH budget will approximate one billion dollars. The most pertinent question that can be asked about the program is whether it is buying one billion dollars a year worth of benefits for the American people. There is no way of definitely answering such a question. The alleviation of human suffering and the improvement of health cannot be assigned a precise monetary value. Even if this were possible, there is an additional strong ingredient of faith that must be invoked to support the continuing expenditure of large sums of money on any research-oriented program. There is never an advance guarantee of a practical outcome; and the results, if any, are as likely to lead to application five, ten, or twenty years from now as they are today. But this is, by comparison with previous periods, an age of scientific sophistication. The technological revolution in which we are engaged has led to an appreciation for the value of science. Most people now know that scientific exploration is not only generally practical, but that over the long run it may be one of the most practical of all human activities in terms of the benefits it brings to society. The justification for the NIH program is largely of this nature—if it is steadily effective in increasing the quality and quantity of health related scientific research, it should ultimately prove to be money well spent.

There are, of course, some indirect bases of measurement. In addition to the qualitative opinions of the institutional scientists and administrators affected by the program, figures may be cited illustrating the very large direct and catalytic effect the NIH program has had on the quantity of funds available for medical research in this country. Since 1947, Federal funds for medical research have risen from \$27 million to \$1,089 million (est.) in 1964. During that same period, non-Federal support of medical research has grown by a factor of ten from \$60 million to \$590 million (est.) in 1964. In FY 1964 NIH alone provides 100% more money for medical research than the total national efforts of seven years ago.

And there are at least qualitative indications that greater expenditures for health research are yielding greater progress in the alleviation of disease. The control of polio, the decrease in the death rate from other infectious diseases, the dramatic reversal in the previous trend of increasing occupancy of mental hospitals, the development of the artificial kidney and the progress in transplanting complete organs—all are recent achievements of medical science that can hardly be unrelated to the increased research in the field. And recent scientific developments such as those in molecular genetics have already suggested important future applications in the relief of disease and human suffering.

x In brief, we consider the NIH program to be sound and recommend its continued support. Its one billion dollar budget is not high, when compared to the more than thirty billion dollars a year the American public pays for assorted health services; the money is on the whole being competently and efficiently employed on a broad spectrum of health-related research; lessons from the past history of science, supported by the current acceleration of medical discovery, strongly suggest a satisfactory future pay-off. Furthermore, as discoveries are made in the life sciences and the physical sciences, new opportunities will be created for health research, and these too should be exploited with the enthusiasm and vigor which has distinguished the NIH program during the past decade. We feel that the Congress in particular deserves considerable credit for its past and continuing support of this kind of farsighted program. We suspect that there are few, if any, one billion dollar segments of the Federal budget that are buying more valuable services for the American people than that administered by the National Institutes of Health.

SUMMARY OF MAJOR RECOMMENDATIONS

1. We consider the NIH program to be sound and recommend its continued support.

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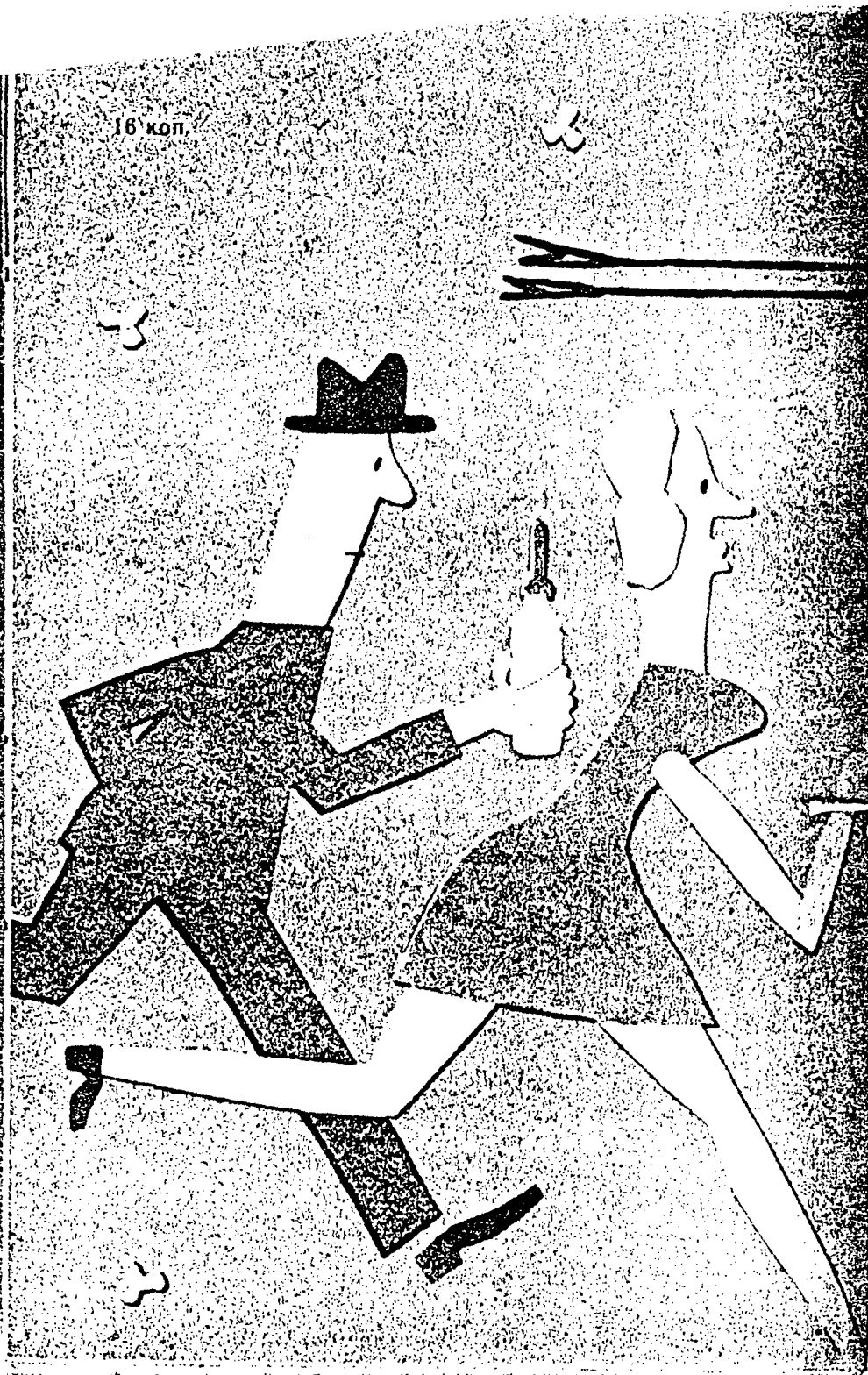
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Aspects of Biomedical Science Policy

BY LEWIS THOMAS, M.D.

Dean, Yale University School of Medicine



An Occasional Paper of the Institute of Medicine is intended to convey observations of particular interest to the Institute's members and friends. The opinions expressed are those of the author. Part I of this Occasional Paper is drawn from Dr. Thomas' article in *The New England Journal of Medicine*, October 12, 1972.

ASPECTS OF BIOMEDICAL SCIENCE POLICY*

LEWIS THOMAS, M.D., *Dean*
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I

I should like to present two different points of view about policy for biomedical science. Although the two viewpoints will seem not only different but even in conflict, they are both my own. Personally, I do not believe them to be in conflict, although, since they concern quite different aspects of today's health care problem, they are, in fact, quite different.

The first view concerns the health of the people and the problems associated with medicine's role in its maintenance. The second concerns the problem of disease.

We spend \$70 billion a year on health, as we keep reminding ourselves, or is it now 80? Whichever, it is a socking sum, and just to mention it is to suggest the presence of a vast, powerful enterprise, intricately organized and coordinated. It is, however, a bewildering, essentially scatterbrained kind of business, expanding steadily without being planned or run by anyone in particular. Whatever sum we spent last year was only discovered after we'd spent it, and nobody can be sure what next year's bill will be. The social scientists, attracted by problems of this magnitude, are beginning to swarm in from all quarters to take a closer look. There doesn't seem to be any doubt about the amount of money being spent, but it is less certain where it goes, and for what.

It has become something of a convenience to refer to the whole endeavor as the Health Industry. This provides the illusion that it is in a general way all one thing, and that it turns out, on demand, a single, unambiguous product, which is Health. Thus, Health Care has be-

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come the new name for medicine. Health Care Delivery is what doctors now do, along with hospitals and the other professionals who work with doctors, now known collectively as the Health Providers. The patients have become Health Consumers. Once you start on this line, there's no stopping. Just recently, in order to correct some of the various flaws, inequities, logistic defects, and near-bankruptcies in today's Health Care Delivery System, the government has officially invented new institutions called Health Maintenance Organizations, already known familiarly as HMO's, spreading out across the country like post offices, ready to distribute in neat packages, as though from a huge, newly stocked inventory, Health.

Sooner or later, we are bound to get into trouble with this word Health. It is too solid and unequivocal a term to be used as a euphemism, and this seems to be what we are attempting. I am worried that we may be overdoing it, taxing its meaning, in order to conceal an unmentionable reality that we've somehow agreed not to talk about in public. It won't work. Illness and death still exist and cannot be hidden. We are still beset by plain diseases, and we do not control them; they are loose on their own, afflicting us unpredictably and haphazardly. We are only able to deal with most of them when they have made their appearance, and we must use the methods of medical care for this, as best we can, for better or worse.

It would be a better world if this were not true, but the fact is that we do not develop diseases just because of being careless about the preservation of Health. We do not become sick only because of a failure of vigilance. Most illnesses, especially the major ones, are blind accidents that we have no idea how to prevent. We have considerably more rhetoric about disease prevention than can be justified by scientific proof today, and we are at risk in overstating the facts. To be sure, there are a few important diseases, such as glaucoma and cervical cancer, which can be more effectively treated if detected early; we might prevent lung cancer if we could only learn to prevent cigarette smoking, and we have some excellent techniques for immunization. But we really cannot extrapolate a very great distance from these achievements. The great majority of chronic disease, including heart disease, cancer, and stroke, remain largely beyond our control. We are really not all that good at preventing disease or preserving health, not yet anyway, and we are not likely to be until we have learned a great deal more about disease mechanisms.

There is disagreement on this point, of course. Some of the believers among us are convinced that once we get a Health Care Delivery System that really works, the country might become a sort of gigantic spa, offering, like the labels on European mineral water bottles, preventives for everything from weak kidneys to moroseness.

It is a surprise that we haven't already learned that the word is a fallible incantation. Several decades of Mental Health have not made schizophrenia go away, nor has it been established that a Community Mental Health Center can yet maintain the mental health of a community. These admirable institutions are demonstrably useful for the management of certain forms of mental disease, but that is another matter.

My complaint about the terms is that they sound too much like firm promises. A Health Maintenance Organization, if well organized and financed, will have the best features of a clinic and hospital and should be of value to any community, but the people will expect it to live up to its new name. It will become, with the sign over its door, an official institution for the distribution of Health, and if anyone thereafter develops, as they surely will, intractable heart disease, or multiple sclerosis, or rheumatoid arthritis, or that majority of cancers that can neither be prevented nor cured, or chronic nephritis, or stroke, or moroseness, the people will begin looking sidelong and asking questions in a low voice.

Meanwhile, we are paying too little attention, and respect, to the built-in durability and sheer power of the human organism. Its surest tendency is toward stability and balance. It is a distortion, with something profoundly disloyal about it, to picture the human being as a teetering, fallible contraption, always needing watching and patching, always on the verge of flapping to pieces; this is the doctrine that people hear most often, and most eloquently, on all our information media. We ought to be developing a much better system for general education about human health, with more curricular time for acknowledgment, and even some celebration, of the absolute marvel of good health that is the real lot of most of us, most of the time.

The familiar questions about the needs of the future in medicine are still before us. What items should be available, optimally, in an ideal Health Care Delivery System? How do you estimate the total need, per patient per year, for doctors, nurses, drugs, laboratory tests, hospital beds, X-rays, and so forth, in the best of rational worlds? My not entirely frivolous suggestion for a new way to develop answers is to examine, in detail, the ways in which the various parts of today's medical care technology are used, from one day to the next, by the most sophisticated, knowledgeable, and presumably satisfied Consumers who now have full access to the system--namely, the well-trained, experienced, middle-aged, married-with-family internists.

I could design the questionnaire myself, I think. How many times in the last 5 years have the members of your family, including yourself, had any kind of laboratory test? How many complete physical examinations? X-rays? EKG's? How often, in a year's turning, have you prescribed antibiotics of any kind for yourself or your family? How many hospitaliza-

tions? How much surgery? How many consultations with a psychiatrist? How many formal visits to a doctor, any doctor, including yourself?

I will bet that if you got this kind of information and added everything up, you would find a quite different set of figures from the ones now being projected in official circles for the population at large. I have tried it already, in an unscientific way, by asking around among my friends. My data, still soft but fairly consistent, reveals that none of my internist friends have had a routine physical examination since military service; very few have ever been X-rayed except by dentists; almost all have resisted surgery; laboratory tests for anyone in the family are extremely rare. They use a lot of aspirin, but they seem to write very few prescriptions and almost never treat family fever with antibiotics. This is not to say that they do not become ill; these families have the same incidence of chiefly respiratory and gastrointestinal illness as everyone else, the same number of anxieties and bizarre notions, and the same number — on balance, a small number — of frightening or devastating diseases.

It will be protested that internists and their households are really full-time captive patients and cannot fairly be compared to the rest of the population. As each member of the family appears at the breakfast table, the encounter is, in effect, a house call. The father is, in the liveliest sense, a family doctor. This is true, but all the more reason for expecting optimal use to be made of the full range of medicine's technology. There is no problem of access, the entire Health Care Delivery System is immediately at hand, and the cost of all items is surely less than for non-medical families. All of the usual constraints that limit the use of medical care by the general population are absent.

If my hunch, based on the small sample of professional friends, is correct, it would appear that these people use modern medicine quite differently from the ways in which we have systematically been educating the public over the last few decades. It cannot be explained away as an instance of shoemakers' children going without shoes. Doctors' families do tend to complain that they receive less medical attention than their friends and neighbors, but they seem a normal, healthy lot, with a remarkably low incidence of iatrogenic illness.

The great secret, known to internists and learned early in marriage by internists' wives, but still hidden from the general public, is that most things get better by themselves. Most things, in fact, are better by morning. Obviously, it is a great time-saver and money-saver for the physician's family that anxiety about disease is not handled as though it were disease itself; there is perhaps a greater willingness to accept anxiety as a natural, often transient, phenomenon. And certainly there is much less ambition to deploy the full technology of medicine as a corrective for the human condition.

It is conceivable that we might be able to provide good medical care for everyone needing it, in a new system designed to assure equity, provided we can restrain ourselves, or our computers, from designing a system in which all 200 million of us are assumed to be in constant peril of failed health every day of our lives. In the same sense that our judicial system presumes us to be innocent until proven guilty, a medical care system may work best if it starts with the presumption that most people are healthy. Left to themselves, computers may try to do it in the opposite way, taking it as given that some sort of direct, continual, professional intervention is required all the time, in order to maintain the health of each citizen, and we will end up spending all our money on nothing but this. Meanwhile, there is a long list of other things to do if we are to change the way we live together, especially in our cities, in time. Social health is another kind of problem, more complex and urgent, and there will be other bills to pay.

II

If taken out of context, my remarks to this point might be interpreted as an argument against intervention — conceivably, as a case against expanding our efforts in medical care. This is not my intention. On the contrary, I believe that we are under obligation to do a great deal more than we are doing today, in both the prevention and treatment of disease. But before we can do the genuinely effective, decisive things that need doing, we are totally dependent on a kind of information about disease that does not yet exist. To explore this dilemma, I should like now to consider certain problems relating to the available technologies of medicine.

The technology of medicine has certain peculiar features that differentiate this field from all the rest. One difference has to do with the economics; that seem to govern all other technological advances but have no discernible influence on the kinds of things we do, or *think* we do, in medicine. For example, we do not build new bridges at great cost without knowing in advance, quite precisely, what the transport requirements will be in the future and having some kind of assurance that the bridges will bear the traffic, meet all foreseeable demands, and stand up to all foreseeable stresses. But we will undertake the development of an artificial heart, at the cost of many bridges, without going through any sort of cost-benefit, logistic, or even moral analysis of what it is that we are making. Indeed, in medicine, it is characteristic of our technology that we do not count the cost, ever, even when the bills begin coming in. I should like to come back to the artificial heart business a bit later on.

