

# II.

## Office of the Director National Institutes of Health

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### INTRODUCTION

The Director of the National Institutes of Health (NIH) provides overall leadership for NIH activities. He maintains close liaison with the Office of the Secretary, U.S. Department of Health and Human Services (DHHS), in matters relating to medical research, research training, education and training in the health professions, human resources, and biomedical communications. The Director also works closely with other DHHS officials to coordinate programs.

The Office of the Director comprises the following positions: a Deputy Director; Deputy Directors for Extramural Research, Intramural Research, and Management; and Associate Directors for Intramural Affairs, Administration, AIDS (acquired immunodeficiency syndrome) Research, Communications, Research on Women's Health, Research on Minority Health, Disease Prevention, Legislative Policy Analysis and Development, Behavioral and Social Sciences Research, Protection From Research Risks, and Science Policy and Technology Transfer.

NIH Director Dr. Harold Varmus and members of his staff represent the NIH by participating in meetings with officials of foreign governments and in international conferences. During fiscal year 1999 (FY 99), the Director participated in several international meetings, including the MIM (Multilateral Initiative on Malaria) Conference, in Durban, South Africa, on March 12, 1999.

### OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) is responsible for coordinating NIH research efforts and related activities relevant to AIDS and the human immunodeficiency virus (HIV), which causes AIDS. For international activities related to AIDS research, OAR collaborates with the NIH Institutes and Centers that support and conduct such research, other organizations in the U.S. Public Health Service and DHHS, and other governmental and nongovernmental organizations. Spe-

cific efforts are described in the chapters for the individual Institutes and Centers.

OAR supports activities (a) that will help to stimulate collaborative AIDS-related research efforts between U.S. investigators and investigators in other countries and (b) that will facilitate access by foreign investigators and care providers to state-of-the-science technical information and information about the clinical management of HIV-infected patients. In addition, OAR staff meet with delegations and individual scientists, officials, and program staff working in AIDS-related prevention programs in other countries, to facilitate a broad understanding of the NIH AIDS-related research programs.

### Highlights of International Activities

OAR continues to support forums for researchers, scientists, and health care administrators in developed and developing countries to meet and exchange information. In collaboration with the International AIDS Society and the American Foundation for AIDS Research, the Canadian Association for HIV Research and OAR cosponsored the 2nd Conference on Global Strategies for the Prevention of HIV Transmission From Mothers to Infants, in Montreal, Quebec, on September 1-6, 1999. The conference included presentations of the most recent scientific information on mother-to-child transmission of HIV and on issues of the highest priority for developing safe, effective, and economical intervention strategies. Workshops addressed specific scientific, clinical, and logistic issues, emphasizing the needs of developing countries. The conference also addressed the growing number of children, some with HIV, who now comprise the orphan crisis caused by the death of parents with AIDS.

OAR represented the NIH at the meeting of the Joint United Nations Program on HIV/AIDS (UNAIDS), entitled Care Within the Context of HIV/AIDS-Related Research in Developing Countries. The meeting was

convened in Geneva, Switzerland, on May 26-28, 1999. The purpose was to bring international scientists, industry, and community representatives together to address critical scientific, socioeconomic, bioethical, and cultural issues associated with the conduct of HIV-related research in developed and developing nations.

### Summary of International Programs and Activities

#### Extramural Programs

OAR does not award grants or contracts in direct support of specific AIDS research projects, but OAR funds may be provided to NIH Institutes and Centers that identify promising opportunities or critical research needs. In FY 99, funds were used to support several such activities through the NIH Institutes and Centers.

The AIDS epidemic continues to escalate in Russia and other countries of Eastern Europe. Building on former research infrastructure in Russia, OAR provided funds through the Fogarty International Center's AIDS International Training and Research Program (AITRP) to accelerate the development of qualitative and quantitative immunologic laboratory capabilities in Russia, in preparation for future research on HIV vaccines.

The HIV Prevention Science Initiative (PSI) is part of OAR's continuing efforts to stimulate a comprehensive HIV prevention program at the NIH. Through the NIH Institutes and Centers, this initiative supports meritorious new grants, supplements to existing grants, and meetings, conferences, and workshops that address one or more of the defined priorities of PSI. The priorities for FY 99, beginning with the primary priority, were as follows:

- HIV prevention among racial and ethnic minorities;
- the relationship between biological and behavioral outcomes;
- sustainability of HIV-prevention efforts;

- international HIV-prevention research;
- legal, ethical, and policy issues in HIV prevention; and

- primary prevention for men who have sexual relations with women.

The 10 PSI projects described here address the priority for international HIV-prevention research.

In an extensive international research program conducted in collaboration with Brazil, investigators at Columbia University, New York, New York, are using combination therapy for prevention of HIV and sexually transmitted disease (STD). A new component of this study will examine experiences with medication adherence. The use of combination antiviral therapies is beginning to spread into the developing world, and little is known about the factors that affect adherence to treatment or the behavioral consequences of these therapies in such settings. The study will combine clinic observations, surveys, focus groups, and interviews with providers, patients, and policy makers in Rio de Janeiro and Porto Alegre.

