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THE ROLE OF THE NIH IN IMPROVING PUBLIC HEALTH

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It is an honour and personal pleasure to participate in this Symposium celebrating the 50th anniversary of the Istituto Superiore di Sanità. On behalf of the U.S. National Institutes of Health, I salute you on this auspicious occasion. There are close ties between the National Institutes of Health and the Italian scientific community, and especially this institution. Professor Pocchiari is a frequent visitor to our offices and laboratories in Bethesda.

We have a large community of Italian scientists collaborating with American investigators in our intramural research programs at NIH. Currently, more than 150 scientists from Italy are working with our scientists in Bethesda. The Italian contingent of guest worker/scientists is the second largest group of foreign nationals participating in research at NIH. Some of them have worked so long and closely with our researchers that we no longer consider them as guests. The distinguished Fogarty scholar, Gaetano Salvatore, has been collaborating with NIH scientists since 1960. Another visiting scientist that we consider one of us is Dr. Salvatore Aloj.

I should also mention that among the scientists who have taken part in our visiting program is Maurizio Pocchiari, son of our host, Professor Pocchiari. The young Dr. Pocchiari was a visiting fellow from October 1, 1980 to September 30, 1983, when he worked with one of our most distinguished scientists, Dr. Clarence Gibbs, Jr., in our Laboratory of Central Nervous System Studies.

As I have learned more about the Istituto, I have been impressed by the ways in which your organization resembles the National Institutes of Health and also how it differs. I have been asked to talk about the NIH and how it fulfills its role in improving public health. I will emphasize some of the traditional concepts of public health, but in doing so, I wish to stress our belief that the most important contribution we can make to public health is through creative research investigation, carried out under the most rigorous standards of excellence.

In one of the administrative publications issued by the National Institutes of Health, the role of the Agency is described in one sentence. The mission of the NIH, briefly stated, "is to uncover new knowledge that will lead to better health for everyone". This characterization correctly identifies research as the central concern of the NIH. It also strongly suggests that improvements in public health are dependent upon new findings from research.

As the principal biomedical research agency of the United States government, the National Institutes of Health conducts or directly supports over 36% of all health–related research in our country. Last year, our one Agency expended roughly the same amount for research as was spent by all of private industry in our country for biomedical research studies.

About 80% of the current NIH annual budget of $4.5 billion dollars is used for the support of research and research training in academic institutions, hospitals, and nongovernmental laboratories throughout the United States and worldwide.

A substantial amount of the funds awarded by the NIH to "outside" organizations is in the form of grants made in response to proposals initiated by individual scientists. In fact, more than one half of our Agency's total budget is allocated to the support of such investigator–initiated research projects. We believe that this nondirective approach to funding research is the most effective means for drawing out from our scientific community the most innovative and useful ideas. At the same time, since most of the research investigators we support are affiliated with universities or academic medical centers, an important dividend of the NIH program is to strengthen the academic environment. We refer to our relationship with academic institutions as a partnership. It is a mutually beneficial partnership that is an important resource for the academic institution and, furthermore, we consider the association to be essential to the NIH if we are to succeed in our mission to improve health by uncovering new knowledge.

More than one half of the total budget of the U.S. Public Health Service is allocated to the National Institutes of Health, a fact that indicates the status

accorded to research as an essential tool for the improvement of public health. In order to state more clearly what the NIH does, I will state what it does not do. The NIH is one of the five agencies of the United States Public Health Service (PHS). Each of the five has responsibility for a major aspect of the federal government's functions with respect to public health. For example, the activities of our sister agency, the Food and Drug Administration, are directed toward protecting the health of the nation against impure and unsafe foods, drugs, biological products, as well as cosmetics and other potential hazards. Another Public Health Service component, the Centers for Disease Control (CDC), is the federal agency charged with protecting the public health of the nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions. The CDC administers federal quarantine activities and regulations, licences clinical laboratories, and in carrying out its mission, maintains close working relationship with state and local health officials. Another agency of the Public Health Service, the Health Resources and Services Administration, is concerned with health care resources problems, their distribution, quality, and cost effectiveness. The Agency also is charged with providing leadership in the delivery of health services and has a variety of specific operational responsibilities as, for example, the Indian Health Service.