This is, plainly, a defect in our system, if we can be said to have a system. It is, in part, explainable by our history, by the brand newness of any kind of technology at all in this field, and our consequent unfamiliarity with any methods, or indeed, any incentive in the first place, for technology assessment in medicine. We have had almost no genuine science to tap into for our technology until just the past three decades. As a profession, we go back a very much longer stretch of time, probably thousands of years. During most of our history, therefore, we have become accustomed to no technology at all, or to pseudotechnologies without science. We acquired the habit, long since, of improvising, of trying whatever came to hand, and in this way, we have gone through our cyclical fads and fashions, generation after generation, ranging from bleeding, cupping, and purging, through incantations and the reading of omens, to prefrontal lobotomy and metrazol convulsions, and we have all gotten quite used to this kind of thing, whether we will admit it or not. Early on, we became accustomed to the demand that a doctor must *do* something; doctors who didn't *do* something, no matter what, were not real doctors, any more than shamans were real shamans until they turned on the good spirits and turned off the bad ones. During the long period when we knew of nothing to do about typhoid fever except to stand by and wait for the patient to struggle through, keeping an eye out for the hemorrhages and perforations that might kill him at any time, the highest level of technology was the turpentine stupe, an elaborate kind of fomentation applied to the belly, very difficult to make without ending up with a messy shambles, and capable, I believe, of doing absolutely no good whatever beyond making everyone feel that the doctor was *doing* something. This, by the way, is not a baroque item of our distant history. I learned to make a turpentine stupe at the Peter Bent Brigham Hospital in 1937; it is, therefore, in my view, a relatively recent, almost modern, example of the way we develop technology, and it is not yet all behind us, as we shall see. We still have our equivalents of bleeding and cupping and turpentine stupes, and they are all around us.

The trouble with this kind of pseudotechnology or magical technology, is that it has become unbelievably expensive in its more modern forms, and, at times, it is dangerous. It is particularly dangerous and expensive when it takes the form of strong drugs, or bizarre diets, or surgery, which it sometimes does.

We may be in danger of forgetting the real reason why we have always done such things in the first place. Why, when we do not understand, even faintly, the underlying nature of a fatal disease and can do nothing about it to change its course, do we feel an obligation to *do* something—and why does society expect us to try? The answer, of

course, is that we must; it is in our nature to try; the very best definition of a physician's occupation ever given is the old one: "to cure sometimes, to relieve often, to comfort *always*." It is that word "*always*" that is operative. And one of the best ways to comfort is to keep trying, no matter what.

But now that science has entered medicine in full force, we must begin to sort out our affairs. From now on, we will need, as never before, to keep these central enterprises—"to cure, to relieve, to comfort"—clearly separated from each other in our minds. They do not really overlap, but we tend to view them, and the public takes, of course, the same view, as though they were all of a piece, all the same body of technology, all derived from science, all modern. I think perhaps one reason we do this is because of an unconscious conviction that dollar values must be placed on all human enterprises, and we do not like to confess to ourselves that so many of the things that we do are simply provided for comfort and reassurance. Somehow, this has come to seem a less significant product than a cure; so we try, consciously or unconsciously, to pretend that there is more continuity than is really there, that everything we do is directed toward the same end.

In fact, in real life, we are engaged in three, maybe four, entirely different kinds of technology in medicine. I have an idea that if we could conduct a sort of technology assessment on ourselves and come to some sort of general agreement about which technology belongs in which category, we might be in a better position to make intelligent plans and forecasts for the future, and we would almost surely be clearer in our minds about how to set priorities for the investment of scientific resources for the future.

Before beginning on my own version of a classification, I would like to make a general declaration of faith and a general confession of optimism. My dogmas are as follows: I do not believe, first of all, in the inevitability of disease; I concede the inevitability of the *risk* of disease, but I cannot imagine any category of human disease that we are precluded, by nature, from thinking our way around. Moreover, I do not believe that when we succeed in controlling or curing one kind of disease we will necessarily, automatically, find that it has been replaced by another.

Even if I am wrong about this, and it should turn out that there is some law of nature that mandates the doling out of new diseases up to some optimal number whenever old ones disappear (which strikes me as a piece of illogic as well as high improbability), I still cannot imagine remaining helpless before all the new ones. Nature is inventive, I grant, but not as inventive as to continue elaborating endless successions of brand new, impenetrable disease mechanisms. After we have

learned enough to be able to penetrate and control the mechanisms of today's disease, I believe we will automatically be well equipped to deal with whatever new ones turn up. I do not say this in any arrogance, it just seems to me reasonable.

I have no more difficulty in imagining a disease-free human society, or at least a society in which major diseases are held under control, than I do with the idea that valuable stocks of animals, or varieties of plants, can be maintained *relatively* free of disease.

I believe that disease is, fundamentally, unnatural. It is not, in my view, a normal or natural part of the human condition for aging human beings to become paralyzed and idiotic for long years before they finally die, any more than it is for young people to develop acute leukemia. I believe that disease results, generally, as the result of biological mistakes: misinterpretations, on the part of cells and tissues, of signals; misuse of information. I believe that there is a general tendency, amounting to a kind of universal natural force, for living things to attempt to join together, to pool resources, to establish symbiotic relationships. Parasitism is what happens when this fundamental drive forces partnerships upon inappropriate, wildly asymmetric partners. To protect against such collisions, we are all provided with chemical signals of identity, by which the life of the earth is regulated and kept balanced. Certain major varieties of disease are due to the panic produced by such signals; for example, most mammals, and even certain invertebrates like *Limulus*, read the signal of the lipopolysaccharide endotoxin extracted from Gram negative bacteria as the news of absolute doom, and so violent an inflammatory reaction is set up inside the whole vascular compartment that the circulation of the blood is brought to a standstill. This happens not because of any intrinsic poisonous properties of endotoxin, but because of the way the information contained in its molecule happens to be read by an animal host. In my view, much of human disease works in this way, and the mechanisms involved are, I believe, quite open to intelligent intervention and reversal whenever we learn more about how they operate.

To say it another way, I do not consider that the ambition to control or eliminate disease, which is an ambition shared by everyone in biomedical science, is either unthinkable or any distance beyond imagining. What makes it seem to many people like an outlandish, even outrageous, way to be talking is that it becomes assumed that we are talking about human happiness, which is really quite another matter, or about human mortality, which is also quite another matter. As to the first, it is, of course, true that disease has long been a major cause of human despair and wretchedness, but this is no reason to believe that we will all become happy, well-adjusted people by being rid of it. We will still be left

with an abundance of worrisome problems, and we will still have more than our share of ample reasons for despair, and no medical science—not even psychiatry—has any foreseeable contribution to make to these matters. War and bombs, failure and anomie, clouding of the sun by particles of our own waste, the shutting off of oxygen, the loss of room to move around—these are problems still to be with us, for some time to come, healthy or ailing, and I hope that no one will suggest that these are in any sense problems for medicine—or we will never get any of them solved. But perhaps human society will be better equipped to think its way through these imponderables if, at least, we no longer have today's roster of diseases to worry us at the same time.

As to mortality, I have a hunch that we will discover, someday, that disease and death are not as inextricably interrelated as we tend to view them today. All the rest of nature undergoes, in its variable cycles, the physiological process of death by the clock; all creatures, all plants, age finally, and, at the end, they all die. Diploid cells in tissue culture have finite life-spans, which are different for different lines of cells and characteristic of particular cell stocks. Some live for 40 generations and then die, others for 70. They do not develop fatal diseases; it is not a catastrophe, they simply reach the end of a life-span programmed for them in their own genomes, and, at the end of that span, they die.

I believe that we are also like this. If we are not struck down prematurely by one or another of today's diseases, we live a certain length of time and then we die, and I doubt that medicine will ever gain a capacity to do anything much to modify this. I can see no reason for trying and no hope of success anyway. At a certain age, it is in our nature to wear out, to come unhinged and to die, and that is that. My point here is that I very much doubt that the age at which this happens will be very drastically changed, for most of us, when we have learned more about how to control disease. The main difference will be that many of us will die in relatively good health, in a manner of speaking, rather after the fashion of Bertrand Russell. Or we may simply dry up and blow away.

And even if our technology were to become so dazzlingly effective as to rid us of all the major diseases that now kill many of us off before our time of wearing out, I doubt that the increase in population caused by this would make more than a marginal difference to the general problem of world over-population. Indeed, it might help some, since there would be smaller numbers of us in hospitals or living out our lives in various degrees of incapacitation and suffering. Being over-populated is bad enough as social problems go, but to be over-populated with so many of us disabled by disease, especially by the chronic diseases of the elderly, let alone schizophrenia, presents an unthinkable prospect for the approaching century.

In any case, we do not really owe much of today's population problem to the technology of medicine. Over-population has been coming on for several centuries, and the alarming upward slope began long before we had developed a genuine capacity to change the outcome of disease. Modern medical science is a recent arrival, and the world population had already been set on what seems to be its irreversible course by the civilizing technologies of agriculture, engineering, and sanitation—most especially the latter. From here on, the potential benefits of medicine greatly outweigh any conceivable hazard; we will perhaps change slightly the numbers of us living at any moment in time, but it lies within our capacity to change very greatly the quality of life.

Well, where do we stand today as a science? This is not the same question, of course, as the one concerning the state of our technology. Our science is the science of the biological revolution, and we have scarcely begun to apply any of it. We do not, in fact, yet know where to begin. In contrast with today's genuinely high technologies of molecular biology, or neurobiology, or cellular biology, with the immense power of their instruments for exploring the most fundamental questions about the processes of life, the condition of our knowledge of disease mechanisms has a primitive, 19th-century look, and our capacity to intervene in disease is not much better. This is the general shape of things today, but tomorrow will be very different indeed. I simply cannot imagine any long persistence of our ignorance about disease mechanisms, in the face of all that is being learned about normal cells and tissues. Our time for the application of science, on a major scale, is approaching rapidly, and medicine will be totally transformed when it happens. The hard problem just ahead will be for us to set priorities and make choices between options. We will be obliged, as never before in our history, to select between alternative possibilities in technology; we will be compelled to make long-range predictions as to the outcome of this course or that; in short, we will be thrust into the business of technology assessment, just like all the other great national enterprises.

It is a curious position that we are in today, poised as we are between the old world of trial-and-error empiricism, superstition, hunch, and resignation to defeat, and the new world, just ahead, of hard information and applied science. We seem to work, as of now, with three different levels of technology.

1. First, and necessarily foremost, is what might be termed the high technology of medicine, equivalent, in its sophistication and effectiveness, to the high technologies of the physical sciences. It is a curious fact that although the accomplishments here represent the major tri-

umphs of medicine to date, most of us tend to take them for granted, and we often forget what they mean for the quality of life in modern society. This is the genuinely decisive technology of modern medicine, exemplified best by methods for immunization against diphtheria, pertussis, and various virus diseases and the contemporary use of antibiotics and chemotherapy for bacterial infections. The capacity to deal effectively with syphilis and tuberculosis represents a milestone in human endeavor, even though full use of this potential has not yet been made. And there are, of course, other examples: the treatment of endocrinologic disorders with appropriate hormones, the prevention of hemolytic disease of the newborn, the treatment and prevention of various nutritional disorders, and, perhaps just around the corner, the management of Parkinsonism and sickle-cell anemia. There are other examples, and everyone will have his favorite candidates for the list, but the truth is that there are not as many as the public has been led to believe.

The point to be made about this kind of technology—the real high technology of medicine—is that it comes as the result of a genuine understanding of disease mechanisms, and when it becomes available, it is relatively inexpensive, relatively simple, and relatively easy to deliver.

Offhand, I cannot think of any important human disease for which medicine possesses the capacity to prevent or cure outright where the cost of the technology is itself a major problem. The price is never as high as the cost of managing the same diseases during the earlier stages of ineffective technology. If a case of typhoid fever had to be managed today by the best methods of 1935, it would run to a staggering expense. At, say, around 50 days of hospitalization, requiring the most demanding kind of nursing care, with the obsessive concern for details of diet that characterized the therapy of the time, with daily laboratory monitoring, and, on occasion, surgical intervention for abdominal catastrophe, I should think \$10,000 would be a conservative estimate for the illness, as contrasted with today's cost of a bottle of chloramphenicol and a day or two of fever. The kind of technology that was evolving for poliomyelitis in the early 1950's, just before the emergence of the basic research that made the vaccine possible, provides another illustration of the point. It is the cost of those kinds of technology, and their relative effectiveness, that must be compared with the cost and effectiveness of the vaccine.

Pulmonary tuberculosis had similar episodes in its history. There was a sudden enthusiasm for the surgical removal of infected lung tissue in the early 1950's, and elaborate plans were being made for new and expensive installations for major pulmonary surgery in tuberculosis hos-

pitals, and then the drug isoniazid and the antibiotic streptomycin came along, and the hospitals themselves were closed up.

It is when physicians are bogged down by their incomplete technologies, by the innumerable things they are obliged to do in medicine when they lack a clear understanding of disease mechanisms, that the deficiencies of the health care system are most conspicuous.

2. This brings me to the second level of technology in this classification, which I have termed the "halfway technology" of medicine. This represents the kinds of things that must be done after the fact, in efforts to compensate for the incapacitating effects of certain diseases whose course we are unable to do very much about. It is a technology designed to make up for disease, or to postpone death.

The outstanding examples in recent years are the transplantations of hearts, kidneys, livers, and other organs and the equally spectacular inventions of artificial organs. In the public mind, this kind of technology has come to seem like the equivalent of the high technologies of the physical sciences. The media tend to present each new procedure as though it represented a breakthrough and therapeutic triumph, instead of the makeshift that it really is.

In fact, this level of technology is, by its nature, at the same time highly sophisticated and profoundly primitive. It is the kind of thing that we must continue to do until there is a genuine understanding of the mechanisms involved in disease. In chronic glomerulonephritis, for example, a much clearer insight will be needed into the events leading to the destruction of capillaries in the kidney. There is solid evidence that abnormal immunologic reactions are the basis for this destruction. If more information can be obtained, it should become possible to intervene intelligently, to prevent the process, or turn it around. When this level of understanding has been reached, the technology of kidney replacement will not be much needed and should no longer pose the huge problems of logistics, cost, and ethics that it poses today.

An extremely complex and costly technology for the management of coronary heart disease has evolved, involving specialized ambulances and hospital units, all kinds of electronic gadgetry, and whole platoons of new professional personnel to deal with the end results of coronary thrombosis. Almost everything offered today for the treatment of heart disease is at this level of technology, with the transplanted and artificial hearts as ultimate examples. When enough has been learned to know what really goes wrong in heart disease, we ought to be in a position to figure out ways to prevent or reverse the process, and when this happens the current elaborate technology will be set to one side.

The impending development of an artificial heart illustrates the kind

of dilemma we are placed in by today's emphasis on halfway technology. Let us assume that heart disease, for all its manifold origins and its complexity, does represent an approachable scientific problem—that if we study the matter with sufficient imagination and energy, making use of all the new information about muscle structure and function and blood coagulation and lipid metabolism, and making capital use of new information along other lines as yet unguessed at by any of us, we will eventually solve this problem, and we will then learn how to intervene before the onset of irreversible muscle or valve disease, to prevent the process or to turn it around. As a non-cardiologist, an outsider, I have total confidence that this can be done, that sooner or later it will be done, and my colleagues who know a lot about heart disease have, I sense, this same kind of confidence for the long term. This, then, is one option and an altogether wise one to adopt. But the artificial heart represents a completely different attitude, basically opposed. To be willing to invest the hundreds of millions of dollars that will probably be necessary for this one piece of new technology almost demands of its proponents the conviction that heart disease represents an unapproachable, insoluble biological problem. It tends, as I see it, to write off scientific research. It assumes that the best we will be able to do, within the next few decades anyway, is to wait until the underlying mechanisms of heart disease have had their free run, until the organ has been demolished and then to put into the chest this nuclear-powered, plastic-and-metal, essentially hideous engine. I am convinced that this is the wrong way to go. Even if it works, which, I am afraid, is not at all unlikely, I cannot imagine how society will solve the problems of cost, distribution, and priority. Who will be entitled to buy and have installed these engines? Those with enough wealth to pay for them? Those who strike the rest of us, or our committees, as potentially useful citizens? Once we have started on this endless line of insoluble problems, there may be no turning back. If ever there were an urgent, overwhelmingly important problem in biomedical science it is with us now. Someone simply must provide us with a solution, quickly, to the problem of coronary arteriosclerosis. If this can be done, the artificial heart can become, overnight, an interesting and ingenious contraption, something clever and decorative but no longer a practical thing, with some of the charm of a Tiffany lamp—a sort of instant antique—and we will all be the better off for this transformation. Otherwise, we are in for real trouble, just ahead, and I'm not sure we have the collective intelligence in medicine to deal with it.