Researchers at the University of California, San Francisco, will focus on the epidemiology of incident HIV infection in relation to variant and drug-resistant strains of HIV in Santos, Brazil. The ability to monitor the HIV epidemic has been severely hampered by the difficulty in measuring HIV incidence. The aims of this study are to determine (1) the incidence of HIV infection among clients using HIV counseling and testing services; (2) the frequency of infection with non-B subtypes of HIV; (3) the frequency of antiretroviral-drug-resistant subtypes present in recently HIV-infected persons; and (4) the behavioral and social factors associated with transmission of drug-resistant HIV subtypes.

Supplemental funds provided through AITRP will support awards to several domestic institutions for training of predoctoral and postdoctoral researchers, including medical students and residents. This initiative will focus on China and India, where the HIV epidemic is spreading rapidly. In addition to providing training opportunities, it will facilitate future international research on prevention of HIV in these countries.

Investigators at Syracuse University, New York, will explore methods to reduce risk of HIV among psychiatric patients in Banga-

lore, India. Qualitative research on adults with a diagnosis of severe and persistent mental illness (SPMI) is expected to determine the prevalence and correlates of HIV risk behavior among adults admitted to short-term treatment for SPMI. The investigators will evaluate the effectiveness of a theory-based intervention to reduce HIV risk for adults living with SPMI. The ultimate goal is to understand the context of risky sexual behavior in this population, in an effort to develop an intervention that can be implemented with psychiatric patients in India.

A study of social interactions and reproductive health at the University of Pennsylvania, Philadelphia, will examine the links between social interactions in networks and the diffusion processes involved in forming and changing AIDS-related attitudes and behavior in two countries in sub-Saharan Africa, Kenya and Malawi. The investigators will determine how network characteristics and the nature of social interactions in networks influence behavior, attitudes, and values in two related areas—AIDS and fertility.

The goal of a study at the University of Puerto Rico, San Juan, is to explore the role of male partners in interventions that emerge from the perspective of empowerment for the prevention of HIV/AIDS among heterosexual women. The research will examine the issue in three different settings, in the Dominican Republic, Mexico, and Puerto Rico.

Research on enteric infections in HIV-positive and HIV-negative African children and the efficacy of treatment with micronutrient supplementation will be conducted at New England Medical Center Hospital, Boston, Massachusetts. Enteric infections remain a leading cause of childhood mortality in developing countries. In regions where HIV infection is prevalent, enteric infections and persistent diarrhea have even greater effects on public health. This study will identify specific enteric pathogens associated with persistent diarrhea in HIV-positive and HIV-negative children in rural South Africa. The investigators will then determine the efficacy of two low-cost micronutrient supplements in the improvement of gut integrity in these populations.

A program of training and monitoring to improve case management for STDs in primary health care clinics will be initiated by

investigators at Columbia University, New York. This program will train nurses working in primary health care clinics in Durban and Hlabisa, South Africa, in this area of STD case management. The workshops for nurses will include education and training in public health measures to control STDs; the importance and epidemiology of STDs, including HIV; interaction between treatable STDs and HIV; history taking and diagnostic skills; counseling, including extensive counseling skills related to HIV; empathy and listening skills; methods of promoting use of condoms; development of patient-oriented service; and the importance of surveillance and monitoring.

Researchers at Columbia University will extend the recent study of STD control to prevent AIDS in Rakai, Uganda. The earlier study demonstrated an association between STDs and incident HIV infection in individuals, an observation compatible with results of other studies. There was, however, no observed effect of STD mass treatment on HIV incidence at the population level or in subgroups that showed a significant reduction in treatable STDs. The new study will address four questions:

1. What proportion of HIV seroconversions were attributable to curable STDs and what proportion to incurable STDs and genital tract conditions?

2. Would more frequent treatment of STDs at the community level result in lower STD prevalence?

3. Is a combination of mass treatment and symptom-based clinical services likely to have a sustainable effect on STD prevalence?

4. Are some STDs and genital tract conditions associated with higher risk of vertical HIV transmission?

The Center for AIDS Prevention Studies at the University of California, San Francisco, and the University of Zimbabwe, Harare, will collaborate to examine HIV risk behavior among men in Zimbabwe. The investigators will study 3,000 patrons of beer halls, to obtain information for the design of HIV prevention strategies for this population. Municipal beer halls are a major feature in the social life of men living in Harare and are a setting associated with high rates of HIV transmission.

### **International Meetings**

In FY 99, OAR cosponsored three interna-

tional meetings and workshops. The 11th Joint Meeting of the AIDS Panels of the U.S.-Japan Cooperative Medical Science Program was held in Toyama, Japan, on March 17-19, 1999. The purpose of these yearly meetings is to enhance collaborations between U.S. researchers and their Japanese colleagues. The meeting program highlighted collaborative efforts between U.S. and Japanese researchers in a variety of scientific disciplines related to HIV/AIDS.

OAR sponsored a workshop entitled Integrated Training for Community Based Health Care Workers, in Nairobi, Kenya, on June 1-5, 1999. The purpose of the workshop was to make new information available to providers of health care and other services, so they can provide better care for patients and clients. The goal of the training was to help translate research findings to improve health care in developing countries. Workshop topics covered the status of the epidemic in Africa; vulnerability of women to infection; treatment of STDs and other factors associated with HIV transmission; vaccine development; nutritional interventions; psychosocial factors; clinical management of patients; legal and ethical issues; community mobilization for HIV prevention and control; special needs of AIDS orphans; and access to up-to-date information. More than 130 participants from urban and rural areas of Kenya, Tanzania, and Uganda attended the meeting. Participants worked in small groups to assimilate research information and discuss how to apply it within the settings of their various care and service projects.