The PHS agency that most resembles the NIH is ADAMHA the Alcohol, Drug Abuse, and Mental Health Administration. This Agency, like NIH, conducts and supports research. It is also charged with providing leadership in the federal effort to reduce and eliminate health problems caused by the abuse of alcohol and drugs and to improve the mental health of the United States generally. Unlike the NIH, however, ADAMHA is substantially involved in providing health care, through regional and neighborhood clinics for subjects with alcohol, drug or mental health problems.

The operation of the NIH encompasses research in its broadest sense. It extends from the most basic studies in the realm of the molecular and cell biology to clinical trials of the safety and efficacy of new drugs and vaccines. The Agency conducts research in its own laboratories, supports research in non–federal laboratories, in universities, medical schools, hospitals and research institutions (more than 1,250) throughout the United States and abroad; it also helps in training of research investigators, and fosters and supports biomedical communications.

Currently, about 62% of NIH's research budget is devoted to studies classed as basic or fundamental. At the same time, however, throughout the Agency, there is a strong sense of the relevance of all research to public health. The name of our Agency is in itself an expression of that policy. We are not the "National Institutes of Biological Research" or the "National Institutes of Biological Science" but the National Institutes of Health.

The NIH administers a comprehensive research program that seeks to understand the nature of disease. The product of this research is essential knowledge about life, disease, and malfunction. The ultimate aim is to prevent disease and premature death and assure each person the maximum opportunity for a productive life free from disability. Prevention and health promotion programs can be as strong as the research base upon which they are founded. Therefore, it is particularly important to strengthen the scientific and technical base.

Each year, the NIH ascertains how much of its total budget is expended for prevention research. In the current year, our expenditures for activities defined as prevention research are in excess of one billion dollars. We define prevention research as that which is designed to yield results directly applicable to measures to prevent disease or the progression of presymptomatic disease. We also consider as prevention research those activities which have a high probability of yielding results that likely will be applicable to disease prevention or health promotion. Basic research efforts of this sort generate the fundamental knowledge that contributes to the development of future preventive interventions.

Such an effort by Dr. Robert Gallo and his associates of the National Cancer Institute recently yielded evidence that a variant of a human cancer virus called HTLV–III is the primary cause of acquired immune deficiency syndrome (AIDS). The scientists were able to isolate the HTLV–III viruses from infected persons; to develop a method for growing the viruses in T– cells in the laboratory in bulk amounts; and to characterize biochemically and immunologically the proteins and genes of the viruses.

It is now predicted that it soon will be possible to have the amounts of viral protein needed for large–scale screening of blood samples by blood banks and diagnostic laboratories. Rapid tests for antibodies to HTLV–III in human blood are already feasible. Scientists also foresee the possibility of the development of new ideas for treatment and the possibility of a vaccine for AIDS.

The developments regarding AIDS provide an example of the immediate relationship that can exist between the most advanced research and the development of an important public health measure, in this case, a large–scale method for screening as a means to prevent the transmission of AIDS through blood transfusion or blood products made from contaminated blood supplies.

Another recent development of consequence to public health was announced on March 30, when the results of tests with an experimental flu vaccine were published in *Lancet*. The new vaccine which contains live virus is given as nose drops. Studies of the level of immunity established in human

subjects suggest that the new vaccine developed through the National Institute of Allergy and Infectious Diseases will prevent the spread of the flu better than flu shots. Studies are underway to determine how long the new vaccine is protective and to learn its safety and effectiveness for people at high risk of serious complications from influenza.

Research of another sort, clinical trials conducted or supported by NIH, also plays a key role in making possible public health advances.

The National Heart, Lung, and Blood Institute recently concluded a multicenter, randomized clinical trial to determine the safety and effectiveness of administration prior to birth of a steroid drug, Dexamethesone, in preventing infant Respiratory Distress Syndrome (RDS), a risk for babies born prematurely before their lungs have sufficiently matured. In the study, mothers at high risk of premature delivery were administered the steroid 24 to 48 hours prior to delivery in an attempt to enhance lung maturation. At birth, premature female infants whose mothers received the drug, were four times less likely to develop RDS than those whose mothers were not. Male infants did not benefit from the treatment. The investigators reporting in the February 1984 issue of the *Journal of Pediatrics*, concluded that careful use of the steroid can be expected to become a part of the management of high–risk deliveries.