Much of what is done in the treatment of cancer, by surgery, irradiation, and chemotherapy, represents halfway technology, in the sense that these measures are directed at the existence of already established

cancer cells, but not at the mechanisms by which cells become neoplastic. The policy problems that confront us now, with the nation's declared commitment to conquer cancer, are somewhat like those involved in the artificial heart question. There will be, for a while, anyway, a running argument between two opposing forces. There will be, on one side, those who believe that cancer is a still unsolved but eminently approachable scientific puzzle, requiring only enough good research by imaginative investigators, on a broad enough biological base, and that provided with enough financial support, and enough time, we will, one way or another, find ourselves home and dry. On the other side, there will be those who believe themselves to be more practical men of the real world, who feel that we have already come about as great a distance toward understanding cancer as we are likely to move for some time, and that we should give the highest priority to applying, on a much larger scale, what we know today about this disease—that with surgery, chemotherapy, and radiation we can now cure or palliate a considerable number of patients, and what we need at this time is more and better technology of essentially today's model. I do not know how this argument will come out, but I believe it to be an issue of crucial, symbolic significance; whichever way it goes, it is possible that this will be the drift of biomedical science for the next decade. I only wish that we could find a more comfortable zone of middle ground between those who believe that everything remains to be learned about cancer and those who believe that we already know enough to cope with it by today's approaches. Personally, I would prefer the middle ground, for I like a comfortable position, but I am afraid that I belong with the first group of extremists in this one—for, to be honest, I regard cancer as an entirely open, entirely unsolved problem, wide open to research, and soluble, and I regard the technology of today's form of therapy as paradigms of halfway technology, directed at the results of the disease rather than at underlying mechanisms.

It is characteristic of this kind of technology that it costs an enormous amount of money and requires a continuing expansion of hospital facilities. There is no end to the need for new, highly trained people to run the enterprise. And there is really no way out of this at the present state of knowledge. If the installation of specialized coronary care units results in the extension of life for only a few patients with coronary disease (and there is no question that this technology is effective in a few cases), it seems to me an inevitable fact of life that as many of these as can be built will be put together and as much money as can be found will be spent. I do not see that anyone has much choice in this. We are obliged, by the very nature of our professional responsibility, to adopt a new technology that will benefit patients with other-

wise untreatable diseases, even when only a very small percentage will be benefitted, even when the costs are very high. Neither we, nor any other sector of society, controls this aspect of our economy. We cannot, like other industries, withhold a technology from the marketplace because it costs too much money or benefits too small a percentage of patients. The only thing that can move medicine away from this level of technology is new information, and the only imaginable source of this information is research.

The best we can do when the economic or logistic problems associated with our technology verge on the insupportable, or when the odds are too high against the success of our procedures, is to try to improve the technology, or to discover an altogether new technology, as quickly as possible. Meanwhile, however, we must continue to employ the less than satisfactory ones.

The near-miraculous achievements of the antibiotic drugs in controlling or eliminating our most serious bacterial infections—such as typhoid or lobar pneumonia, or epidemic meningitis—are useful indicators of the future direction of technology in medicine. They are, in fact, pieces of solid evidence that technology does work. But they should not be mistaken for symbols of the whole of medicine.

And this brings me to the third level of technology. This is the large body of what is best termed "non-technology." It is, in effect, the substitute for technology that medicine has always been compelled to use when we are unable to alter either the natural course of disease or its eventual outcome. A great deal of money is spent on this. It is valued highly by the professionals as well as the patients. It consists of what is sometimes called "supportive therapy." It tides patients over through diseases that are not, by and large, understood. It is what is meant by the phrases "caring for" and "standing by." It is absolutely indispensable. It is not, however, a technology in any real sense.

It includes the large part of any good doctor's time that is taken up with simply providing reassurance, explaining to patients who fear that they have contracted one or another lethal disease that they are, in fact, quite healthy.

It is what physicians used to be engaged in at the bedside of patients with diphtheria, meningitis, poliomyelitis, lobar pneumonia, and all the rest of the infectious diseases that have since come under control.

It is what physicians must now do for patients with intractable cancer, severe rheumatoid arthritis, multiple sclerosis, stroke, and advanced cirrhosis. One can think of at least 20 major diseases that require this kind of supportive medical care because of the absence of an effective technology. I would include a large amount of what is called mental disease and most varieties of cancer in this category.

The cost of this non-technology is very high and getting higher all the time. It requires not only a great deal of time but also very hard effort and skill on the part of physicians; only the very best of doctors are good at coping with this kind of defeat. It also involves long periods of hospitalization, lots of nursing, lots of involvement of non-medical professionals in and out of the hospital. It represents, in short, a substantial segment of today's expenditures for health. It is not as great a financial problem for the future as halfway technology, but between them, non-technology and halfway technology will sooner or later drive any system of health care that we may devise into bankruptcy.

If I were a policy-maker, interested in saving money for health care over the long haul, I would regard it as an act of prudence to give high priority to a lot more basic research in biological science. This is the only way to get the full mileage that biology owes to the science of medicine, even though it seems, as used to be said in the days when the phrase still had some meaning, like asking for the moon.

science

the endless frontier

A report to the President on a
Program for Postwar Scientific Research

By Vannevar Bush

*Director of the
Office of Scientific Research and Development*

July 1945

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SUMMARY OF THE REPORT

Scientific Progress Is Essential

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(1) Progress in the war against disease depends upon a flow of new scientific knowledge. New products, new industries, and more jobs require continuous additions to knowledge of the laws of nature, and the application of that knowledge to practical purposes. Similarly, our defense against aggression demands new knowledge so that we can develop new and improved weapons. This essential, new knowledge can be obtained only through basic scientific research.

Science can be effective in the national welfare only as a member of a team, whether the conditions be peace or war. But without scientific progress no amount of achievement in other directions can insure our health, prosperity, and security as a nation in the modern world.

For the War Against Disease

We have taken great strides in the war against disease. The death rate for all diseases in the Army, including overseas forces, has been reduced from 14.1 per thousand in the last war to 0.6 per thousand in this war. In the last 40 years life expectancy has increased from 49 to 65 years, largely as a consequence of the reduction in the death rates of infants and children. But we are far from the goal. The annual deaths from one or two diseases far exceed the total number of American lives lost in battle during this war. A large fraction of these deaths in our civilian population cut short the useful lives of our citizens. Approximately 7,000,000 persons in the United States are mentally ill and their care costs the public over \$175,000,000 a year. Clearly much illness remains for which adequate means of prevention and cure are not yet known.

(2) The responsibility for basic research in medicine and the underlying sciences, so essential to progress in the war against disease, falls primarily upon the medical schools and universities. Yet we find that the traditional sources of support for medical research in the medical schools and universities, largely endowment income, foundation grants, and private donations, are diminishing and there is no immediate prospect of a change in this trend. Meanwhile, the cost of medical research has been rising. If we are to main-

tain the progress in medicine which has marked the last 25 years, the Government should extend financial support to basic medical research in the medical schools and in universities.

For Our National Security

The bitter and dangerous battle against the U-boat was a battle of scientific techniques—and our margin of success was dangerously small. The new eyes which radar has supplied can sometimes be blinded by new scientific developments. V-2 was countered only by capture of the launching sites.

We cannot again rely on our allies to hold off the enemy while we struggle to catch up. There must be more—and more adequate—military research in peacetime. It is essential that the civilian scientists continue in peacetime some portion of those contributions to national security which they have made so effectively during the war. This can best be done through a civilian-controlled organization with close liaison with the Army and Navy, but with funds direct from Congress, and the clear power to initiate military research which will supplement and strengthen that carried on directly under the control of the Army and Navy.

And for the Public Welfare

One of our hopes is that after the war there will be full employment. To reach that goal the full creative and productive energies of the American people must be released. To create more jobs we must make new and better and cheaper products. We want plenty of new, vigorous enterprises. But new products and processes are not born full-grown. They are founded on new principles and new conceptions which in turn result from basic scientific research. Basic scientific research is scientific capital. Moreover, we cannot any longer depend upon Europe as a major source of this scientific capital. Clearly, more and better scientific research is one essential to the achievement of our goal of full employment.

- 3
- a) How do we increase this scientific capital? First, we must have plenty of men and women trained in science, for upon them depends both the creation of new knowledge and its application to practical purposes. Second, we must
- b) strengthen the centers of basic research which are principally the colleges, universities, and research institutes. These institutions provide the environment which is most conducive to the creation of new scientific knowledge and least under pressure for immediate, tangible results. With some notable exceptions, most research in industry and in Government involves application of existing scientific knowledge to practical problems. It is only the colleges, universities, and a few research institutes that devote most of their research efforts to expanding the frontiers of knowledge.

Expenditures for scientific research by industry and Government increased from \$140,000,000 in 1930 to \$309,000,000 in 1940. Those for the colleges and universities increased from \$20,000,000 to \$31,000,000, while those for

research institutes declined from \$5,200,000 to \$4,500,000 during the same period. If the colleges, universities, and research institutes are to meet the rapidly increasing demands of industry and Government for new scientific knowledge, their basic research should be strengthened by use of public funds.

(4) For science to serve as a powerful factor in our national welfare, applied research both in Government and in industry must be vigorous. To improve the quality of scientific research within the Government, steps should be taken to modify the procedures for recruiting, classifying, and compensating scientific personnel in order to reduce the present handicap of governmental scientific bureaus in competing with industry and the universities for top-grade scientific talent. To provide coordination of the common scientific activities of these governmental agencies as to policies and budgets, a permanent Science Advisory Board should be created to advise the executive and legislative branches of Government on these matters.

The most important ways in which the Government can promote industrial research are to increase the flow of new scientific knowledge through support of basic research, and to aid in the development of scientific talent. In addition, the Government should provide suitable incentives to industry to conduct research (a) by clarification of present uncertainties in the Internal Revenue Code in regard to the deductibility of research and development expenditures as current charges against net income, and (b) by strengthening the patent system so as to eliminate uncertainties which now bear heavily on small industries and so as to prevent abuses which reflect discredit upon a basically sound system. In addition, ways should be found to cause the benefits of basic research to reach industries which do not now utilize new scientific knowledge.

We Must Renew Our Scientific Talent

(5) The responsibility for the creation of new scientific knowledge—and for most of its application—rests on that small body of men and women who understand the fundamental laws of nature and are skilled in the techniques of scientific research. We shall have rapid or slow advance on any scientific frontier depending on the number of highly qualified and trained scientists exploring it.

The deficit of science and technology students who, but for the war, would have received bachelor's degrees is about 150,000. It is estimated that the deficit of those obtaining advanced degrees in these fields will amount in 1955 to about 17,000—for it takes at least 6 years from college entry to achieve a doctor's degree or its equivalent in science or engineering. The real ceiling on our productivity of new scientific knowledge and its application in the war against disease, and the development of new products and new industries, is the number of trained scientists available.

The training of a scientist is a long and expensive process. Studies clearly show that there are talented individuals in every part of the population, but with few exceptions, those without the means of buying higher education

go without it. If ability, and not the circumstance of family fortune, determines who shall receive higher education in science, then we shall be assured of constantly improving quality at every level of scientific activity. Y The Government should provide a reasonable number of undergraduate scholarships and graduate fellowships in order to develop scientific talent in American youth. The plans should be designed to attract into science only that proportion of youthful talent appropriate to the needs of science in relation to the other needs of the Nation for high abilities.

Including Those in Uniform

The most immediate prospect of making up the deficit in scientific personnel is to develop the scientific talent in the generation now in uniform. Even if we should start now to train the current crop of high-school graduates none would complete graduate studies before 1951. The Armed Services should comb their records for men who, prior to or during the war, have given evidence of talent for science, and make prompt arrangements, consistent with current discharge plans, for ordering those who remain in uniform, as soon as militarily possible, to duty at institutions here and overseas where they can continue their scientific education. Moreover, the Services should see that those who study overseas have the benefit of the latest scientific information resulting from research during the war.

The Lid Must Be Lifted

While most of the war research has involved the application of existing scientific knowledge to the problems of war, rather than basic research, there has been accumulated a vast amount of information relating to the application of science to particular problems. Much of this can be used by industry. It is also needed for teaching in the colleges and universities here and in the Armed Forces Institutes overseas. Some of this information must remain secret, but most of it should be made public as soon as there is ground for belief that the enemy will not be able to turn it against us in this war. To select that portion which should be made public, to coordinate its release, and definitely to encourage its publication, a Board composed of Army, Navy, and civilian scientific members should be promptly established.

A Program for Action

6 The Government should accept new responsibilities for promoting the flow of new scientific knowledge and the development of scientific talent in our youth. These responsibilities are the proper concern of the Government, for they vitally affect our health, our jobs, and our national security. It is in keeping also with basic United States policy that the Government should foster the opening of new frontiers and this is the modern way to do it. For

many years the Government has wisely supported research in the agricultural colleges and the benefits have been great. The time has come when such support should be extended to other fields.

The effective discharge of these new responsibilities will require the full attention of some over-all agency devoted to that purpose. There is not now in the permanent governmental structure receiving its funds from Congress an agency adapted to supplementing the support of basic research in the colleges, universities, and research institutes, both in medicine and the natural sciences, adapted to supporting research on new weapons for both Services, or adapted to administering a program of science scholarships and fellowships.

Therefore I recommend that a new agency for these purposes be established. Such an agency should be composed of persons of broad interest and experience, having an understanding of the peculiarities of scientific research and scientific education. It should have stability of funds so that long-range programs may be undertaken. It should recognize that freedom of inquiry must be preserved and should leave internal control of policy, personnel, and the method and scope of research to the institutions in which it is carried on. It should be fully responsible to the President and through him to the Congress for its program.

Early action on these recommendations is imperative if this Nation is to meet the challenge of science in the crucial years ahead. On the wisdom with which we bring science to bear in the war against disease, in the creation of new industries, and in the strengthening of our Armed Forces depends in large measure our future as a nation.

Part One

INTRODUCTION

Scientific Progress Is Essential

* We all know how much the new drug, penicillin, has meant to our grievously wounded men on the grim battlefronts of this war—the countless lives it has saved—the incalculable suffering which its use has prevented. Science and the great practical genius of this Nation made this achievement possible.

Some of us know the vital role which radar has played in bringing the Allied Nations to victory over Nazi Germany and in driving the Japanese steadily back from their island bastions. Again it was painstaking scientific research over many years that made radar possible.

What we often forget are the millions of pay envelopes on a peacetime Saturday night which are filled because new products and new industries have provided jobs for countless Americans. Science made that possible, too.

In 1939 millions of people were employed in industries which did not even exist at the close of the last war—radio, air conditioning, rayon and other synthetic fibers, and plastics are examples of the products of these industries. But these things do not mark the end of progress—they are but the beginning if we make full use of our scientific resources. New manufacturing industries can be started and many older industries greatly strengthened and expanded if we continue to study nature's laws and apply new knowledge to practical purposes.

Great advances in agriculture are also based upon scientific research. Plants which are more resistant to disease and are adapted to short growing seasons, the prevention and cure of livestock diseases, the control of our insect enemies, better fertilizers, and improved agricultural practices, all stem from painstaking scientific research.

Advances in science when put to practical use mean more jobs, higher wages, shorter hours, more abundant crops, more leisure for recreation, for study, for learning how to live without the deadening drudgery which has been the burden of the common man for ages past. Advances in science will also bring higher standards of living, will lead to the prevention or cure of diseases, will promote conservation of our limited national resources, and will assure means of defense against aggression. But to achieve these objectives—to secure a high level of employment, to maintain a position of world leadership—the flow of new scientific knowledge must be both continuous and substantial.

Our population increased from 75 million to 130 million between 1900

and 1940. In some countries comparable increases have been accompanied by famine. In this country the increase has been accompanied by more abundant food supply, better living, more leisure, longer life, and better health. This is, largely, the product of three factors—the free play of initiative of a vigorous people under democracy, the heritage of great natural wealth, and the advance of science and its application.

Science, by itself, provides no panacea for individual, social, and economic ills. It can be effective in the national welfare only as a member of a team, whether the conditions be peace or war. But without scientific progress no amount of achievement in other directions can insure our health, prosperity, and security as a nation in the modern world.

Science Is a Proper Concern of Government

It has been basic United States policy that Government should foster the opening of new frontiers. It opened the seas to clipper ships and furnished land for pioneers. Although these frontiers have more or less disappeared, the frontier of science remains. It is in keeping with the American tradition—one which has made the United States great—that new frontiers shall be made accessible for development by all American citizens.

Moreover, since health, well-being, and security are proper concerns of Government, scientific progress is, and must be, of vital interest to Government. Without scientific progress the national health would deteriorate; without scientific progress we could not hope for improvement in our standard of living or for an increased number of jobs for our citizens; and without scientific progress we could not have maintained our liberties against tyranny.

Government Relations to Science—Past and Future

From early days the Government has taken an active interest in scientific matters. During the nineteenth century the Coast and Geodetic Survey, the Naval Observatory, the Department of Agriculture, and the Geological Survey were established. Through the Land Grant College Acts the Government has supported research in state institutions for more than 80 years on a gradually increasing scale. Since 1900 a large number of scientific agencies have been established within the Federal Government, until in 1939 they numbered more than 40.