In addition, OAR cosponsored the Global Research Network Meeting on HIV Prevention in Drug Using Populations, in Atlanta, Georgia, on August 26-28, 1999. Cosponsors were the National Institute on Drug Abuse (NIDA); the Centers for Disease Control and Prevention (CDC); Health Canada; UNAIDS; and the World Health Organization (WHO) Program on Substance Abuse. The meeting provided an opportunity (1) to identify emerging issues in the AIDS epidemic with implications for prevention of HIV, hepatitis B, and hepatitis C; (2) to discuss the nature, status, and effectiveness of HIV prevention efforts among injecting drug users in different countries; and (3) to increase research capacity through collaborative efforts nationally and internationally.

## **OFFICE OF RESEARCH ON WOMEN'S HEALTH**

The Office of Research on Women's Health (ORWH) was established in September 1990, within the Office of the Director of NIH, to serve as the focal point for research on women's health. The Office has the following mandate:

- to strengthen, develop, and increase research for diseases, disorders, and conditions that affect women and to determine gaps in knowledge about such conditions and diseases;

- to ensure that women are appropriately represented in biomedical and biobehavioral research studies, especially in clinical trials supported by the NIH; and

- to develop opportunities and support for recruitment, retention, reentry, and advancement of women in biomedical careers.

ORWH works in partnership with the NIH Institutes and Centers to ensure that research on women's health is an integral part of the scientific fabric at the NIH and throughout the scientific community.

Research on women's health is a global concern, and ORWH has worked with investigators, health care providers, and women's health advocates around the world on studies and activities to improve the health of women. ORWH has cosponsored international conferences, and staff members have made presentations at scientific meetings abroad. ORWH staff have also provided information about policies and programs on women's health research at the NIH to colleagues from other countries, including Australia, Austria, Belgium, Canada, Denmark, Germany, Israel, Italy, Mexico, and Slovenia.

The Medical Advisor to the Director of ORWH made a presentation at the 2nd Congress on Psychiatric Diseases in Women, which was held at the University of Vienna, Austria, on November 12-14, 1998, under the auspices of the World Psychiatric Association. The presentation was entitled Drug Addiction in Women: Overview and Practical Guidelines.

The Director of Programs and Management served on the Public Health Service's U.S.-Israel Planning and Steering Committee for Women's Health, of the Joint U.S.-Israeli Conference on Women's Health: Promoting Health Across the Generations. The conference was convened by the U.S. Secretary of

Health and Human Services, Donna Shalala, with Israeli Minister of Health, Yeshoua Matza. The Director continues as a liaison with Israeli delegates on issues regarding research on women's health. The Director of ORWH and the Director of Programs and Management attended the conference, which was held in Jerusalem, Israel, on December 1-3, 1998. This conference enabled the exchange of information on a range of global health topics covering the life span of women. Information was presented on each country's programs and policies, and the meeting provided an opportunity for participants to identify shared interests and activities, examine health challenges for women, and highlight future opportunities for mutual advancement of women's health. Broad priority areas and strategies to improve the health of women in Israel and the United States were identified. Welcoming remarks, which provided valuable information on the NIH programs and policies for research on women's health, were delivered by the Director of ORWH on behalf of the NIH.

An International Women's Health Conference, on Crossing Borders into the 21st Century, was held in Iowa City, Iowa, on March 1, 1999. The Director of ORWH presented the NIH Research Agenda for the 21st Century. The purpose of this conference was to present multidisciplinary views of global and women's health issues to a diverse audience of practitioners, researchers, and students. The information provided participants with the knowledge to expand research and clinical initiatives in gender-specific medicine, as well as international and interdisciplinary research in women's health.

ORWH, in conjunction with the National Institute on Aging (NIA) and the SPRY (Setting Priorities for Retirement Years) Foundation, funded the Conference on Older Adults, Health Information, and the World Wide Web, which was held at the NIH Natcher Center, in March 1999. The conference was attended by 333 participants from Canada, Europe, and the United States, including 27 exhibitors providing hands-on experience with Web sites that are user friendly for older adults. The participants represented a diversified group of researchers; managers of Web sites; hardware and software manufacturers; local area agen-

cies on aging; and others seeking new information on how to increase older adult's access to new information via the Internet and the Web. The Director of Programs and Management represented ORWH at this conference.

The Medical Advisor to the Director of ORWH gave a presentation entitled A New Era in Women's Health, at the 4th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research, in Crystal City, Virginia, on May 25, 1999. This presentation was part of a workshop that provided an overview of the field of women's health research and ways in which gender can be incorporated into general research on outcomes, particularly for clinical trials.

In Indianapolis, Indiana, the Director of ORWH provided the keynote address on the Agenda for Women's Health as a Model for International Application, at the 10th International Conference on Women's Health Issues, on June 19, 1999. The International Council on Women's Health Issues is a non-profit association dedicated to promoting the health, health care, and well-being of women throughout the world through participation, empowerment, advocacy, education, and research. The council's membership comprises a multidisciplinary network of women's health providers, planners, and advocates from all over the globe. The membership constitutes an international professional and lay network of those committed to improving women's health and quality of life. Through its commitment to improving the health and well-being of women worldwide, the Council on Women's Health Issues is dedicated to the following objectives:

- exploring the biological, socioeconomic, cultural, political, and spiritual factors affecting the health and development of women over the life span;
- examining the reciprocal relationships between and among cultural and social structural dimensions that influence the health and well-being of women;
- identifying areas of need and facilitating, implementing, and evaluating solutions to potential and actual health problems of women of all ages;
- encouraging a multidisciplinary and multisectorial approach to promoting women's health and well-being;

- promoting and supporting women's health research; and

- influencing policy related to women's health worldwide.