The results of another clinical trial conducted by the National Heart, Lung, and Blood Institute were announced on January 12. At that time, the findings of a major clinical trial showed for the first time that the reduction of elevated blood cholesterol results in a reduction in risk of heart attack. The ten–year trial was carried out in 12 clinical centers in the United States and Canada. A total of 3,806 men who were healthy except for elevated blood cholesterol concentrations were assigned randomly into two groups. Each group received instruction for a moderate cholesterol–reducing diet. One group was then administered a cholesterol–lowering drug (cholestyramine); the other group received a placebo. Compared with the placebo group, the drug–treated group experienced a 24% reduction in fatal heart attacks and 19% reduction in nonfatal heart attacks. The findings are expected to have a considerable impact on American medical practice.

I have given a few examples of the direct translation of research into applicable means for disease prevention. In recent years, the NIH has become involved in another type of public health activity – health promotion or health education programs. The outstanding example of such an effort at the NIH is the National High Blood Pressure Education Program.

An estimated 60 million Americans have high blood pressure that increases their risk of illness and premature death. Of these persons, 35 million need some form of continuing treatment – the remaining 25 million have borderline high blood pressure that requires medical surveillance. Untreated hypertension is the largest single contributor to stroke and a major contributor to heart disease and kidney failure.

The High Blood Pressure Education Program, started in 1972, has helped to improve hypertension control in the nation. With physicians and the public better informed about hypertension, patient visits and medication prescriptions for hypertension have increased, as has the number of persons whose hypertension is well controlled. Associated deaths, especially from stroke, have declined rapidly and dramatically since the education began and there has been a decrease in cardiovascular mortality in our country of over 40%. While a direct cause and effect relationship cannot be demonstrated, certainly it appears that this program has contributed substantially to gratifying progress in public health.

Another type of public education program was launched in March of this year by the National Cancer Institute. The program is a major federal effort to increase public awareness of the possibilities for cancer prevention. It presents a challenge to the American people to learn what they can do everyday to control their own cancer risks. It is a kind of second generation awareness program, partly designed to counter the public confusion and pessimism generated by earlier warnings against various cancer causes. An opinion survey, conducted last year by the Cancer Institute, revealed that many people believe, quite erroneously, that "everything causes cancer", and that there is not much a person can do to prevent it.

The new program will be based on the most recent scientific information related to cancer cause and prevention and will offer specific tips for individual action.

The high blood pressure and cancer awareness programs are relatively rare activities for the NIH. Most of our informational activities for the general public are not so highly structured and are mostly responsive in nature. Even so, the NIH provides a substantial amount of health–related information directly to the general public. Each year we receive 400,000-500,000 inquiries from members of the general public, either by mail or telephone. The NIH takes seriously its obligation to provide requested information to members of the public, and a large part of its annual expenditure of $7 million for printing and distributing publications is allocated to materials for the public inquirer. Over the past decade, the NIH has taken an increasingly active role in communicating the findings of research to the health professional community. Obviously the output of biomedical research, in terms of individual findings, covers a very broad spectrum, ranging from discoveries at the frontiers of biology to readily applicable means of disease prevention, diagnosis, or treatment. Each element in the array of findings is

useful either to the research scientist or to the clinician or to both. However, the busy practitioner would not only be inundated by the sheer volume, if the full output of published results were channeled to him or to her, but certainly would not have time to identify these findings which might be applicable to practice. For this reason, it is essential that there be a sorting out process and that communications efforts be concentrated on the relatively small portion of current research output that is ready for use by the health professional in patient care. There are many channels of communications with the practitioner, some are highly structured others are patterns of custom.

Academic health centers are key communicators. They take seriously their responsibility for the continuing education of their own graduated and, in many instances, for health professionals practicing in their geographic area. Specialty and professional organizations support many individual programs of continuing education as well.