Much of the scientific research done by Government agencies is intermediate in character between the two types of work commonly referred to as basic and applied research. Almost all Government scientific work has ultimate practical objectives but, in many fields of broad national concern, it commonly involves long-term investigation of a fundamental nature. Generally speaking, the scientific agencies of Government are not so concerned with immediate practical objectives as are the laboratories of industry nor, on the other hand, are they as free to explore any natural phenomena without regard to possible economic applications as are the educational and private research institutions. Government scientific agencies have splendid records of achievement, but they are limited in function.

* We have no national policy for science. The Government has only begun to utilize science in the Nation's welfare. There is no body within the Government charged with formulating or executing a national science policy. There are no standing committees of the Congress devoted to this important subject. Science has been in the wings. It should be brought to the center of the stage—for in it lies much of our hope for the future.

There are areas of science in which the public interest is acute but which are likely to be cultivated inadequately if left without more support than will come from private sources. These areas—such as research on military problems, agriculture, housing, public health, certain medical research, and research involving expensive capital facilities beyond the capacity of private institutions—should be advanced by active Government support. To date, with the exception of the intensive war research conducted by the Office of Scientific Research and Development, such support has been meager and intermittent.

For reasons presented in this report we are entering a period when science needs and deserves increased support from public funds.

Freedom of Inquiry Must Be Preserved

* The publicly and privately supported colleges, universities, and research institutes are the centers of basic research. They are the wellsprings of knowledge and understanding. As long as they are vigorous and healthy and their scientists are free to pursue the truth wherever it may lead, there will be a flow of new scientific knowledge to those who can apply it to practical problems in Government, in industry, or elsewhere.

Many of the lessons learned in the war-time application of science under Government can be profitably applied in peace. The Government is peculiarly fitted to perform certain functions, such as the coordination and support of broad programs on problems of great national importance. But we must proceed with caution in carrying over the methods which work in wartime to the very different conditions of peace. We must remove the rigid controls which we have had to impose, and recover freedom of inquiry and that healthy competitive scientific spirit so necessary for expansion of the frontiers of scientific knowledge.

* Scientific progress on a broad front results from the free play of free intellects, working on subjects of their own choice, in the manner dictated by their curiosity for exploration of the unknown. Freedom of inquiry must be preserved under any plan for Government support of science in accordance with the Five Fundamentals listed on page 32.

The study of the momentous questions presented in President Roosevelt's letter has been made by able committees working diligently. This report presents conclusions and recommendations based upon the studies of these committees which appear in full as the appendices. Only in the creation of one over-all mechanism rather than several does this report depart from the specific recommendations of the committees. The members of the committees have reviewed the recommendations in regard to the single mechanism and have found this plan thoroughly acceptable.

THE WAR AGAINST DISEASE

In War

The death rate for all diseases in the Army, including the overseas forces, has been reduced from 14.1 per thousand in the last war to 0.6 per thousand in this war.

Such ravaging diseases as yellow fever, dysentery, typhus, tetanus, pneumonia, and meningitis have been all but conquered by penicillin and the sulfa drugs, the insecticide DDT, better vaccines, and improved hygienic measures. Malaria has been controlled. There has been dramatic progress in surgery.

The striking advances in medicine during the war have been possible only because we had a large backlog of scientific data accumulated through basic research in many scientific fields in the years before the war.

In Peace

In the last 40 years life expectancy in the United States has increased from 49 to 65 years largely as a consequence of the reduction in the death rates of infants and children; in the last 20 years the death rate from the diseases of childhood has been reduced 87 percent.

Diabetes has been brought under control by insulin, pernicious anemia by liver extracts; and the once widespread deficiency diseases have been much reduced, even in the lowest income groups, by accessory food factors and improvement of diet. Notable advances have been made in the early diagnosis of cancer, and in the surgical and radiation treatment of the disease.

These results have been achieved through a great amount of basic research in medicine and the preclinical sciences, and by the dissemination of this new scientific knowledge through the physicians and medical services and public health agencies of the country. In this cooperative endeavor the pharmaceutical industry has played an important role, especially during the war. All of the medical and public health groups share credit for these achievements; they form interdependent members of a team.

Progress in combating disease depends upon an expanding body of new scientific knowledge.

Unsolved Problems

As President Roosevelt observed, the annual deaths from one or two diseases are far in excess of the total number of American lives lost in battle during this war. A large fraction of these deaths in our civilian population cut short the useful lives of our citizens. This is our present position despite the fact that in the last three decades notable progress has been made in civilian medicine. The reduction in death rate from diseases of childhood has shifted the emphasis to the middle and old age groups, particularly to the malignant diseases and the degenerative processes prominent in later life. Cardiovascular disease, including chronic disease of the kidneys, arteriosclerosis, and cerebral hemorrhage, now account for 45 percent of the deaths in the United States. Second are the infectious diseases, and third is cancer. Added to these are many maladies (for example, the common cold, arthritis, asthma and hay fever, peptic ulcer) which, though infrequently fatal, cause incalculable disability.

Another aspect of the changing emphasis is the increase of mental diseases. Approximately 7 million persons in the United States are mentally ill; more than one-third of the hospital beds are occupied by such persons, at a cost of \$175 million a year. Each year 125,000 new mental cases are hospitalized.

* *Notwithstanding great progress in prolonging the span of life and in relief of suffering, much illness remains for which adequate means of prevention and cure are not yet known. While additional physicians, hospitals, and health programs are needed, their full usefulness cannot be attained unless we enlarge our knowledge of the human organism and the nature of disease. Any extension of medical facilities must be accompanied by an expanded program of medical training and research.*

* ***Broad and Basic Studies Needed***

Discoveries pertinent to medical progress have often come from remote and unexpected sources, and it is certain that this will be true in the future. It is wholly probable that progress in the treatment of cardiovascular disease, renal disease, cancer, and similar refractory diseases will be made as the result of fundamental discoveries in subjects unrelated to those diseases, and perhaps entirely unexpected by the investigator. Further progress requires that the entire front of medicine and the underlying sciences of chemistry, physics, anatomy, biochemistry, physiology, pharmacology, bacteriology, pathology, parasitology, etc., be broadly developed.

Progress in the war against disease results from discoveries in remote and unexpected fields of medicine and the underlying sciences.

Coordinated Attack on Special Problems

Penicillin reached our troops in time to save countless lives because the Government coordinated and supported the program of research and development on the drug. The development moved from the early laboratory stage to large scale production and use in a fraction of the time it would have

taken without such leadership. The search for better anti-malarials, which proceeded at a moderate tempo for many years, has been accelerated enormously by Government support during the war. Other examples can be cited in which medical progress has been similarly advanced. In achieving these results, the Government has provided over-all coordination and support; it has not dictated how the work should be done within any cooperating institution.

Discovery of new therapeutic agents and methods usually results from basic studies in medicine and the underlying sciences. The development of such materials and methods to the point at which they become available to medical practitioners requires teamwork involving the medical schools, the science departments of universities, Government and the pharmaceutical industry. Government initiative, support, and coordination can be very effective in this development phase.

Government initiative and support for the development of newly discovered therapeutic materials and methods can reduce the time required to bring the benefits to the public.

Action is Necessary

✕ The primary place for medical research is in the medical schools and universities. In some cases coordinated direct attack on special problems may be made by teams of investigators, supplementing similar attacks carried on by the Army, Navy, Public Health Service, and other organizations. Apart from teaching, however, the primary obligation of the medical schools and universities is to continue the traditional function of such institutions, namely, to provide the individual worker with an opportunity for free, untrammelled study of nature, in the directions and by the methods suggested by his interests, curiosity, and imagination. The history of medical science teaches clearly the supreme importance of affording the prepared mind complete freedom for the exercise of initiative. It is the special province of the medical schools and universities to foster medical research in this way—a duty which cannot be shifted to Government agencies, industrial organizations, or to any other institutions.

Where clinical investigations of the human body are required, the medical schools are in a unique position, because of their close relationship to teaching hospitals, to integrate such investigations with the work of the departments of preclinical science, and to impart new knowledge to physicians in training. At the same time, the teaching hospitals are especially well qualified to carry on medical research because of their close connection with the medical schools, on which they depend for staff and supervision.

✕ Between World War I and World War II the United States overtook all other nations in medical research and assumed a position of world leadership. To a considerable extent this progress reflected the liberal financial support from university endowment income, gifts from individuals, and foundation grants in the 20's. The growth of research departments in medical schools has been very uneven, however, and in consequence most of the important work has been done in a few large schools. This should be corrected by build-

ing up the weaker institutions, especially in regions which now have no strong medical research activities.

The traditional sources of support for medical research, largely endowment income, foundation grants, and private donations, are diminishing, and there is no immediate prospect of a change in this trend. Meanwhile, research costs have steadily risen. More elaborate and expensive equipment is required, supplies are more costly, and the wages of assistants are higher. Industry is only to a limited extent a source of funds for basic medical research.

* *

It is clear that if we are to maintain the progress in medicine which has marked the last 25 years, the Government should extend financial support to basic medical research in the medical schools and in the universities, through grants both for research and for fellowships. The amount which can be effectively spent in the first year should not exceed 5 million dollars. After a program is under way perhaps 20 million dollars a year can be spent effectively.

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29 Extra
39-41 inter
41 history
42-44 inter

BIOMEDICAL SCIENCE AND ITS ADMINISTRATION

The Wooldridge Committee Report

The Initial NIH Commentary

April 1965

INDEX

	<u>Page</u>
<u>BACKGROUND</u> -----	1
The Summary Assessment-----	3
The Approach to the Initial NIH Commentary-----	5
<u>PLANS AND POLICIES</u> -----	7
The Prefatory Notions-----	8
The Nature of the Mission of NIH-----	9
The Rate of Growth-----	13
Balance and the Master Plan-----	14
The Policy and Planning Framework-----	17
The Committee's Proposals-----	18
The NIH View-----	19
Strengthening and Expanding the Planning Function at NIH-----	20
Advisory Support for the Director NIH-----	23
The Reordering of Authority Relationships-----	25
Access to and Participation in the Higher Councils of DHEW-----	26
<u>EXTRAMURAL PROGRAMS</u> -----	29
General Comments	
The nature of the NIH-nonfederal relationship-----	29
Program size versus quality-----	33
<u>INTRAMURAL PROGRAMS</u> -----	38
<u>COLLABORATIVE PROGRAMS</u> -----	45

BIOMEDICAL SCIENCE AND ITS ADMINISTRATION
The Wooldridge Committee Report

The Initial NIH Commentary

BACKGROUND

In the Fall of 1963, President Kennedy requested that a qualitative evaluation of the programs of the National Institutes of Health be ^{made} ~~under-~~ ~~taken~~ under the auspices of the Office of Science and Technology in the Executive Office of the President. The implementation of this request was stalled by the death of the President, but in early 1964, President Johnson reviewed the situation and on his own behalf requested that the study be executed "to provide assurance that such a large Federal enterprise is being conducted with maximum effectiveness." In addition to this primary objective the Office of Science and Technology perceived in this Presidential request a unique opportunity to examine the practicability of submitting a large segment of the federally supported research and development effort to an objective and dispassionate assessment. Thus in this respect the study of the National Institutes of Health was a pilot procedure, which, if successful, would constitute a precedent for the use of the President's Science Advisor and the OST for the assessment of other parts of the Federal research and development enterprise.

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The membership of the Committee, under the Chairmanship of Dr. Dean E. Wooldridge, was rapidly constituted, Panels of technical experts appointed, the scope of the study defined, and the modus operandi--on the spot examination of activities supported by funds appropriated to the NIH--decided upon. The NIH arranged several orienting and briefing sessions for the staff of the Committee and responded to a series of requests for information and for data during the early phases of the study, when the sampling techniques were being developed and the samples constituted. In addition, the Director, NIH, accompanied by members of his immediate staff and by representatives from both the PHS and the DHEW met with the Study Committee on two occasions (January 9 and June 25, 1964), each of about a day's duration.

During the first meeting, the NIH outlined to the Committee its programs and problems; during the second, the Director, NIH, responded to a wide range of questions concerning the problems and prospects of future NIH development which the members of the Committee considered germane and important. Except for these formal contacts with the OD-NIH, the study centered largely in the institutions and projects which turned up in the sample. The NIH itself was one of these; intramural scientists were interviewed in connection with their research programs, and administrative personnel about the nature and problems of their managerial responsibilities. The data in the Report--on the size of the pool of experts utilized, on the numbers and distribution of grantee institutions visited, on the population of investigators interviewed, on the number of "business offices" contacted, etc.--reflects the care with which the study was conducted.

See 7-1-7

The Summary Assessment

The major conclusion of the report was a resounding vote of confidence in almost every element of the existing NIH program. This summary judgment of merit is both heartening and rewarding to all of the ~~dedicated and devoted~~ people in the PHS and the DHEW, who have participated directly or indirectly in the development of the structure of programs and operations which comprise the NIH.

Among the specific elements which the Committee singled out for approval it is particularly pleasing to note the following:

1. The quality of the research conducted and supported under the auspices of the NIH was deemed to meet high standards of excellence, if not, indeed, to set these standards. In spite of the enormously rapid growth in research expenditures during the last decade, the overall quality of the effort was adjudged to have improved steadily rather than deteriorated.
2. The institutions and the investigators supported by the NIH were found to exercise great care and probity in the expenditure of public funds.
3. The system used by the NIH to evaluate applications for support--peer group judgment--was endorsed. This system was accorded a major role in maintaining high standards of excellence, and in sustaining the confidence of the scientific community in the competence and fairness of the decision-making process.

4. The benificent impact of the NIH program in improving the quality and quantity both of research and teaching in biomedical institutions was recognized, and the accomplishment of this desideratum without the feared Federal control was viewed as a notable achievement.
5. The past and present leadership, in both the Executive and Legislative Branches of the Federal Government were given fulsome praise for the design and operation of the program.

The staff of the NIH was, on the whole, profoundly reassured by the primary conclusion of the study, to wit,

"that the activities of the National Institutes of Health are essentially sound and that its budget of approximately one billion dollars a year is, on the whole, being spent wisely and well in the public interest" and that "we suspect that there are few, if any, one billion dollar segments of the Federal budget that are buying more valuable services for the American people than that administered by the National Institutes of Health."

Having stated unequivocally its general assessment of the activities of the NIH, the Committee proceeded to ask searching questions about specific aspects of discrete program components now in being, but especially about the adequacy of the existing organizational and functional framework for future activities. Out of this, a series of recommendations, both corrective as well as innovative, were offered,

as logical conclusions from explicitly or implicitly formulated assumptions and from a more or less straightforward argument.

The Approach to the Initial NIH Commentary

The [redacted] proposes [redacted] to the Report both [redacted] [redacted]. In this [redacted] [redacted]s, discussion is [redacted] to what appear [redacted] be [redacted] [redacted] [redacted] [redacted] which are [redacted]. Seriatim [redacted] [redacted] of the specific [redacted] [redacted]s of the Committee [redacted] [redacted] the more extended [redacted] necessary to deal definitively with them [redacted] [redacted].

The NIH finds some of the Committee's criticisms reasonable and its recommendations acceptable; others require more careful evaluation. The feasibility of implementing a few is questionable within presently available authorities or delegations. Finally, the NIH is inclined to disagree with several of the Committee's conclusions. The acceptability of a recommendation does not necessarily imply agreement with the assumptions or arguments from which it was derived; convergence upon a common operational mode from quite different premises will be apparent in subsequent discussion.

Each member of the Committee brought to this study an outlook and a set of concerns related to his own background, training, experience and career development, and reflecting his own institutional affiliations. Thus, the preoccupations of university administrators (primarily interested in the educational process), of university scientists (primarily focused on a specific technical discipline or specialty), and of industrial

managers (primarily concerned with the organization and operation of large scale technical development projects), are woven tightly into the fabric of this Report.

The Federal Government enters into partnership with these societal institutions to achieve certain purposes that are defined as public since they were specifically funded by representatives of the people, the Congress. The aspirations of the Government may, and often do, differ sharply from those of the other partners. Thus a university scholar, interested in science as an end in itself, may, with propriety, be tendered funds by, and accept funds from, a Federal agency interested in science as a means to an end, e.g., the solution of a problem in some specific category of disease. Thus, it should be emphasized that in much of the following discussion, the NIH is not so much contesting the conclusions and the recommendations of the Committees as it is emphasizing another source, the public purpose to be served, somewhat more strongly than the Committee might reasonably be expected to have done.

The reach of many of the Committee's recommendations, particularly those which have to do with organizational matters, is very broad. A definitive view of certain of these proposals is not possible or appropriate at the NIH levels. In certain instances, however, comment has been made to provide a beginning point for the broader discussions which must take place.

The major categories in which the Committee offered advice concerned Plans and Policies, the Extramural Policies, the Intramural Program and the Collaborative Activities. This categorization will be followed in the ensuing discussion.