The Medical Advisor to the Director of ORWH developed and chaired two symposia on perinatal drug dependence and fetal and child outcomes at the annual scientific meeting of the College on Problems of Drug Dependence, in Acapulco, Mexico, on June 14–17, 1999. The college, which is partially funded through conference grants from NIDA, is dedicated to promulgating the most recent research in the field of drug dependence, through plenary sessions, symposia on specific issues, poster sessions, and selected invited oral presentations.

ORWH cooperated with NIA, the National Institute of Child Health and Human Development (NICHD), the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Heart, Lung, and Blood Institute (NHLBI) to cofund and participate in the International Conference on Fetal Origins of Adult Disease. The conference was held in Rockville, Maryland, on September 2, 1999. Specific adult diseases and their potential relationship to fetal origins were discussed. The Director of ORWH provided remarks, which included the commitment to this innovative area of research as a facet of the research agenda for women's health for the 21st century.

## **OFFICE OF RESEARCH ON MINORITY HEALTH**

With a focus on addressing and eliminating health disparities in minority populations, the Office of Research on Minority Health (ORMH) was established within the Office of the Director of NIH, to serve as the focal point for NIH-supported research on minority health and research training. Minorities at all stages of life have poorer health and higher rates of premature death than the majority groups in the United States. For diseases such as asthma and AIDS, the information base on why minority populations are the hardest hit is well established; less is known about how to reduce the disproportionate burden of these illnesses. For other health conditions, such as lupus and certain cancers, the reasons for higher incidence in minorities are still unclear. Historically, the 1985 report of the Secretary's Task Force on Black and Minority Health (the

Heckler report) identified six causes of death that collectively accounted for more than 80% of the excess mortality among minority groups in the United States. These causes of death were cancer; cardiovascular and cerebrovascular diseases; dependency on alcohol, tobacco, or drugs; diabetes mellitus; homicide and accidents (unintentional injuries); and infant mortality.

ORMH has a twofold mission: extending healthy life and reducing the burden of illness among minorities through targeted research and expanding the participation of underrepresented minorities in all phases of biomedical and behavioral research. Accordingly, ORMH is responsible (1) for stimulating new research ideas to improve the health status of minority groups in the United States across the life span and (2) for promoting programs aimed at expanding the participation of underrepresented minorities in all aspects of biomedical and biobehavioral research.

The field of minority health and training addresses a broad range of issues, including the following:

- educating minority communities about important NIH policies and programs;
- conducting technical assistance workshops;
- supporting national conferences on minority health issues; and
- supporting the NIH minority research supplement programs.

ORMH promotes health research and training primarily through the Minority Health Initiative (MHI), a comprehensive program with the aims of (1) developing and testing interventions that will reduce the disproportionate burden of disease among minority populations and (2) creating successful strategies to promote healthy behaviors across the life span. MHI sponsors and cosponsors training initiatives that focus on research training across the educational pipeline, to ensure the representation of minorities in careers related to health research. MHI is administered by ORMH and implemented in collaboration with the NIH Institutes and Centers.

## **International Activities**

In collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), ORMH continues to support the Minority Training Program in Tropical Medicine at

the Malaria Research and Training Center, at the University of Mali, Bamako, which is sponsored by the University of Maryland, Baltimore. In this program, advanced undergraduates and senior medical students from U.S. universities are able to receive first-hand experience in Africa in short-term rotations at the malaria laboratory and in field research, as well as in clinical work—all at the NIH-supported Malaria Research and Training Center established by the University of Mali and the University of Maryland Medical School. The program aims to encourage participants to develop biomedical research careers in infectious and tropical diseases.

The Fogarty International Center and ORMH have jointly supported the Minority International Research Training (MIRT) program since 1993. The program offers opportunities in international research training to qualified minority undergraduates and graduate and medical students, who are underrepresented in biomedical and behavioral research careers. The MIRT program aims to (1) increase awareness of international research issues and opportunities, (2) acquaint students with a range of career opportunities in biomedical research, and (3) encourage participants to pursue postbaccalaureate degrees and careers in biomedical research, especially in areas related to minority health problems. MIRT programs are supported at seven historically black colleges and universities (HBCUs). Twenty-one additional HBCUs participate in MIRT programs as members of consortia with nonminority research-intensive universities.

## OFFICE OF DISEASE PREVENTION

The Associate Director for Disease Prevention participated in several international activities related to prevention during FY 99. Activities included presentations on prevention research and on the use of traditional medicine, at the International Conference on Heart Health in Developing Countries, in New Delhi, India, on October 10–14, 1999.

The Associate Director was a liaison member to the National Academy of Sciences' Institute on Medicine panel that developed the report on Control of Cardiovascular Diseases in Developing Countries: Research, Development, and Institutional Strengthening

and has been active in follow-up related to this report. The report noted the paucity of research and of programs addressing cardiovascular disease in developing countries, despite the growing importance of cardiovascular disease in the health of their populations. Follow-up meetings were held with scientists from developing and industrial countries. The aims of these meetings are to plan a research agenda, develop a scientific advisory panel, and seek support for research projects.