The NIH now engages in the very considerable amount of direct communication with practicing health professionals. During the average year, it sponsors about 100 seminars and other meetings for practicing physicians which in the aggregate are attended by perhaps as many as 10,000 doctors. In a typical year, the NIH responds to more than 80,000 inquiries from physicians, either by mail or telephone, and prepares more than 170 different publications for the use of physicians. In addition, the NIH publishes some 135 different informational brochures for the physicians to use in patient education. Three–quarters of a million copies of such publications are distributed upon request to practitioners in a normal year.

The National Cancer Institute supports 20 comprehensive cancer centers scattered throughout the nation which exert a significant impact through effective cancer control, demonstration and outreach programs. These centers are focal points for community efforts to assure widespread use of the best available methods for early detection and diagnosis of cancer and dissemination both at the lay and professional levels. The centers are designed to be places to which individuals and their physicians can turn for information, help and advice.

In addition, the multidisciplinary general clinical research centers supported by the NIH at 75 medical centers have served as demonstration and communication centers for more than two decades.

In 1978, the NIH Director created a new unit in the central administration charged with improving the transfer of research findings from the laboratory to their application in the diagnosis, prevention, or treatment of disease. In carrying out its charge, the newly established office of medical applications of research began by launching a novel activity called the Consensus Development Conference.

The Consensus Development Conference provides a neutral forum for a thorough public discussion of the scientific pros and cons of new modes of treatment or preventive measures as well as of long–established practices about which doubt or question may have arisen. Over 40 such conferences have been held; at each, a consensus panel of experts in the relevant disciplines, usually including lawyers, ethicists and others with direct interest in the problem under discussion, sit as a kind of jury. They hear statements from responsible spokespersons representing differing points of view on the subject under discussion. Usually the testimony lasts for two days, following which the panel attempts to develop a statement of consensus on the question under discussion.

The first consensus conference addressed a question that had been raised about the risks versus benefits of mass screening of all women for breast cancer, using X–ray. Did the benefits of such diagnostic screening outweigh the potential of adverse effects from ionizing radiation? In this instance, the consensus panel included not only leading oncologists and surgeons but also psychologists, attorneys, clergymen, and representatives of women's groups. The panel recommended that women under 50 not be subjected to X–ray screening in the absence of certain predisposing factors. Although the consensus statements have no effect as regulation, it is obvious that they would be regarded as important.

Recent conferences have covered such diverse subjects as "Dental sealants in the treatment of tooth decay"; "Hip joint replacement"; "The use of estrogen therapy to prevent or retard osteoporosis"; and "Uses of ultrasound imaging in pregnancy".

Results of the consensus conferences are published in the *Journal of the American Medical Association* as well as other medical journals. Copies of the consensus statements are mailed promptly to some 22,000 physicians nationwide who have asked to be given such information. The primary purpose of the consensus conference is to aid in the transfer of research–derived information to the practicing health professional, but there has also been substantial public interest in this activity. It is not unusual to have 30 newspaper, magazine, and television reporters present at the announcement of the panel's consensus statement. At one recent conference, 60 reporters attended the briefing at the end of the conference.

Lastly, I will mention a highly important and unique component of the National Institutes of Health that constitutes a critical instrument for improving public health: the National Library of Medicine. The Library collects, organizes, and makes available biomedical information to investigators, educators and practitioners and carries out programs designed to strengthen medical library services in the United States and in other countries. As the central resource of the existing national biomedical information system, it is essential element in the public health establishment in our country. The Library's comprehensive collections and in-

formation services at its main headquarters on the NIH campus in Bethesda are used extensively by health professionals and health science students. But more importantly, the NLM serves as a national resource for all U.S. health science libraries. Lending of books and other services are provided through a regional medical library network serving well over 2,000 hospital and medical school libraries.

The Library's computer based medical literature and analysis retrieval system (MEDLARS) was established to permit health professionals, throughout the nation and in many parts of the world, to achieve rapid access to NLM's vast store of biomedical information. The Istituto Superiore di Sanità is directly connected with the National Library of Medicine and acts as the hub for some 40 MEDLARS terminals serving the scientific community throughout Italy.

In closing, permit me to reemphasize my earlier statements about the dependence of successful public health programs upon the knowledge base that can be produced only through active research. As you begin the second half-century of the life of this important Institution, I would urge that you continue to foster the spirit of inquiry and that the maximum feasible investment of human and other resources be devoted to the search for indispensable knowledge.