PLANS AND POLICIES

The Report contains an interesting analysis of the forces instrumental in determining the growth of the NIH enterprise during the last two decades. It notes: the magnitude of unrequited need for support for biomedical research at the beginning of this period, and the corollary that with so many high priority needs, the order in which they were met was not initially a primary concern; the fortuitous presence in pivotal positions in the Executive agencies of public administrators of unusual competence; the coincidence of this latter phenomenon with the emergence of men of equivalent ability and dedication as key members of the Congressional Committees related to the NIH; the sophisticated understanding of the problems, the shared purpose, and the mutual compatibility of these men.

The Committee's message is that this concatenation, however fortuitous, is too improbable to rely upon as a solid foundation for future development. Henceforth, reliance should be placed upon institutional rather than upon individual performance, upon regularization and formalization of relationships rather than upon inter-personal compatibility, upon process and procedure rather than upon fortuity.

In looking toward the future, the Committee also predicted that the recent exponential growth rate of the expenditures of the NIH would not be likely to continue for the next decade. The consequent relative scarcity of resources would require increasing attention to the problem of selecting between desirable alternatives in such a way as to derive the maximum benefit from the expenditures of this organization.

Against this assessment of the present state of affairs governing the operation of the National Institutes of Health, a series of recommendations were made which together constitute the major innovative elements in the Report. This set of proposals presents two aspects. First, they emerge in a context of certain prefatory notions concerning the mission of NIH, future rate of growth, and the need for "balance" and a "master plan" for the further development of NIH. Because these views constitute the starting point of the Committee's arguments they require careful evaluation and comment. Second, a series of specific actions and changes are set forth: the merits, appropriateness, feasibility and desirability of which must be individually evaluated.

In this initial examination these two matters are approached separately in that order.

The Prefatory Notions

Clearly a major premise of the Committee is that the NIH should be viewed as an integral enterprise, committed to a broad mission and functioning under the direction of a single manager, whose internal authorities and autonomy vis-a-vis higher levels of government should be maximized, and who should be provided greatly expanded resources (internal planning as well as external advisory machinery) for the decision-making responsibilities of the managerial role. This concept emerges from interesting and, in some respects, controversial, views of the key underlying nature of the mission of NIH, its further growth and the allocation of resources. In the NIH opinion these views need some qualification:

The nature of the mission of NIH

Several quotations from the Report may serve to highlight the view taken therein of the nature of the mission of NIH.

"... the primary de facto mission of NIH is the stimulation and support of health-related and biomedical research."

"Its broad mission of management of virtually all aspects of the Nation's health requires NIH to concentrate most of its efforts on basic research, leaving for directed, developmental effort only those research discoveries which appear to be susceptible to exploitation. The 'disease category' nature of the NIH organizational structure makes the task more difficult but not impossible."

"One of the accomplishments of the NIH management has been that of making a scientifically inappropriate organizational structure an executive arrangement for performing its real mission."

(*) While the Report does not succeed in presenting a completely unambiguous position on its definition of this agency's mission, the general tenor of the discussion conveys a sense that the NIH is perceived as a science agency interested in biological and medical problems, and not a health agency applying science and technology to the solution of health and health-related problems. Some clarification of this would appear to be desirable.

It is certainly true that a fraction of the resources available to the NIH are expended in the pursuit of scientific objectives which are difficult for anyone other than an expert to relate clearly and immediately to health or to disease, categorical or otherwise. It is also true that many scientists supported by the NIH, particularly those in academic institutions, view themselves as concerned with science only for the sake

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of science. From a purely operational point of view it may be difficult to distinguish between fundamental research performed with the intent to develop knowledge, which could be applied to modify disease, from that undertaken simply for expanding man's fund of knowledge. It is also possible, as noted earlier, for a difference in intent to exist between the scientists performing research and the agency supporting their efforts.

* * On the other hand, administrators of a public enterprise may not depart from the intent of Congress, expressed in both statutory enactments and in legislative history.

The legislative enactment under which the NIH functions, authorizes and instructs the Surgeon General, PHS, to:

* * * "...conduct...and encourage cooperation with and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research investigations, experiments, demonstrations, and studies relating to the cause, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man..."

This statement of mission in the current PHS Act is a lineal descendent from legislative language traceable to legislation in 1912 when the Service was authorized to "study and investigate the diseases of man."

Under such a mandate, no responsible official of this organization would knowingly authorize the expenditure of funds unless convinced that the obligation could be related to a bona fide health objective. However, the evolution of the interpretation of how directly related to a health objective is the immediate purpose of some specific expenditure deserves comment.

The Congress began to focus on specific categories of disease in 1937, with passage of the National Cancer Act. The rapid pace of program expansion occurring after World War II made it possible to enlist an ever-widening spectrum of scientific disciplines in the fight against disease and thereby to broaden and strengthen the general and non-categorical scientific base on which the disease-oriented research was built. Thus a series of derivative missions--the operational imperatives to sustain a comprehensive attack upon health problems--began to emerge.

It should be reemphasized that these missions are indeed derivative from, and indispensable for, the discharge of the primary statutory mission of this agency. They now include: the support of research in fundamental science, upon which the applied clinical sciences draw so heavily for ideas and trained personnel; the support of training for research; support for the construction of facilities and for the development of national and regional resources for research; and, increasingly, carefully planned general support for the research and research training purposes of educational and research institutions on whose continuing viability the long-term national research effort is so crucially dependent.

Under this concept and approach the goals implicit in the statutory mission must be pursued with vigor through the mobilization of all appropriate instrumentalities, institutional forms, and organizations.

Explicitly, the NIH cannot limit its operations to those most familiar to many members of this Committee and its Panels--the traditional research project grant, submitted in behalf of a small team of university scientists,

and funded at a relatively modest level--but must also utilize other devices and agents such as contracts of a variety of types with a wide range of industrial enterprises, in order to achieve the public purposes specified in the statutes which created this organization and its constituent parts.

In its discussion of the mission of the National Institutes of Health, the Committee concluded that organization around a categorical concept and mission has made more difficult of achievement the tasks to which this agency is dedicated, and identified as "one of the accomplishments of the NIH management," the "making scientifically inappropriate organizational structure an effective arrangement for performing its real mission." This thesis is flattering but open to challenge. In the NIH view, what is more impressive is that the dominant categorical orientation of NIH programs and their clear identification with both the duration and quality of human life may, in no small measure, be responsible for the excellence which has characterized these activities, the scope and magnitude of present day support for the biomedical sciences and for the depth and breadth of public support of its operations!

The idealistic and humanistic motivations that operate in the medical research environment cannot be discounted in explaining its attraction for first class intellects and in locating the wellsprings of the high esprit de corps, dedication and self-sacrifice which characterized so many research workers in this area. In this light, the principle of

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a separate effort
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organization along categorical lines can well be viewed as one of the profoundly influential innovations in the process of transforming national aspirations into the necessary scope and magnitude of public action. As such we would hope that it was preserved, along with the continued exercise of wide latitude and discretion in selecting other ways and means operationally required to secure health-oriented goals.

Thus in the NIH view, this organization is a health agency, engaged in medical research and the support of the scientific, academic and technological effort necessary to the advancement of capability for the diagnosis, treatment, and prevention of disease and the understanding of the underlying biological and behavioral processes.

Rate of growth

The Report of the Committee asserts clearly and in numerous places that in the future, the National Institutes of Health must be prepared to justify its claims upon and use of public resources on a far more national basis than was required in the past, and that to discharge this responsibility, sophisticated planning machinery will be required.

The stated basis for the assertion is twofold. The first is in deference to well-established principles for the administration of organizations, especially when they become large in size and in scope of responsibility. The second is related to the Committee's perception of the imminence of a curtailment in growth rate, forcing the NIH to choose between worthy claimants for increasingly limited resources.

In general, the NIH would agree without reservation that rational justification of its budgets to the higher levels of the Executive and to

Well said!

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the Congress is important. However, the NIH does not find congenial the implication that some inexorable law of economics, over which we have no control, limits the commitment of the people of this affluent nation to the quest for a longer and a healthier life. Today the NIH budget represents about 0.15 percent of the Nation's gross national product. While viewing as unexceptionable the assertion that public funds be allocated prudently and intelligently, the NIH also feels that every effort should be made to convince the American people that this nation is rich enough to explore every reasonable opportunity to eradicate disease and to finance every professionally competent individual willing to dedicate his career to this goal.

The analysis in Appendix III of the Report is, to the extent that it is concerned only with economics, insufficiently comprehensive. We would hope the growth rate will continue to reflect opportunities for progress--including the wherewithal to attract dedicated, idealistic and talented young men and women into careers in this field--as well as economic exigencies.

Balance and the master plan

The Committee Report in several places emphasizes the increasing importance of "balance" in the allocation of resources across NIH programs and the development of a "master plan" covering all major aspects of NIH activities contemplated in the foreseeable future. It notes that such matters will become of increasing importance as the scope and requirements of NIH programs compel greater discrimination in respect to the direction and magnitudes of future development.

Without doubt, questions relating to the distribution of effort have become increasingly critical as NIH, in one generation, has been transformed from a modest research activity to a large-scale, complex, far-flung enterprise deeply involved in the achievement of interrelated national objectives of health, research, and education. However, if balance is construed as precisely optimum allocation of resources in relation to missions, objectives, national needs, and scientific opportunities, it is unlikely that such perfection can be achieved.

NIH also has reservations about its ability to develop a "master plan" of the scope and detail that seems, from an overall assessment of the Report, to have been in the mind of the Committee. The recurring allusions to optimal utilization of resources, maximal benefits from overall expenditure, optimum levels of activities, national needs and requirements, suggest that the Committee really envisages the construction of a mathematical programming model which would accurately describe the interrelationship of all of the elements in the program of the NIH and accurately predict the behavior of the whole system as changes occurred, or were induced, in the behavior of subsystems.

X. While anxious to bring to more or less homogeneous components of program these tools of analysis, the NIH would be less than candid not to state that the progress is likely to be slow. The dimensionals of the matrix necessary to encompass this program are many and include: categories of disease (heart, neurological diseases, cancer, etc.); scientific disciplines (genetics, biochemistry, physiology, etc.) which may or may not intersect with disease categories; types of activity (research, development, training, education, demonstration, service, etc.); sponsors (academic

institutions, industrial enterprises, state hospitals, Federal laboratories, etc.); nature of the instrumentality (grant, research contract, procurement contract); character of activity (basic research, applied research, advanced development, etc.); etc.

Therefore in respect to these two aspects of the Committee arguments namely, the implicit view of the further rate of growth of NIH and the concept of "balance" and the "master plan," NIH is inclined to somewhat different attitudes. Although annual rates of growth comparable to those that took place in the latter part of the 1950's do seem unlikely, the ingredients of further substantial increases are present. Given a set of attitudes toward the vigor and magnitude of the scientific attack upon major disease problems comparable to that which motivates the national space effort, the present state of the art in many fields coupled with the growing interest and availability of industrial capacity could well precipitate another period of explosive growth.

In like manner a less grand view of the scope and role of the planning process than that connoted by the term "master plan," is in the NIH view, both more seemly and more realistic. The nature and degree of planning will vary at the several operational levels and in the different program areas. It is conceivable that planning can become quite formal and detailed in development programs while in the area of basic research, a large measure of intuition will continue to heavily influence many decisions despite efforts to structure the process of assessment in respect to needs and opportunities in science.

The Policy and Planning Framework

Despite our less than sanguine views of the feasibility and utility of a "master plan" the certain prospect of further growth in NIH programs demands careful consideration of the Committee's recommendations concerning the framework for the development of plans and policies at NIH. The Committee's argument in this respect is tightly reasoned and of considerable force. Its structure is as follows:

1. The essential function of NIH is to transmute the national desire for the conquest of the major diseases into the basic scientific effort and resources essential to the eventual achievement of the primary task. reaching
starting
2. In the pursuit of this task it has acquired the principal role in government in respect to the advancement of the biomedical sciences.
3. Looking to the future, the major problems that will be presented in the discharge of this responsibility center in:
 - a. The influence that will be exerted over the distribution of effort in the sciences relevant to health, the resources utilized and the institutions involved.
 - b. The continuing potential for the policies under which government support is provided to extend undue and inappropriate government control.
4. The wise resolution of these problems demands a broad base of information, access to the views and judgment of non-government experts, and arrangements that ensure that major policy and planning decisions are at all times in good alignment therewith.

5. The exercise of this role, the matters to be dealt with, and the importance of these processes involve a combination of scope and cohesiveness that warrants a high degree of self-sufficiency in their management and direction.
6. The prime issue is therefore the kind of machinery that should be established to assure that the influence of NIH upon the direction of science is in keeping with the best judgment of the scientific community. *jud*

The Committee's proposals

As a consequence of this flow of argument the Committee sets forth a series of proposals:

1. The formation of a policy and planning council composed of prominent non-government scientists and laymen to provide high-level advisory service to the Director of NIH.
2. The development of enlarged and capable planning staff to supply analyses and arguments bearing upon major policy and planning matters to the Director of NIH and for the consideration of the Policy and Planning Council.
3. A reordering of relationships amongst the Office of the Surgeon General, the Director of NIH and the Institute Directors and advisory councils to enhance and focus more sharply the authorities and responsibilities of the Director of NIH.
4. Easier access to and greater participation in the Councils of higher authority in the Department of Health, Education, and Welfare for the Director of NIH.

5. An immediate start upon the building of this decision-making machinery.

The Committee concludes that all of these actions are ultimately essential if the management, planning and policy determining capabilities of NIH are to be commensurate with the importance of its activities.

The NIH view

The reservations that have been expressed about the Committee's conception of the mission of NIH, its predictions on growth, and its vision of the scale of master planning suggest the need for some circumspection in considering the Committee's proposals for a decision-making framework. The specific actions recommended have far-reaching consequences and a potential for introducing major perturbations into the existing administrative structure of DHEW. Certain of these proposals must necessarily require detailed study at, and extended discussions between, various organizational levels as well as externally before final conclusions can be drawn and action committed. The full range of issues presented by these proposals encompasses matters that transcend the competence if not the propriety of comment by the National Institutes of Health. Nevertheless some expression of view by NIH on some of these matters, however tentative, and diffident it may be, is an essential base for discussion.

In general, NIH believes that the Wooldridge Committee's argument for more deliberate attention to the further development of plans and policies at the NIH level in a more capable and structured context, providing access to sound and well organized information and the informed judgment of the

scientific community, is on the whole, well taken and persuasive. There is, of course, the prospect of widely different views of the nature and scope of planning, on the value and role of an NIH advisory group, and the needful modifications in existing functional and organizational relationships. Nonetheless, it is the NIH conclusion that the matters which form the basis of the Wooldridge Committee's recommendations in this area are valid and important considerations; that the objectives sought through its recommendations in general are desirable and merit vigorous and purposeful effort."

As we have noted, the precise means chosen to work toward these objectives, as well as the pace of their pursuit, are various, can be controversial, and in many respects are quite beyond resolution at this organizational level. NIH is convinced, however, that certain steps, in consonance with the spirit of the Committee's advice, can be taken which are both desirable from the NIH point of view and feasible within the existing organizational and functional framework. Accordingly the following actions are proposed:

Strengthening and expanding the planning function at NIH

For some time it has been a conviction in the Office of the Director of NIH that NIH programs and operations have been in the midst of a major transition by virtue of the evolving interplay of a complex set of scientific, operational, fiscal and political factors. Among these many forces four are clearly evident: ⁽¹⁾ The growing competition for resources, ⁽²⁾ the emerging scientific and technical potential for the pursuit of specific objectives, ⁽³⁾ the concern focusing upon the long-term economic and social consequences of Federal research expenditures, and the ⁽⁴⁾ influence exerted

How do (3) and (4) differ? Geographic distribution, etc

upon the course and direction of science and its relevant institutions.

These are matters demanding intensive study, the findings of which must be brought to bear upon the formulation of plans and policies. Continuing efforts have been made at NIH to emphasize the need for purposeful engagement with these changing circumstances, to develop a disposition and capacity to consider such questions, to bring about a more direct confrontation of Advisory Councils and Institute staffs in this area, and to advance generally the role of planning, program analysis and orderly program development in the administration of NIH activities.

While much has been done and significant changes in both attitudes and operating practice have taken place, there remains a basic ambivalence concerning the scope and role of such functions in the conduct of scientific programs. In large part this ambivalence arises from a tendency for views of the planning process to assume an unnecessary and distracting polarity. One pole is the view that the concept of planning and its related activities involves the administration of science programs on a teleological principle with all parts bearing a purposeful relationship and resulting from deliberate and a priori determinations. The other pole is the view that planning is anathema in anything to do with science; that the most progress emerges from an unstructured setting in which serendipity is fostered by basing administration on the principle of laissez-faire and with a minimum of deliberate acts and processes. While neither point of view is wholly tenable, much less a basis of action, their presence suggests the current stage of development of these functions and the rate at which further evolution can take place.

Progress toward more sophisticated attitudes and approaches to the appropriate role for and use of the planning and analytical function in the conduct of NIH programs can be substantially advanced by a major upgrading of the quality, professional scope and dimensions of the staff in the Office of the Director concerned with the overall prospective development of the National Institutes of Health, its policies and programs.