The Office of Disease Prevention sponsored the travel of several scientists from developing countries to a meeting in South Africa to refine a strategy for research on cardiovascular disease, and the Associate Director participated in the Global Forum on Health Research, in Geneva, Switzerland, on June 8–10, 1999. The Associate Director serves as an advisor on research to the steering committee of the Cardiovascular Disease Research Initiative in Developing Countries, a group providing direction to the follow-up of the Institute on Medicine report.

The Associate Director also is on the editorial board of *Current Controlled Trials*, an international electronic journal of clinical trials being developed by the *British Medical Journal*.

## Office of Dietary Supplements

The Office of Dietary Supplements (ODS) was established by the Dietary Supplement Health and Education Act of 1994 (Public Law 103-417), which amended the Federal Food, Drug, and Cosmetic Act "to establish standards with respect to dietary supplements." ODS was organized within the Office of the Director of NIH. Formal operations began in November 1995, with the mission of strengthening knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public, to foster an enhanced quality of life and health for the U.S. population.

In FY 99, ODS cosponsored a major international workshop on Zinc and Health: Current Status and Future Directions, which was held at the NIH Natcher Conference Center, in Bethesda, Maryland, on November 4–5, 1998. The workshop was organized by ODS and cosponsored with the American

Dietetic Association; the American Society for Clinical Nutrition; CDC; the U.S. Department of Defense; the U.S. Food and Drug Administration; the Center for Food Safety and Applied Nutrition; and seven Institutes, Centers, and Offices of the NIH.

The purpose of this workshop was to review and update the base of scientific knowledge on zinc. The last 5 years have seen a virtual explosion of interest in and understanding of the spectrum of functions of zinc at subcellular levels. Zinc is a component of numerous proteins in the body, which are involved in a variety of metabolic processes. Zinc is so ubiquitous in cellular metabolism that even minor impairment of an adequate supply is likely to have multiple biological and clinical effects. Given the central roles of zinc in cellular growth and differentiation, the effects of zinc deficiency are pronounced in tissues and organs with rapid cell turnover, especially the immune system.

Thirty-five speakers from Australia, Europe, and the United States presented information that focused on six key areas where zinc supplementation may play a role in prevention, reduction, or treatment of disease. Discussion included the importance of zinc in the following areas: nutrition; the gastrointestinal tract and the immune system; antioxidant defense functions; cellular mechanisms; the central nervous system; and growth and specific disease entities. The proceedings of the workshop will be published as a supplement to the *Journal of Nutrition* in May 2000.

Also in FY 99, ODS and other NIH Institutes cosponsored several additional international workshops and conferences. ODS, in conjunction with the National Institute of Dental and Craniofacial Research (NIDCR), held a workshop entitled International Collaborative Research Project on Fluorides: Research Needs to Identify Opportunities for International Research on Fluorides for Oral Health, at the NIH, in Bethesda, Maryland, on February 1, 1999. Other cosponsors included the Oral Health Division of CDC and a number of private groups. A working group met in February 1999 to review the current guidance documents for existing high-priority recommendations and to formulate new recommendations for discussion at the workshop. A full range of research needs was highlighted. Discussion

focused on population-based studies, as well as basic research needs. Participants in the working group identified high-priority projects. NIDCR worked with CDC and other Federal partners to identify ways to address these recommendations for future research, and the recommendations were an integral part of the discussions at the international conference, at the NIH, in Bethesda, on May 10–12, 1999.

ODS and the National Institute on Alcohol Abuse and Alcoholism cosponsored and participated in a Workshop on the Essentiality of Omega-6 and Omega-3 Fatty Acids, in Rockville, Maryland, on April 7–9, 1999. Additional cosponsors included the International Society for the Study of Fatty Acids and Lipids; the Center for Genetics, Nutrition, and Health, Washington, D.C.; and industry representatives. The workshop was truly international, bringing together scientists from academia, government, international organizations, and industry, from Australia, Canada, Denmark, France, Italy, Japan, Norway, Switzerland, the United Kingdom, and the United States. The purpose of the meeting was to assess the state of knowledge and gaps in knowledge about the requirement for various types of omega-6 and omega-3 fatty acids in growth, development, health maintenance, and disease prevention or treatment. Additionally, the participants were asked to evaluate the need for proposing a daily recommended intake of these fatty acids. A summary statement and a consensus document from the meeting's deliberations were distributed to all participants.

The workshop entitled Micronutrients and Infectious Diseases: Cellular and Molecular Immunomodulatory Mechanisms was organized by NIAID's Division of Microbiology and Infectious Diseases and was cosponsored by ODS. The meeting was held in Bethesda, Maryland, on September 16–17, 1999. A major problem associated with the development of effective strategies for prevention of infectious diseases is the lack of understanding of the basic mechanisms involved in the alteration of host responses. The purpose of this workshop was to bring experts from across the globe together to examine current information on the potential mechanisms by which nutritional deficiencies alter the host responses to bacterial infection. The proceedings from this meet-

ing will be published in the *Journal of Infectious Diseases* in 2000.

At the 1999 Annual Meeting of the Association of Chemoreception Sciences, ODS cosponsored a workshop with the National Institute on Deafness and Other Communication Disorders, to evaluate Nutritional Implications of Cephalic Phase Responses. Cephalic phase response is a reflex response that can be triggered by the appearance, odor, taste, or texture of foods. It accounts in part for subsequent physiological responses associated with eating food. The workshop was held as a satellite symposium. The aim of the meeting was to foster collaborative research between sensory scientists with expertise in the chemical senses and nutritional scientists with expertise in physiology and metabolism. Seven scientists on the forefront of the field from five countries spoke on a range of topics. The proceedings are to be published in *Appetite*, a journal that is widely read by nutritionists and psychologists interested in human feeding.

#### **Office of Rare Diseases**

The Office of Rare Diseases (ORD) interacts with the international community in three ways:

1. offers information on request to patients, their families and friends, physicians, and researchers on specific rare diseases, in the United States and abroad, through written responses, telephone calls, and visits to the Web site (<http://rarediseases.info.nih.gov/ord/>);
2. fosters a research environment with NIH health science administrators, to promote international research on disease; and
3. provides support for national and international scientific workshops, symposia, and conferences, to stimulate research on rare diseases and conditions, with primary consideration for support for meetings on disease for which research is lacking or lagging or is likely to be stimulated.

In FY 99, ORD saw an increase in international inquiries about rare diseases, particularly through visits to the Web site and by direct inquiries, electronically and by mail, to the ORD office. In addition, ORD continued to cosponsor the Medical Genetics and Rare Disorders subfile in the Combined Health Information Database. The remainder of this database is produced by other health-related agencies of the Federal

Government; it lists health promotion and education materials and program descriptions for rare diseases and other diseases. The Medical Genetics and Rare Disorders subfile contains information on approximately 1,000 patient groups for rare diseases in Canada, the United Kingdom, and the United States.

The Director of ORD worked with European Union administrators and scientists to develop legislation to stimulate research on rare diseases. The goal was to assist foreign countries, including Italy and Spain, to develop a focus on research on rare diseases that is similar to the focus in the United States.

In FY 99, ORD cosponsored nine national and international workshops that brought together scientists with common research interests.

The National Institute of Arthritis and Musculoskeletal and Skin Disorders and the Acid Maltase Deficiency Association, together with ORD, cosponsored the 3rd International Workshop of the Acid Maltase Deficiency Association, at the NIH, in Bethesda, Maryland, on December 3–5, 1998. Attendees included researchers from Australia, Belgium, China, France, Italy, Japan, the Netherlands, Scotland, and the United States. Discussion included mechanisms of disease, animal models, new therapies, population studies, and patient concerns. The speakers emphasized therapies, including enzyme replacement and gene therapy, which have shown promising results in animals.

With NIAID, ORD cosponsored a conference on Crohn's disease, at the NIH, in Bethesda, on December 14, 1998. (Crohn's disease is a debilitating inflammatory bowel disease.) Presenters included scientists and physicians from the United Kingdom and the United States, who reviewed the state of knowledge relevant to microbial etiology of Crohn's disease and identified needed research.

With NICHD and the United Leukodystrophy Foundation, ORD cosponsored a conference to evaluate Therapies of X-Linked Adrenoleukodystrophy, in Baltimore, Maryland, on January 22–23, 1999. This meeting focused on the degree of effectiveness and safety of two potential therapeutic approaches, lovastatin and 4-phenylbutyrate. The meeting was attended

by researchers, physicians, and members of voluntary support groups from Australia, Brazil, Canada, Chile, China, France, Germany, India, Italy, Japan, Korea, Mexico, the Netherlands, Spain, and the United States. As a result of this meeting, the United Leukodystrophy Foundation plans to submit a research grant application to NICHD to study therapies for X-linked adrenoleukodystrophy.

The National Institute of Nursing Research and ORD cosponsored a meeting in Bethesda, Maryland, in March 1999, to plan the Summer Genetics Institute, which will be held at the NIH, in Bethesda, and will begin in June 2000. The purpose of this meeting, which included participants from Canada and the United States, was to examine the proposed course content and to plan the laboratory component of the 8- to 10-week summer program for advanced clinicians, graduate students, and junior faculty. The purpose of the program is twofold: to advance research capacity for faculty and graduate nurses and to develop genetic counselors and practitioners with expertise in genetics, to deliver health care to patients and families.

With the Wellcome Trust of the United Kingdom, ORD cosponsored the 1st International Conference on Trimethylaminuria (Fish Malodor syndrome), at the NIH, in Bethesda, on March 29–30, 1999. The participants included patients and their families, as well as physicians and researchers from many scientific and medical disciplines, from Australia, Brazil, Canada, Germany, Korea, New Zealand, the United Kingdom, and the United States. Investigators presented the results of their studies and began to discuss future research collaborations.

NINDS and ORD cosponsored a workshop on Batten Disease: Basic Biology and Therapy, in Bethesda, on April 1–2, 1999. Participants came from Australia, Canada, the United Kingdom, and the United States. Discussion focused on methods to translate advances in basic science into treatment approaches; to expand the knowledge base in Batten disease; and to transcend gene discovery by moving toward targeted gene and protein therapies and pharmaceutical approaches.

With NHLBI and ORWH, ORD cosponsored a grantee meeting on Primary Pul-

monary Hypertension, in Bethesda, on May 12, 1999. Participants included physicians from Canada, the United Kingdom, and the United States. The meeting was held in conjunction with a program announcement issued by NHLBI to stimulate basic research on the development and progression of primary pulmonary hypertension. Most research on this condition focuses on gene expression in and growth and interactions of smooth muscle cells and endothelial cells of the blood vessels and on the balance of various biological mediators of dilation or constriction of the vasculature. Recently, investigators are searching for the gene responsible for the devastating effects of this disease.