This conclusion had been reached some time ago and, though substantially supported by the recommendations of the Wooldridge Committee, was the consequence of an independent examination and assessment of this matter.

The results of this review are reflected in the proposals for a fundamental overhauling of the planning and analysis function in the Office of the Director contained in the Preliminary Budget Proposals for Fiscal Year 1967 submitted to the Surgeon General by NIH. These proposals are believed to be in accord with the concept of the Wooldridge Committee for expanded and enhanced staffing in support of the decision-making processes at NIH.

In summary, the changes proposed would abolish the Office of Program Planning as it now exists, establish a new position of Associate Director for Planning (to permit the appointment at the top 208(g) salary level of an outstanding scientist-administrator to provide broad professional leadership for the development and conduct of the planning process at NIH) and reorganize the planning and analytical functions into a new, more sophisticated and professionally capable framework.

The full details of functional assignment and personnel requirements for this new framework have not been resolved. At the present moment, however, it is our projection that for FY 1967 an aggregate operating level of 75 positions and \$1,400,000 will be required. This will entail an

Who does
this review?
Oppose
New Director
& H. H. H.

increase of \$830,000 and 37 positions above the 1966 President's budget.

A full presentation of these proposals complete with functional statements and staffing requirements in support of this Preliminary 1967 Budget request will be submitted to the Surgeon General in the very near future.

Advisory support for the Director of NIH

The full concept and role of the Policy and Planning Council as proposed by the Wooldridge Committee involves rather drastic modifications of existing operating and functional relationships, the ultimate realization of which would require legislative action. A conclusive NIH view on these ideas, to the extent that it is appropriate, will be possible only after extensive discussion and deliberation. In general, and as a beginning point for such discussion, we believe that the objective sought by the Committee in this recommendation, namely to provide the Director of NIH with access to and a framework for external advice, is a valid and important matter.

A candid view of the circumstances within which the Director of the National Institutes of Health operates must recognize two crucial sets of circumstances:

1. Advisory Councils perform a most significant role in the conduct of NIH programs and exert a powerful and pervading influence upon policies and events in the individual program areas. Yet this framework of advice is statutorily responsible to the Surgeon General and, by virtue of delegation, centered in and responsive to the individual Institute and Division programs without any functional reference to the Director of the NIH.

2. The Director of NIH, by virtue of his position and the de facto operating circumstances, must exert the first level of executive responsibility across the processes of policy formulation, program development and budget formulation encompassing the full range of Institute and Division programs. In the discharge of this responsibility he must be concerned with the identification of new areas of needs, the tempering of enthusiasm, the judgment between short-term versus long-term benefit, the state of the art, the availability of resources, the balance between capital investment and operating expenditure, the relevance of economic, political, scientific considerations and evolving public policy. He must reach his decision concerning all these matters on the basis of the views of his staff, the information and analysis he can command and assimilate and in the final context of his own intuition and values without benefit of any formal framework of external advice.

When in the context of these circumstances, occasions arise in which the judgment of the Director is significantly at variance with the views of a program advisory group on an important matter he must maintain his position without recourse to consultation or independent advice. These occasions, although not frequent, have had undesirable and unwarranted consequences. On the one hand, they have generated misunderstanding and imputations of arbitrariness in the conduct of the Director's function. On the other hand, by forcing inappropriate matters to the level of the Office of the Surgeon General for decision they have unnecessarily arrayed the NIH and OSG in apposition.

The NIH is therefore of the opinion that some device to provide
the Director of NIH with advice on overall plans and policies and
consultation in the reaching of decisions is an important and needed
addition to the framework of NIH administration. An immediate,
practicable and suitable arrangement for this purpose would be the
formal establishment of an advisory group for the Director, comprised
of members selected from the several Institute and Division Advisory
Councils and Boards of Scientific Counsellors.

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 considered
 as a*

Whatever might be the official status of such a group, so long as it was, de facto, advisory to the Director of NIH it would in considerable part serve the intent of the Wooldridge Committee in its recommendation for the establishment of a Policy and Planning Council. Experience with the use of an inter-council group of this nature in the discharge of the Director's function would provide useful insight into the need for any further evolution of this or some other advisory arrangement.

The reordering of authority relationships

The Wooldridge Committee takes the view that the authorities of the Director of NIH should be increased, the autonomy of the separate Institutes diminished and the appointment of Advisory Councils and Institute Directors vested in the Director of NIH. It would appear that these recommendations reflect the dominant organizational philosophy of the group, namely that the structure of administration should clearly provide for the cohesive and unhampered management and direction of NIH functions. While in accord with this managerial principle, the NIH, at first view, is of the opinion that no major

circumstance in respect to present organizational relationships seriously contravenes it.

It is perhaps an unfortunate but nonetheless inescapable condition of public administration that the extent of authority available at any level of operations can never be commensurate with the responsibilities and obligations imposed thereon. This is no less true at the Office of the Surgeon General than it is at the level of NIH or, for that matter, at the Institute and Division level. All public administrators must come to terms with this basic incongruity. The important matter is whether the administrative framework intrinsically denies the exercise of the critical authority at any level. In the NIH view there is no such intrinsic fault in existing authority relationships.

While it is probable that the explicit delegations and patterns for the exercise of authority might be more realistically aligned, this seems to be a matter of lesser urgency and needful of more studious assessment.

Access to and participation in the higher councils of DHEW

A further recommendation of the Committee is that "the size and importance of the NIH program should be recognized by the provision to its Director of easier access to and greater participation in the councils of higher authority in the DHEW."

The Committee's recommendation appears to dwell on two points. The first is their belief in the need for more direct participation by NIH staff when discussions are held and decisions are made concerning basic

matters of policy affecting the NIH. The second--which is referred to on page 16--is a very general recommendation that "experts," in the Executive Branch should look into the organizational position of NIH within the DHEW.

On the first aspect of this recommendation, NIH has long felt that it should be represented directly at the organizational point at which decisions are made which primarily affect matters of NIH policy and programs. In practice, this would mean that if the Surgeon General is to make the final decision, NIH should present its proposals to him. If it is to be the Secretary, the Bureau of the Budget, the Office of Science and Technology or another Executive Agency, NIH believes that as a matter of principle NIH staff should be present in these policy discussions. The nature and importance of the budget cycle and the crucial role played therein by the Comptroller of the Department places an exceptional premium upon participation in budget discussions in which critical decisions affecting the support and content of NIH programs are made.

As to the broader issue of the organizational position of NIH, we defer recommendation on the action to be taken to higher echelons. Much depends on the ultimate resolution of the question raised earlier in this document as to whether NIH is basically a health agency or a science agency. If it is determined that this question and the organizational position of the NIH should be studied by governmental experts, NIH would, of course, wish to have the opportunity to comment on the substance, method and scope of the study, but the determination of next steps is appropriately made outside of NIH.

* In summary, therefore, the NIH is in general accord with most of the thrust and proposals encompassed in the Wooldridge Committee comment on plans and policies. NIH does, however, take a notably different view of the mission of NIH and would approach such concepts as "optimum balance" and "master plan" with caution. Nonetheless, the need for greater investment in planning and analytical activities in the Office of the Director, NIH, seems clear, and a detailed proposal to this end will be forthcoming. In concept, the need of the Director of NIH for external advice and consultation is accepted and the use of an inter-council arrangement for this purpose is proposed. No serious fault is found in the relationships of authority between the Institutes and the Office of the Director, NIH. However, NIH access to the higher councils of HEW is viewed as necessary, particularly when critical budgetary decisions are in process. On the other hand the organizational position of NIH in HEW is appropriately a matter for consideration elsewhere.

Concurrence

EXTRAMURAL PROGRAMS

The comments in the report on the quality of extramural research and the administration of extramural programs are distinctly favorable, and the recommendations which it offers are quite constructive. Certain issues raised by the study deserve consideration in their own light and, therefore, are included in this part of the NIH response. The NIH hopes to be able to respond more fully at a later date with detailed examination of the individual recommendations.

General CommentsThe nature of the NIH-nonfederal relationship

* Basic to many of the findings and recommendations of the Committee and Panels is an appreciation of the intricate, dynamic, and important relationship between the NIH as a federal granting agency and the non-federal sector in which its extramural funds are utilized. That sector presents many faces--a grant-supported investigator, a grantee institution, the scientific community, a professional society, etc. The totality of the Wooldridge Report mirrors its breadth and depth, its magnitude and complexity, as well as its strengths and contradictions. Because the extramural segment is a significant part of the NIH's total effort, and because a viable relationship is essential to its success, the NIH must continually analyze its programs, policies, and procedures, as well as any contemplated changes in them, with proper appreciation for their widespread influence. Although the objectives of the NIH and its outside "clienteles" are consistent, their achievement may involve differences between the two parties as to concept or method.

An aspect of that relationship which is receiving particular attention at this time is the effort by the NIH to strengthen and enhance the environment in which its extramural programs are conducted. The Report speaks specifically to this need in several contexts, urging the NIH to continue various approaches currently underway as well as to explore additional possibilities.

The NIH not only concurs in, but figuratively applauds the Committee's insights here, the thoughtful discussion of its objective and the suggestions for possible approaches to implementation. While the NIH is not, at this point, ready to accept all of the proposals as most appropriate for adoption without further consideration, it definitely agrees with the underlying concepts and finds these supportive of actions already adopted or contemplated. For example, in the Spring of 1963, the Director, NIH, initiated a series of staff actions to determine the desirability and feasibility of modifying the NIH grants management policies and procedures so as to locate decision-making on certain interim actions within the grantee institutions.

Following extensive staff exploration and discussions with representatives of the scientific and academic communities, a one-year pilot study was initiated in the Fall of 1964. Involving seven representative institutions, the study seeks to test the hypothesis that such modifications are indeed desirable and feasible. If the pilot study proves successful, the NIH expects to increase considerably the number of institutions whose grant programs would be covered by these modifications. The NIH strongly

*Not clear
that the
environment
is being
improved*

believes that such moves would not only promote increased managerial capability within the research environment, but would enhance the qualitative assessment of research and the routine control of expenditures from grant funds.

In somewhat greater detail, NIH reacts as follows to some of the specific issues raised in the Report under this heading of NIH-nonfederal relationships.

The Report recommends that a grantee institution should designate one of its executives to assume responsibility for the pertinence of NIH-supported work to the institution's overall science/education program, for qualitative adequacy of projects, and for proper expenditure of funds.

The above describes--at least in theory--the nature of responsibilities currently held by grantee institution executives with respect to NIH funded programs. But in point of fact, NIH recognizes that executives with these functions will not be found in most grantee institutions. Many factors contribute to this. One fairly common allegation is that the nature of NIH programs and policies precludes institution executives from assuming the authorities they would need to determine the science/education program of their institution. This, in NIH view, both exaggerates and distorts NIH impact. Moreover, the NIH has taken a series of steps in recent years to encourage or to provide assistance toward the end sought. For example, it has always been recognized that NIH grants are made to an institution for the support of a designated project or other activity. This NIH-institution (vis-a-vis, the investigator) relationship has been firmly reiterated in recent years in both published

documents and statements to the Congress and elsewhere. Furthermore, a series of funding mechanisms directed particularly at the environment in which the research is conducted provide a valuable and prominent instrument for this purpose. The programs of graduate training grants, the research facilities construction program, the general research support grant, and the research career award program are all designed with this objective in mind.

The latter two activities also represent positive evidence of our expectation that the institution itself will maintain surveillance of the "qualitative adequacy of the project activities to be performed," as the Report recommends. While NIH agrees that further strengthening of institutional role in these qualitative matters would be desirable--and should in fact be possible--feasible approaches must be worked out with care. Some of the difficulties seen: The nature and strength of past traditions; the habit of dependence on the NIH system of peer judgment and national selection; potential conflicts between institutional assessment and that by agency review panels; the lack of broad competence in many institutions. More specific NIH thoughts or proposals on this issue will have to follow later.

With respect to institution responsibility relative to the "expenditure of the funds" involved, considerable change has taken place in NIH grantee institutions in the past few years and additional improvement certainly can be anticipated. Increased administrative capability and awareness within those institutions and a clarification and strengthening by the agency of its procedures will bring closer . . . the objective

sought in this matter. A variety of activities ranging from more reasonable methods of disbursement of NIH funds and more comprehensive audit systems to the establishment of grants management officers and units within the DRG and Institutes/Divisions constitute visible evidence of positive action by the NIH.

The Report recommends "additional funding of program projects in strongly managed institutions."

NIH concurs in this recommendation; but it also endorses the cautionary note added by the Committee. These factors point toward caution: First, program project expansion would have to come at the expense of small or individualized grants. In periods of limited funding availability, the development of promising new program areas might have to be held back because of long-term, large-scale commitments to program projects. Also, while the workload in study sections might be somewhat eased by the smaller number but larger size that these grants represent, the greater complexity of such grants generally exacts more varied expertise in the review than is needed for regular project grants. Net savings in review time, therefore, might not amount to much.

Also warranting caution is the apparent assumption by the Committee that strong institutional management should or would lead naturally to a proper environment for program projects. NIH finds no logical basis for this view; and would, in fact, re-order priorities. In future as well as past awards of program project grants, the first criteria for institutions must be that they afford a proper research environment; only if this

environment is found need the factor of management strength be considered. If NIH elects to increase its total commitments through program project grants in the future, a good starting point for its search for favorable research environments would be in the more strongly managed institutions. But it would be hoped that neither NIH nor any one else could overlook the fact that the scientific productivity sought pertains to the scientific community and not to the administrative community.

*Point this
out in the
conclusion*

The Report recommends that research costs attributable to salaries of investigators be handled by a two-party contract involving NIH and the institution alone.

In this recommendation, too, the Committee's main concern is to strengthen the role of grantee institutions in NIH supported research. It seeks this by adding specific administrative responsibilities, and by halting what is seen as a potentially significant drain on internal authority. The underlying fear is that direct interchange between NIH and investigator applicants on the issue of salary support, weakens the relationship between the investigator and his parent institution.

How best to use grants funds to pay for investment of professional time has long been one of the most troublesome problems confronting Federal granting agencies. Scientists needing and meriting support must somehow be supported; and the quite different standards and information needs for scientific review, audit, and ordinary payroll must somehow be brought to terms with the peculiarities of the scientific work week. The specific aspect referred to by this recommendation represents only one component of that problem yet it is difficult to disassociate it from the whole.

om time to time, this matter has been reviewed within the NIH but so
or proposed modifications have fallen short of needs in one crucial area
another. With this recommendation as stimulus, NIH intends to re-open
study of this problem; but we would urge as even more pertinent a new
effort to develop government-wide grant-salary concepts.

The Report also recommends enlargement of the amount of General
Research Support Grants.

Clearly, the NIH agrees with this recommendation, having supported
not only gradual increases in the amounts available for these grants, but
extension of eligibility for such support to other types of institutions.
A study undertaken by the National Academy of Sciences at the request of
the NIH may well provide justification for further expansion of this program.
Since the NAS study represents the first in-depth assessment of this rela-
tively new program, action on this recommendation of the Committee should
await study findings.

The Report recommends new procedures for payment of grantee institutions
for research costs.

The proposal is to eliminate payment of indirect costs as an allowable
percentage of direct costs; instead, grantee institutions could claim all
direct or reasonably allocable costs of the research being conducted
therein.

The intent of this recommendation again finds concurrence within the
NIH. Indeed, the NIH, the PHS, and the DHEW have long supported the need
for more appropriate means of funding research grants--particularly the
so-called "indirect cost" component.

Beyond this general affirmative comment, however, the complexity of the problem and the as yet incompletely assessed impact of the recent issuance of a revised BOB Circular A-21, make any detailed comment premature. For this reason, we would propose to treat this recommendation in a separate document to be provided at a later date.

The Report recommends that NIH use its granting authority "to encourage" institutions to develop administrative ability to handle responsibility for grants of their investigators; it further recommends curtailment of grants to institutions that do not improve to needed levels.

NIH prefers to emphasize the affirmative rather than the punitive aspects of this proposition. NIH has already developed a mechanism for assessment of individual and institutional scientific capabilities that has received wide acclaim from a variety of prominent sources, the latest of which is this report. At the same time, NIH recognizes that there is probably some minimal level of administrative competence needed in grantee institutions to assure the favorable environment essential to research productivity. How to determine what this needed level is, constitutes the problem. Because of a continuing desire to promote the managerial health of grantee institutions and to keep better informed as to the state of that health, NIH recently instituted a study to develop the criteria to assess institutional administrative capabilities.

Program size versus quality

Frequent comments and allusions in the report on the quality of the extramural activity rightly can be viewed with great satisfaction by the NIH and by all others concerned. Implicit in this assessment, however,

is the recognition that, in its role as the principle source of research and training support in the biomedical sciences, the NIH has a responsibility for the totality of that effort. This role is obviously a consequence of the mission but undoubtedly it is also a consequence of the sheer size of the NIH extramural activity.

In this context, therefore, it must be appreciated that the agency cannot be as selective in awarding its funds as are smaller organizations, including most foundations. Rather than concentrating its awards on only the very highest quality research, the NIH must be prepared to provide support in behalf of the majority of all biomedical research adjudged meritorious.

INTRAMURAL RESEARCH

There is every reason to be proud of the intramural research done at NIH and it is odd that a report which, at every turn, praises its high quality should also make necessary a defense of this oldest of all NIH activities.

The recommendation of the Committee is that the role of the intramural program be reexamined with the clear implication that its scope ought to be curtailed. The recommendation reads as follows:

The Committee is not convinced that it is sound for the Federal Government to conduct large amounts of scientific research of the kind that non-Federal institutions are equipped to carry out. A majority of the NIH intramural program appears to be of this nature. We recommend this question as an early agenda item for the consideration of the new Policy and Planning Council. If reductions are decided on, they should be carefully executed, to ensure the preservation of high quality in the remaining activities.

In the justification for this recommendation, the Committee makes the following points:

- "the NIH scientist has at least as much, and probably more, 'academic' freedom than his university counterpart";
- "he finds it relatively easy to secure modern equipment needed for his work";
- "he is better shielded from 'red tape' annoyances than are most university scientists"; and
- "he has fewer distractions to keep him away from his laboratory.... he can devote all his time to research";

The Committee concludes that:

- "for some scientists, especially those to whom teaching is either unimportant or a positive drawback, the NIH intramural establishment offers an unusually favorable environment";
- it succeeds "in attracting a higher caliber of research man than the lower salaries would ordinarily permit"; and

-- it is "an asset that should be protected".

In the light of these views, it is clear that the Committee's reservations do not reflect misgivings about the quality or management of the intramural program. On the contrary, the Committee frankly states that its suggestion that the level of this program be reduced "is based upon a conviction that the government should not undertake the direct conduct of research activities that fit precisely into the pattern of scientific work that the universities or other non-government institutions are equipped to perform". This is an ideological argument reflecting political and social predilections rather than professional or scientific judgment. The Committee does not pretend otherwise--it frankly labels as such its "bias" in favor of the intermingling of basic research and higher education.

NIH, on the whole, shares this bias and has repeatedly stressed, especially in testimony before Congressional committees, the value of the interaction of research and graduate education. The totality of the extramural programs give expression to this bias by being heavily engaged with research training objectives and by the strong orientation of the research-support programs toward academic institutions.

X NIH does not, however, share the view--implicit in the Committee's recommendation--that basic research can best be done, or should only be done, in an academic environment. While the interplay of these two activities is helpful to both, it is not equally helpful to both.

It can be--and often is--well argued that good graduate education is not possible in the absence of good research; it cannot be so convincingly argued that good research is impossible in the absence of a formal teaching program. Many outstanding research institutions--including NIH itself--attest the falseness of such an assertion.

In connection with the question of teaching and research, it should be noted that the Committee's report makes no mention of the great amount of informal but most effective teaching--teaching at the bench--that is done at NIH. In clinical investigations and in the introduction of young scientists to the work going on at the research frontiers, the unique facilities of a major research institution like NIH and the involvement of its staff with the leading-edge of inquiry in particular fields of science offer opportunities for teaching which few universities can match. NIH is, without doubt, one of the country's leading institutions for post-doctoral training in the fields with which it is concerned. In view of the Nation's urgent need for more high-quality institutions for research and for teaching, the view of the members of the Committee's Biochemistry Panel who "believe that serious consideration should be given to establishing a teaching institution at Bethesda, either a two- or a four-year medical school, or even a university" is, perhaps, more realistic than the suggestion that NIH should divest itself of any considerable part of its existing in-house research programs.

The Committee's preference for restricting the role of the Federal Government to "types of work that are uniquely suited to performance in Federal facilities" lies beyond the reach of objective rebuttal. The consensus of American political thought has abandoned the view that government should only do what cannot be done elsewhere and now seems to agree that the government should actively concern itself with tasks of truly national interest. To pursue this purely ideological aspect of the argument would be productive only if the question were whether an intramural program should be established, de novo, at NIH. This is not the question.

X The intramural facilities and staff of NIH have evolved logically, in response to national concern with major health problems, from the one-man bacteriological laboratory established at the Marine Hospital on Staten Island in 1887. The first of the present constellation of Institutes was created, by the National Cancer Institute Act of 1937, for the express purpose of

X ["conducting researches, investigations, experiments and studies relating to the cause, diagnosis and treatment of cancer; assisting and fostering similar research activities by other agencies, public and private; and promoting the coordination of all such researchers and activities and the useful application of their results, with a view to the development and prompt, widespread use of the most effective methods of prevention, diagnosis, and treatment of cancer....."

The Public Health Service Act of 1944 and the Acts creating subsequent Institutes contain similar language. The primary role assigned to NIH by the Congress for the pursuit of its various categorical missions is therefore to conduct research.

The statement in the Committee's report (in connection with the discussion of decision-making machinery on page 17) that "The NIH now considers its intramural research to be essentially an enlargement and extension of the extramural programs" overlooks the historical development of NIH and reflects neither the present NIH attitude nor its legislative mandate. The NIH, as the research arm of the Public Health Service, has as its first concern the scientific resolution of disease and health problems--it regards its extramural programs simply as one of the means by which it may further this primary objective.

The mission of NIH, in its broadest terms, is to expand the national capability to conduct research bearing on the prevention, alleviation and cure of disease. To this end, the principal thrust of its extramural programs is directed to the creation of centers of excellence for biomedical research by increasing the number and raising the quality of research facilities, investigators and research projects. The intramural part of the NIH establishment is a superb specimen of the type of research environment which the NIH extramural programs are designed to create and it would be in direct opposition to the purpose of these programs to curtail the NIH intramural operation. It would be extremely short-sighted to diminish the scope or effectiveness of an establishment that is the flourishing prototype of the sort of institution of which the Nation has an increasing need merely because it has developed inside the framework of a Federal agency instead of on a university campus or other nonfederal site.

While the intramural program is not, in any sense, an extension of the extramural program, its value to the extramural program should not be underestimated. The Committee's statement that an NIH scientist "is only slightly more likely than a university scientist to become involved in NIH activities other than his own research project" is only partially true. The NIH scientist is no more likely than his university counterpart to become formally involved in the extramural program, such as by appointment to a Study Section, because a deliberate effort is made to give the membership of the review groups a wide geographic distribution--in order to draw on all segments of the scientific community but also to facilitate site visits. He is, however, by his presence on the NIH campus, very much more likely to be consulted on program problems and for information and advice on the varied technical questions that arise during the review of grant applications. The volume of informal consultation with intramural staff is largely undocumented but is high enough to elicit occasional complaints from the scientists that too much of their time has to be spent in this way.

So long as the NIH grant programs were largely concerned with strengthening the national research base, the extramural and intramural activities could--and did--remain largely independent. However, due to encouraging progress in the basic sciences, more attention can be given to the deployment of effort in support of specific program purposes. The time has come when it is feasible to think,

in practical terms, of a comprehensive Institute approach to each of NIH's categorical missions in which the intramural and extramural programs can function as an inter-dependent team. Several Institutes--notably NCI--have already taken steps to involve their intramural staff on a more formal and continuing basis in the development of Institute policy. This trend will clearly continue. The extramural programs have now reached a stage of development where their need for constant sophisticated scientific guidance is such that it might be asked if an intramural program would not have to be created, if one did not already exist.

The intramural activity also makes a significant but subtle contribution to the extramural programs which is difficult to describe. The role of NIH as an outstanding research institution pervades the Bethesda campus and provides a setting that has imperceptibly, but nonetheless profoundly, influenced the development of the whole organization. The prestige conferred on the whole of NIH by the eminence of some of its scientific staff and the solid base of experience provided by NIH's direct involvement with the leading-edge of research has won for it an acceptance--by the scientific community, by the public and by the Congress--which it could not have achieved--and would not be able to maintain--as merely a government agency charged with responsibility for the disbursement of Federal grant-in-aid appropriations.

The limitation of NIH's intramural activities to those things that could not be done in nonfederal institutions would seriously damage the effectiveness of the entire program. Unlike the physical sciences, the biomedical sciences are still largely at the stage where many fundamental concepts need to be developed and where, consequently, research must continue to rely heavily on the ingenuity and incisiveness of the individual investigator. Large-scale developmental projects--such as those in nuclear physics and space research--are not yet feasible in the biomedical sciences to take the place, in a Federal institution, of the traditional individual research projects. The application of a "uniquely-suited-to-performance-in-Federal-facilities" criterion would leave NIH with those projects which university scientists find uninteresting and those which industry finds unprofitable. A program consisting of such projects would lack cohesiveness, could not hold together a competent staff, and would be a very questionable investment of public funds. It may be assumed that the Committee is not seriously suggesting that NIH embark on such a course.

A reduction in the size of the NIH intramural program--without reference to any arbitrary criterion of what work is appropriate to it--need not, of course, have such drastic consequences. The Committee (in the section of the report on "Plans and Policies") says that

"We have been unable to find any analysis leading to the conclusion that the present 10,000-man level of intramural activities in NIH is more nearly optimum.....than would be, say, a 5,000-man or a 20,000-man level".

Leaving aside the inadvertent error in the figure used (NIH has a total staff of about 10,000; the intramural staff, as noted elsewhere in the report, is "more than half of the 10,000 employees"), this statement is correct. There is no analysis and no conclusion that the present level of intramural employment is optimum. The intramural programs have been staffed by each Institute, in carrying out its categorical mission and the legislative injunction to conduct research, to exploit research opportunities within the limits of available funds, available space, and available research talent.

If the resources at the disposal of each Institute had been half as large or twice as large, its present research staff might also have been half or twice as large.

There is, no doubt, a size--analogous to critical mass in atomic reactors--below which a research institution would be too thinly spread to be productive in so broad a field as that encompassed in the categorical missions of NIH. There may also be a size above which policy direction, program management, and coordination of services becomes inefficient or impossible. But the area between these two points is very broad, and what criteria would establish the optimum point within it? The size of the staff has been, and will probably continue to be, determined by the number of people required and available to carry out the mission of NIH as set forth and funded by the Congress, in response to the proposal laid before it by the President and the expressed desire of the public. For the foreseeable future the size so determined may be safely accepted as optimum for practical purposes.

It is, in fact, predictable that in the next few years NIH intramural staff will grow considerably. The new National Institute for Child Health and Human Development, created on the initiative of the late President Kennedy, is now organizing its intramural program; three additional research buildings have been authorized by the Congress; and new challenges--in such fields as leukemia, toxicology, the development of an artificial heart, etc.--provide fresh impetus for expanded research efforts. The optimum intramural program for the NIH will use available facilities to the maximum for the most vigorous pursuit of the challenges and opportunities presented by developments in the biomedical sciences.

Productive research effort emanates from the human intellect and not from any special administrative or institutional setting. It behooves our society to provide support for research effort through as many channels as may prove productive. The NIH intramural program provides, in its scope and resources, a research facility which to date is unmatched by any university anywhere. It can and does retain a staff uniquely qualified for and dedicated to investigation. The record of achievement of this staff in both applied and basic research is widely renowned and reflects the uniquely liberal and sympathetic environment in which it works. The imposition of arbitrary limitations on so flourishing an activity would not serve the interests of the scientific community, the progress of biomedical research or the legitimate hopes and aspirations of the American people.

COLLABORATIVE ACTIVITIES

Those portions of the Report of the Committee which refer to the Collaborative (i.e., "targeted or planned") Activities of the NIH present special difficulties. The Report projects puzzling ambivalences towards these programs and advances sweeping generalizations--including specific criticisms of the Cancer Chemotherapy Program--that either do not follow logically from facts presented, or are based on assertions which are incomplete or inaccurate. The most striking ambivalence is the juxtaposition of the recommendation that the "origination, organization and management of Collaborative programs should be an important and continuing function of NIH" with: the unfavorable assessment of many aspects of most of the ongoing projects of this type encountered in the course of the study; the imposition of restrictive limits on the initiation of such activities in the future; and the advocacy of an arbitrary philosophy of smallness that never has governed other efforts--such as space exploration--to achieve commensurable national purposes, and that might well be self-defeating in the search for solutions to important health problems--such as the prevention or cure of cancer.

The serious criticisms of the National Cancer Institute's Cancer Chemotherapy Program--made first by the Collaborative Programs Review Group and repeated in the Committee Report itself--required detailed reply. The preparation of a detailed document addressing itself to these

criticisms has not been completed. However, several comments can be made at this time.

The NIH would take issue with, and view as unjustified, criticisms of the NIH and the NCI expressed in the Report which center on: failure to solicit outside scientific advice to guide decisions in the initiation and continuing administration of the program; exaggeration to the Congress at the time the program was initiated of the promise inherent in the proposed approach; dearth of pilot testing prior to program initiation; and inadequate level of effort for the feedback of information to program participants. On the other hand it is difficult to counter the assertion that "NIH has not made a convincing case for the direction and magnitude of the Cancer Chemotherapy program," since this organization was never either requested or given an opportunity to do so during the course of the study.

In taking issue with the assessment accorded the Collaborative Activities in general and the Cancer Chemotherapy Program in particular, the NIH does not intend to challenge the competence or conscientiousness of the Review Group which was faced with examining, in a limited period of time, a broad and only partly familiar area. On the other hand, this institution is of the view that activities of this character fall quite outside the traditional patterns for the conduct of scientific research which prevail in academic environments and must be assessed against standards of excellence which differ from those applicable to traditional grant-supported research projects. They acquire thereby a set of characteristics which make them relatively non-amenable to meaningful

judgment against the experience of the overwhelming majority of biomedical scientists.

The NIH is convinced that the methodology approach of the study was inappropriate when applied to the evaluation of programmed activities. The essential character of the evaluation design--as in other parts of this study--was to visit randomly selected discrete research projects for the purpose of appraising their individual excellence and to solicit opinions of and attitudes about the NIH from scientists and administrators in the institutions sponsoring the selected projects. However satisfactory a device for evaluating a system of project grants this might have been--especially when the evaluators were familiar with the methods and problems of central administration through their experience as participants in the activities of Study Sections and Councils, and when the only generally specified purpose of the overall program was to support meritorious science with no more supervision than that necessary to assure prudent expenditure of public funds--the evaluation of a carefully planned, highly coordinated, and sharply armed program is quite another thing, especially when the Review Group performing the evaluation is unfamiliar with the program concepts and administration.

In activities of the character under discussion; it is the soundness of the total effort rather than the attributes of random parts that really counts. Evaluation must, in the view of the NIH, begin in the central program office with an assessment of the realism of goals, the ingenuity manifested in the choice of approaches, the imagination exhibited in defining the range and variety of options, and the shrewdness in estimating

the probabilities of success in the light of "state of art" knowledge.

The metric of excellence for these activities is built in: the extent to which the specified objective, the program goal, was achieved.

The Report recommends that:

"with respect to the Cancer Chemotherapy Program we advocate the appointment of an ad hoc committee to make a study and recommend any necessary changes."

The NIH accepts this recommendation and will shortly submit a proposal for its full-scale implementation. Clearly, the methodology and the design of the study will have to take into account those nuances which, having been overlooked in the effort just completed, render the conclusions reached irrelevant. It is imperative that the NIH secure an objective evaluation of this program, but the frame of reference for the enquiry must be carefully designed to secure an appropriate assessment.

Memorandum

To: Melanne
Fr: Liz Bowyer
Da: 2/17/94
Re: Briefing book for Friday, 2/18

Attached are some materials that I did not include in the briefing book, but that may be helpful for you.

* Letter sent through Senator Daschle's office from a republican businessman supporting the health care plan

* Memo from Cabinet Affairs on Secretary Espy's health care activities

* A working group draft on CLIA (the Lennox Medical Center doctor has questions on it)

* Briefing materials on the treatment of Indians in the Health Security Act (3 Native Americans are on the panel with her at the Great Plains Summit)

I asked Steve Edelstein and Joe Trahern (Political) to put as much information in their briefings as possible on the members HRC will be with, particularly the four we discussed.

* Although it's not noted in the briefing book, Lisa will do verbal briefings for all of the media interviews

2/17/94

To: Liz Bowyer
From: Rick Weiland, Daschle State Director
Re: Attached letter to Mrs. Clinton

I thought you might want take a look at this.

Mark Griffin owns several Sioux Falls area retail pharmacy stores. He is in his early forties, a moderate republican, past president of the Sioux Falls Development Foundation and current Chairman of *Forward Sioux Falls*, a joint economic development venture between the Sioux Falls Development Foundation and the Sioux Falls Chamber of Commerce. He has also become a very good friend of Senator Daschle and this office.

Mark is extremely supportive of health care reform and the Clinton Plan. He believes in the employer mandate and prescription drug coverage. He has worked with Ron Ziegler (Nixon press secretary) of the National Association of Chain Drug Stores on a number of different health care reform fronts. I'm told this organization is one of the White Houses biggest allies.