ORD and NIAID cosponsored the workshop on the Discovery of Human Immune Response Genes, at the NIH, in Bethesda, on September 27, 1999. Attendees included researchers and scientists from the United Kingdom and the United States. Discussion focused on the premise that common gene families involved in regulation of the immune system contribute to susceptibility to or protection from autoimmune and other immune-mediated diseases.

With NIAMS and the Osteogenesis Imperfecta Foundation, ORD cosponsored a meeting on New Research Strategies in Osteogenesis Imperfecta, in Bethesda, on September 27, 1999. Participants included researchers, physicians, and members of the voluntary support organizations for patients with osteogenesis imperfecta, from Canada and the United States. This scientific meeting resulted from a unique public and private partnership to increase the pace of research on this disorder. Researchers debated cutting-edge gene, cell, and drug therapies for osteogenesis imperfecta.

## **OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH**

The Office of Behavioral and Social Sciences Research (OBSSR) was established in July 1995, within the Office of the Director of NIH, to serve as the focal point for NIH research on behavioral and social sciences. OBSSR is guided by a strategic plan in the fulfillment of its responsibilities and works in partnership with the NIH Institutes and Centers to accomplish its goals. Major responsibilities of OBSSR include the following:

- providing leadership and direction for

the development and implementation of a trans-NIH plan to increase the scope of and support for behavioral and social sciences research and training;

- developing initiatives to stimulate research in the behavioral and social sciences arena;

- integrating a psychosocial perspective across the research areas of the NIH; and

- providing leadership to ensure that findings from behavioral and social sciences research are disseminated to the public.

The contribution of behavioral and social factors to health is important, both within the United States and internationally. OBSSR does not make grants directly. However, in FY 99, the Office provided training funds through the Fogarty International Center to an investigator studying population-based medicine in the United Kingdom. In addition, OBSSR is sponsoring a conference jointly with the North Atlantic Treaty Organization and the Wellcome Trust. The meeting will be held in Budapest, Hungary, on May 20–24, 2000. This conference will examine stress- and gender-related factors in the increase in cardiovascular disease in Central and Eastern Europe.

OBSSR staff have also been involved with the development of the Canadian Institutes of Health Research. The Director of OBSSR and staff met with members of the Interim Governing Council, which was charged with developing a plan for the formation of a new organization within the Canadian government. That organization would become the primary source of support for health research in Canada. Input was sought on how the NIH and OBSSR have integrated behavioral and social sciences research into the programs of the NIH. In June 1999, the Special Assistant to the Director of OBSSR went to Toronto, Ontario, to participate in the review of applications. The applications were responding to a solicitation requesting designs for institutes, including a health-related social science research institute or a plan for the incorporation of social science research across the proposed Canadian Institutes of Health Research. On September 17–18, 1999, staff also participated in a conference in Quebec, Quebec, where the proposals generated through this funding solicitation were presented and discussed.

Since January 1999, OBSSR staff have been participating in an initiative to develop

intervention guidelines for countries torn by traumatic events. These guidelines focus on both practice and public policy. Repairing the political and economic consequences of events such as war and disaster has long been a focus of United Nations efforts, but the psychological effects of traumatic events have been largely overlooked. The goal of the ongoing initiative is to produce a report for the United Nations that will bring strategies for trauma intervention to social and public policy makers, building on research findings generated over the past two decades. Contributors represent each continent, with representatives drawn from both developed and developing countries.

### **OFFICE FOR PROTECTION FROM RESEARCH RISKS**

In FY 99, the Office for Protection From Research Risks (OPRR) successfully negotiated more than 1,200 assurances (Protection of Human Subjects Assurance Identification/Certification Declarations) for research conducted in 100 countries outside the United States. OPRR also negotiated 54 Animal Welfare Statements of Compliance with institutions in 18 countries outside the United States. In FY 98, OPRR's Human Subjects Assurance Branch established and now maintains regular contacts with the United Kingdom's Cancer Research Campaign, which includes 19 research sites, and with the European Organization for Research and Treatment of Cancer (EORTC), which includes 110 research sites. Both of these organizations collaborate with DHHS in international multicenter clinical trials.

The OPRR Deputy Director continues to serve as an advisor and liaison to the Standing Ethics Committee of the Canadian Medical Research Council. During 1999, council efforts were devoted to the implementation of the Tri-Council Policy Statement, entitled Ethical Conduct for Research Involving Humans. In September 1999, the Deputy Director participated in the conference on Revision of the Declaration of Helsinki (Finland), in London, England.

OPRR staff met with scientists from several countries in FY 99. Included were scientists and administrators from Australia, Belgium, Brazil, Canada, China, Italy, New Zealand, Taiwan, and member countries of EORTC. Staff also met with numerous U.S. Depart-

ment of State science advisors posted in countries around the world.

### **OFFICE OF EXTRAMURAL RESEARCH**

In FY 99, the Deputy Director for Extramural Research participated in several international activities. In January 1999, she met with the WHO Global Forum for Health Research, in Geneva, Switzerland. She also participated in the Research Workshop on Adolescent Sexual and Reproductive Health, in Gramado, Brazil, on February 1-5, 1999. In July, she served on the Scientific Review Committee on Social Science Research and Reproductive Health, of WHO's Human Reproduction Program.