Mrs. Clinton might want to mention his letter in her opening remarks. We have a significant elderly population here in South Dakota and the small town pharmacies are in many respects as important to the community as the local post office. They view the Clinton plan as a big plus for the elderly and for the small town pharmacy.

I hope this is of some help. I am also having someone put together some additional background that you might want to take a look at. Thanks!



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February 16, 1994

Mrs. Hillary Rodham Clinton
The White House
Washington, D.C.

Dear Mrs. Clinton:

As an owner of a retail pharmacy, I am writing to congratulate you and the President for your efforts to reform the nation's health care system with the goal of providing guaranteed private insurance coverage of basic health benefits for all Americans that cannot be taken away.

My company, Lewis Drugs, Inc., has been family owned and operated for over 50 years and we employ 20 community pharmacists who provide important prescription drug and medication counseling to hundreds of patients weekly. Many of our patients are elderly. They require access to prescription drugs and pharmacy services, but lack such coverage and frequently cannot afford the high prices of drugs charged retail community pharmacies by manufacturers.

We agree with your view that prescription drug coverage is essential for all, especially for the elderly in the Medicare program, half of whom lack such coverage. Any health plan that provides coverage for doctors, medical tests, and hospitalization, but not for the medicine to treat the illness, is incomplete. It is a fact that 3 out of 5 doctor visits result in a prescription. Drug therapy and pharmacy services must not be viewed as an afterthought.

In communicating the merits of your plan, I urge you to stress, especially in any conversations with the elderly, one essential message. Manufacturers who make the drugs the elderly need are trying to force them to get their medicines somewhere else rather than the drug store they are used to using and want to send the elderly to a managed care plan that will eliminate the elderly's right to get their medicines from the pharmacy of their choice. The elderly need to be told the manufacturers' proposal is not right. The President's plan will not only provide them with prescription drug coverage through Medicare program, but it also will let them continue going to the pharmacy of their choice.

As recently as February 8, representatives of several drug companies in testimony before the House Energy & Commerce Subcommittee on Health urged Congress to move the Medicare prescription drug benefit out of Medicare and into managed care operations. This is not right and we

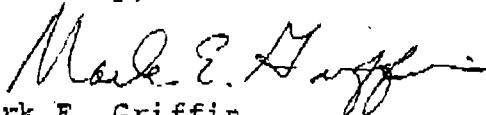
Page 2

are telling our elderly patients what drug manufacturers are trying to do to them. I hope that you will communicate the same information when you discuss the merits of your program with the elderly.

The proposal advocated by the drug companies in last week's hearing is really designed to protect drug manufacturers from making their fair share contribution, via Medicare rebates, to cost savings in the Medicare outpatient drug program. This managed care proposal is nothing more than a thinly veiled attempt by manufacturers to shift their appropriate contribution to health care cost savings to retail pharmacies.

Lewis Drugs, as a member of the Community Retail Pharmacy Health Care Reform Coalition formed by the National Association of Chain Drug Stores and the National Association of Retail Druggists, is a proud supporter of the President's plan. We look forward to working with you in achieving meaningful health care reform that will guarantee comprehensive health insurance and benefits for all Americans.

Sincerely,



Mark E. Griffin
President/C.E.O.

MEG/lkh

By January 1, 1996, the National Quality Management Program completes demonstration projects for new performance standards and revises standards according to the findings. Demonstration projects evaluate the impact of these standards in assuring quality of care, reducing cost and burdens on providers.

Current standards are retained until new ones are tested, promulgated, evaluated and implemented. In the interim, government agencies responsible for licensing and certifying health care institutions coordinate inspections, reduce paperwork and control the number of inspections.

Medicare Peer Review Organizations. The peer review organization system under Medicare continues until the new quality system is implemented and the Secretary of the Department of Health and Human Services determines that Medicare enrollees are protected adequately through National Quality Management Program. PROs will end at that time.

During the interim, the PRO program is streamlined. (See Administrative Simplification)

The Clinical Laboratory Improvement Act. Regulations of clinical laboratory testing are refocused to emphasize quality protection while reducing administrative burdens.

Regulation will continue for labs that:

- a) perform a comprehensive menu of tests; or
- b) perform a large volume of tests (50,000 or greater); or
- c) engage in critical testing (a test is critical if an answer is needed quickly or an error can result in serious harm to an individual); or
- d) conduct testing to monitor care while it is being delivered.

- Ease regulatory burden on laboratories performing simple tests

Exempt laboratories performing waived tests and microscopy from all requirements under CLIA, including registration and payment of fees to the DHHS. Approximately 79,000 labs will be exempted. (under review)

Add more simple tests to the list of waived tests.

In accordance with recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC), the physician-performed microscopy category will be expanded to include those tests performed by midlevel health care providers (e.g. nurse practitioners, physician's assistants, nurse midwives, etc.).

- Ease regulatory burden on laboratories performing moderate complexity tests

Create a new category of moderately complex tests that are performed using FDA-approved, highly reliable equipment that would be subject to less stringent inspection requirements.

By January 1, 1996, the Secretary of the DHHS issues a report on the extent to which regulation of laboratories performing moderate complexity tests should continue. Within six months, the Secretary determines, based on the report, where continued regulation for these laboratories is necessary.

- Revise personnel standards to provide needed relief in urban and rural areas

In accordance with recommendations by the CLIAC, all individuals who are currently engaged in laboratory testing or supervision will be able to continue to perform such testing (in the absence of evidence of demonstrated poor performance).

To address the concerns of rural and underserved areas, the DHHS will modify personnel requirements for certain laboratory positions.

- Focus proficiency testing primarily on education

DHHS will only take proficiency-related enforcement actions where a laboratory's performance is extremely poor or it has failed to take corrective action when proficiency testing problems are identified.

DHHS will work with Congressional committees to develop a modified approach to cytology proficiency testing.

- Streamline inspections

DHHS will target on-site inspections at high-volume, high-risk labs, and they will be announced. (under review)

- Expand information and education activities

To eliminate confusion and misinformation with respect to CLIA requirements, DHHS will work with professional groups to expand activities in information and education.

February 17, 1994

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: DANA HYDE
Cabinet Affairs

SUBJECT: Secretary Espy's Health Care Activities

Just recently Secretary Espy began to focus on health care. Three weeks ago Greg Lawler, Larry Levitt and Bob Van Hook briefed the Secretary on the general policy and rural specific issues. Since then he has done one health care event: a visit to a rural Texas clinic with Cong. Laughlin. The event received good press coverage and Espy seemed comfortable with the topic.

Espy's staff is working closely with us and HHS on producing documents (i.e a rural health care pamphlet), writing op-ed pieces and reaching out to the rural community. USDA has more political appointees and resources in the states than any other agency. The missing piece has been a high (or mid) level of involvement by the Secretary.

To that end, it would be helpful if you could obtain a commitment from the Secretary to make health care a priority in the coming months. I have worked with Chris Jennings and Jack Lew to identify a number of targeted members that Espy could be effective in swaying. If he were to actively engage in the health care debate, both through travel and targeted media, it could make an appreciable difference.

January 23, 1994

NOTE TO CHRIS JENNINGS

From Bob Van Hook

The briefing on January 24 with the staff of the Senate Committee on Indian Affairs went reasonably well, but they were somewhat skeptical about our ability to deliver the comprehensive benefit package for Indian people through programs of the IHS on a timely basis.

As states come on line with health care reform, the IHS programs will need to begin to offer the comprehensive benefit package. If they wait until they are required to assure the benefit package in 1999, Indian people have inferior coverage in the interim between the time the states come on line and 1999. In addition, if the IHS programs do not offer the entire benefit package in reformed states, they will place themselves at a serious enrollment disadvantage in the long run.

I think we are headed for a political explosion when they put together:

- our large fy1995 budget cuts for IHS;
- the very significant staffing reductions under Reorganizing Government; and
- the funding offsets (which may be unrealistic considering that a significant portion of their benefit package funding will come from appropriations).

It is likely that Congress and various Indian constituencies are going to be angry when they try to reconcile these cuts with their (and our) perception of the IHS's immediate needs for startup funding to get the local units up to speed and able to deliver the full benefit package.

This is an instance where good budget politics does not necessarily make good health reform politics. We could be accused of being less than honest about our commitment to Indians, and I think our critics would have a lot to stand behind. Someone needs to get to OMB and consider a change in our budget positions.

The other major concern of the staff of the Committee was that the Act does not clearly spell out the way the IHS plan will work. This, they report, increases the distrust of Indian people and hence, the people who represent them.

cc: Phil Lee
Judy Feder

**ANSWERS TO QUESTIONS FROM THE COMMITTEE
ON THE TREATMENT OF INDIANS IN THE HEALTH SECURITY ACT**

1. Question:

Subtitle D of Title VIII of the Act addresses the provisions of health care services to American Indians and Alaska Natives (AI/AN) who are currently eligible to receive health care services from the Indian Health Service (IHS), however the subtitle does not address whether the IHS will be considered to be a regional health alliance or a health care provider. Which is it? How will this work? ((The attached questions from the Committee elaborate on this question.))

Answer:

Indians receive special treatment under the Health Security Act in recognition of the historic government-to-government relationships between the Federal government and tribes.

- AI/ANs currently eligible for IHS programs under the Indian Health Care Improvement Act and Indians in an area served by an Urban Indian program are eligible for special treatment based on their status as AI/ANs. These eligible Indians will be able to choose to enroll with a program of the Indian Health Service (IHS) or with an alliance health plan. Indians enrolling with a program of the IHS will not be required to go through an alliance.
- Programs of the IHS may be those run by the IHS, tribal governments, or urban Indian health programs (I/T/U). Each of these programs is considered a health plan-like entity, responsible for assuring to enrollees the availability of services guaranteed under the comprehensive benefit package.
- I/T/U programs are not expected to deliver all comprehensive benefit package services directly, rather many services will be purchased from other providers under contract, especially in smaller, more isolated programs.
- I/T/U programs will be certified by the Secretary according to health plan certification criteria the Secretary deems relevant to these programs to assure the scope and quality of services and the stability of the program. I/T/U programs normally will not be certified by States. The exception is if a tribal contractor under P.L. 638 decides to compete as a health plan within a regional alliance, in which case it must be certified by the State.
- The IHS will not be designated as an alliance, rather it will provide technical and organizational assistance to local I/T/U programs to help them arrange for services not

directly available through the local program. Where the IHS directly operates health care programs, it will be considered a health care provider.

- Non-Indian family members of eligible Indians enrolling with a program of the IHS would enroll with the I/T/U program which would certify the enrollment to the appropriate regional alliance for premium payment to the I/T/U program.
- All I/T/U programs may elect to be automatically certified as essential community providers (ECP). As an ECP, all health plans in the area would be required to contract with them, if the ECP wishes. The decision to provide services to non-Indian people resides with the I/T/U program, presumably in consultation with the appropriate tribal government as provided in the Indian Health Care Improvement Act. The only instance envisioned in which an I/T/U program would not be paid by an alliance health plan is when the program, itself, decided it not to provide services to non-Indian people because it could not provide such service without diminishing services to enrolled Indians.
- Indians enrolling with a program of the IHS will pay no cost sharing regardless of whether the service is provided by an IHS or non-IHS provider.

2. Question:

If there are no IHS facilities in an area, is it anticipated that Indian patients would receive care from a non-IHS provider at no cost to the patient, as if the health care service had been provided by the IHS?

- If there is no I/T/U program geographically available to an otherwise eligible Indian, he/she must enroll in an alliance health plan and will be responsible for all appropriate cost sharing. The exemption from cost sharing is only available to Indians enrolling with a program of the IHS.
- It is anticipated that I/T/U programs will establish enrollment guidelines that will restrict enrollment to Indians (and possibly their families) that live near their facilities.
- Programs of the IHS will develop arrangements to provide all benefit package services either through I/T/U facilities or through outside providers. Indians enrolling in IHS plans will receive all services in the comprehensive benefit package without charge, regardless of who provides the service.

3. Question:

The Health Security Act contemplates that each family will elect to participate in a regional health alliance, and that the election applies to or includes all family members. The Act provides that those AI/ANs who are currently eligible to receive health care services from the IHS would continue to receive care from the IHS. However, it is not uncommon that not all members of an AI/AN family are eligible to receive IHS care. In those instances in which not all members of an AI/AN family are eligible for IHS care, is it anticipated that a family regional health alliance election by non-IHS eligible family members would be binding on IHS-eligible family members?

Answer:

Under the Health Security Act, eligible Indians will be treated as if they were a families, i.e., they may enroll separately, even if their families choose to enroll in either a regional alliance health plan or an IHS program.

Additional (TOUGH) questions from the Committee briefing on Jan. 23 (NOT CLEARED WITH THE WHITE HOUSE):

Question:

What happens if an IHS plan is competing with other providers and loses? Does the IHS plan go out of business?

Answer:

This is a pretty hypothetical question. Our working assumptions are that approximately 85 percent or more of eligible Indians will enroll with an IHS program rather than a health plan offered through an alliance. This is primarily because of the absence of enrollee cost with the IHS program, and because in many areas, the IHS program is the only convenient alternative.

If, however, the local Indian people choose not to enroll in their local program, the IHS program could either open its enrollment to non-Indian populations or shrink its services to fit its means.

If an Indian program chooses to compete as a health plan in a regional alliance and fails, the Indian part of the plan would remain supported by the normal funding arrangements.

Question:

Given the current IHS system, won't there need to be a massive infusion of resources to get the IHS facilities up to the level to be able to provide the comprehensive benefit package? Are there projections of these costs? Are there projections by local units?

Answer:

It is important to remember that assuring access to the comprehensive benefit package is not the same as assuring that each program can provide the full range of services directly. We envision that most Indian programs will contract-out for most of the benefit package services.

Nevertheless, we recognize that some Indian facilities will need upgrading to meet the challenges of the Health Security Act. Therefore, we have included an authorization for funding facility construction and renovation during the first 5 years of reform (FY1996-2000). In addition, the Act authorizes a new revolving loan fund which could be used to help Indian programs prepare for assuring the full benefit package.

Obviously, all of the implementation issues have not been fully

addressed, and we will need to explore more fully the scope of facility and other needs.

Question:

What happens if a State is on a fast track to implement health care reform and is ready to provide the comprehensive benefit package before the IHS programs in the State are? Can an Indian enroll in both? Could someone start in the health alliance and switch to the IHS later?

Answer:

Our working assumption is that the IHS would work to bring the Indian programs in the fast-track States on-line with health reform first, and that the programs would be able to assure the comprehensive benefit package for AI/ANs when the States are ready for reform.

If by chance the Indian program were not ready when the State came on line, the Indian people would have a choice of enrolling with an alliance health plan or continuing to receive services through the Indian health program until it could assure the full benefit package.

Switching plans is possible for Indians and non-Indians alike under the Health Security Act.

Question:

Isn't there a disconnect between, on the one hand, the FY 1995 budget deficit reduction initiatives, the Downsizing Government" plan which would eliminate about 1,000 FTEs from the IHS, and the IHS program reductions through "offsets," and on the other hand the build-up that would be necessary for the IHS to provide the full benefit package by (at the latest) January 1, 1999?

Answer:

Fluff, fluff, fluff.... but, Yes.

Question:

Congress has never appropriated enough funds for Indian health, even to fulfill current obligations under the Indian Health Care Improvement Act. Are we then raising unrealistic expectations in the Health Security Act? Is the Administration prepared to ask Congress for all the funds it needs to get Indian programs up to speed and maintain them once they are operational?

Answer:

The Health Security Act will bring several new funding streams into Indian programs that are not dependent on the Federal budgetary process. For example, employers will make premium payments through health alliances for Indians enrolled in IHS programs. Also, the Secretary will make payments to Indian programs from capped entitlement funds equivalent to the amount of premium discounts for which low-income, non-employed Indians would otherwise have been eligible.

As we move into the implementation phase of health care reform, we will begin to have a clearer picture of the funding needs to develop the capacity of Indian programs to assure the benefit package. In fact, we are already beginning some pre-implementation planning. When we determine the precise degree of needs, we will advise Congress of any additional requirements to assure that this important population is not disadvantaged.

Question:

What is the meaning of Section 8307 that reaffirms that the IHS is the payer of last resort for Indians eligible for contract health services under a program of the IHS? Does this mean that Indians will have to satisfy all of the requirements of other health programs before they are eligible for coverage of benefit package services under health care reform?

Answer:

The intent of this section is to assure that the IHS not be required to pay for services for which other programs should pay. For example, the Medicare program will continue outside of health care reform, and it is expected that Medicare will be billed before the IHS is required to pay for the service.

Obviously, this provision does not change the other provisions in the Act which allow an Indian to enroll with a program of the IHS and receive full benefit package services from the program. Only if the Indian person has another type of coverage would the "payer of last resort" provision come into play.