The Deputy Director has served since 1995 as the NIH representative on the board of trustees of the Human Frontiers in Science Program, a multinational program that supports international cooperation in molecular biology and research into brain functions, through the award of research grants and fellowships and through funding of related conferences and workshops. In 1999, the Deputy Director became cochair of the board of trustees, which met in Strasbourg, France, in March and May. She cochaired the planning for the third part of the celebration of the 10th anniversary of the Human Frontiers in Science Program, which will take place in Washington, D.C., on December 10-11, 1999.

In addition, staff of the Office of Extramural Research routinely provide briefings to visiting international scientists. For example, senior staff spoke with seven members of the German Bundestag and visiting scientists and administrators from the Korea Science and Engineering Foundation. Similarly, the Office of Policy for Extramural Research Administration met with representatives of the International Delegation of the Community of Sciences to discuss the NIH Commons and CRISP, new systems for the electronic exchange of information. Other senior staff members met with representatives of the Executive Committee of the Canadian Medical Research Council in July 1999, to discuss organizational structures within the NIH and their ability to meet research priorities.

### **OFFICE OF INTRAMURAL RESEARCH**

The Office of Intramural Research (OIR), under the leadership of the Deputy Director for Intramural Research, oversees the conduct and management of the NIH intramural research program, the world's largest biomedical research enterprise. Approximately one-third of the nearly 5,000 doctoral-level trainees and staff are foreign scientists participating in the NIH Visiting Program. They are sponsored under nonimmigrant visas (e.g., J-1, H-1B, and O-1 visas). Policy oversight with respect to application for the visa and to the visa waiver program is provided by OIR. Special requests for visa extensions or sponsorship are reviewed by several OIR committees, such as the J-1 Visa Extension Review Committee and the O-1 Visa Committee. These committees work closely with the International Services Branch of the Fogarty International Center to deal with the Immigration and Naturalization Service and the Department of State on waiver and visa matters.

In FY 99, the Deputy Director and OIR staff held several discussions with representatives of the Singapore Economic Development Board about potential scientific collaborations between the NIH intramural program and Singapore. This is an example of the facilitating role OIR plays in bringing together foreign officials and appropriate NIH staff in discussions of international cooperation.

In honor of the NIH visit of Dr. Gro Harlem Brundtland, Director General of WHO, OIR held a poster session featuring presentations on some of the international research conducted and supported by the NIH. Presenters at the event, which was held on November 29, 1998, included both intramural and extramural scientists.

### **Senior Advisor to the Deputy Director for Intramural Research**

The Senior Advisor to the Deputy Director for Intramural Research serves as the DHHS representative on the Interagency Arctic Research Policy Committee, chaired by the National Science Foundation. In this capacity, he also serves as the focal point for the human health aspects of the Arctic Monitoring and Assessment Program (AMAP), one of the components of the Arctic Council. In 1997, the Arctic Council superseded the for-



mer Arctic Environmental Protection Strategy; the United States is one of the eight signatory nations.

The Senior Advisor was appointed in 1998 as the DHHS liaison for Arctic Council activities. At the first ministerial meeting of the Arctic Council, in Iqualuit, Baffin Island, in September 1998, the United States accepted the chairmanship of the Arctic Council for the 2-year period 1998–2000. The Senior Advisor attends monthly meetings of an Arctic policy group, which is convened by the Department of State to consider issues related to the Arctic Council. In FY 99, the Senior Advisor participated in several international meetings related to the AMAP effort. The AMAP-2 Human Health Subprogram group met in Reykjavik, Iceland, in October 1998, and in Ottawa, Ontario, in September 1999, to discuss planning for the next phases of the AMAP-2 Human Health Subprogram. In December 1998, the Senior Advisor attended the AMAP-2 Working Group 12 meeting convened in Helsinki, Finland.

During FY 99, the Senior Advisor also met with a number of foreign delegations and dignitaries, including representatives from China, Korea, Norway, Singapore, and Taiwan. These meetings involved discussions of (a) the administration and management of the NIH intramural program; (b) mechanisms for establishment of collaboration between the NIH and foreign organizations; and (c) collaborative opportunities for research on health in the Arctic region.

#### **Office of Education**

In response to the growing interest in the NIH Clinical Electives Program among students in foreign medical schools, the Office of Education expanded the eligibility criteria to include students from the international community. This policy change, which was made in September 1999, became possible due to a modification to the B-1 visa authority that now enables students in foreign medical schools to enter the United States temporarily to participate in an elective clerkship at a medical school's hospital.

As a Federal biomedical research agency with a clinical research hospital, the NIH is considered by the Department of State to be an appropriate institution for elective clerkships.

In the summer of 1998, the Office of Education implemented the NIH Predoctoral Visiting Fellow Program, through the University of Maryland, College Park. The Program enables doctoral-level students in foreign institutions to spend up to 1 year engaged in research training at the NIH. Scientists in NIH intramural laboratories participate in teaching, advising, and mentoring the participants in this Program, who are considered as advanced special students. In 1999, seven students from four countries participated in the Program.

#### **Office of Human Subjects Research**

For FY 99, the Office of Human Subjects Research reported that 10 protocols for research on human subjects were approved, involving studies in nine foreign countries.

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