

Appendices

LEGISLATIVE CHRONOLOGY

NOV. 1, 1948

The National Microbiological Institute was established under authority of section 202 of the Public Health Service Act, as implemented by General Circular No. 55, Organization Order No. 20, dated October 8, 1948.

DEC. 29, 1955

NIAID was established (replacing the National Microbiological Institute) under authority of the Omnibus Medical Research Act (Public Law 81-692, 64 Stat. L. 443), as implemented by a Public Health Service Briefing Memorandum of November 4, 1955, from the Surgeon General to the Secretary of Health, Education, and Welfare.

NOV. 4, 1988

NIAID was provided with additional authorities for AIDS research under Title II of the Health Omnibus Programs Extension of 1988 (HOPE legislation) (Public Law 100-607), the first major law to address AIDS research, information, education, and prevention.

AUG. 14, 1991

The Public Health Service Act was amended by Public Law 102-96, the Terry Beirn Community-Based AIDS Research Initiative Act of 1991, which reauthorized NIAID's Community Programs for Clinical Research on AIDS (CPCRA). CPCRA was renamed in honor of Mr. Beirn (an AIDS activist and congressional staffer who died in 1991) and was reauthorized for an additional 5 years.

JUNE 10, 1993

The Public Health Service Act was amended by Public Law 103-43, the National Institutes of Health Revitalization Act of 1993. This comprehensive legislation required NIAID to include research on tropical diseases in its mission statement and directs the Secretary, U.S. Department of Health and Human Services, to ensure that individuals with expertise in chronic fatigue syndrome or neuromuscular diseases are appointed to appropriate NIH advisory committees.

DEC. 14, 1993

The Preventive Health Amendments of 1993 were passed, which included provisions requiring the Director, NIAID, to conduct or support research and research training regarding the cause, early detection, prevention, and treatment of tuberculosis. (The Institute already had authority to conduct such research under its authorities in Title IV, Public Health Service Act.)

NOV. 29, 1999

The fiscal year 2000 Appropriations Act (Public Law 106-113) established the NIH Challenge Grants program to promote joint ventures between the NIH and the biotechnology, pharmaceutical, and medical device industries. A one-time funding level of \$20 million was provided within the Public Health and Social Services Emergency Fund.

OCT. 17, 2000

The Children's Health Act (Public Law 106-310) required the Directors of NIAID and the National Institute of Arthritis and Musculoskeletal and Skin Diseases to expand and intensify the activities of their Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

NOV. 13, 2000

The Public Health Improvement Act (Public Law 106-505) authorized the NIAID Director to establish a program of clinical research and training awards for sexually transmitted infections.

Previous Directors

Victor H. Haas, M.D., 1948–1957

Justin M. Andrews, Sc.D., 1957–1964

Dorland J. Davis, M.D., D.P.H., 1964–1975

Richard M. Krause, M.D., 1975–1984

TECHNOLOGY TRANSFER

Technology transfer in Federal laboratories facilitates the dissemination of new technologies and research materials developed by Government scientists. This technology transfer fuels further innovation and commercialization by the extramural research and development community, ultimately resulting in an improvement in the public health and an increase in the competitiveness of U.S. industry. Federal legislation mandates and defines the Government's technology transfer activities. The key pieces of legislation are the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995.

The NIAID Office of Technology Development (OTD) accomplishes technology transfer by facilitating the transfer of significant research advances and resources to the broader scientific community and the development of collaborative relationships between NIAID scientists, industry, and academia. NIAID uses various mechanisms to accomplish these ends, including Material Transfer Agreements (MTAs), Cooperative Research and Development Agreements (CRADAs), Materials-CRADAs (M-CRADAs), Confidential Disclosure Agreements (CDAs), Clinical Trial Agreements (CTAs), Drug Screening Agreements (DSAs), and, through the NIH Office of Technology Transfer (OTT), the patenting of inventions and the negotiation of various license agreements.

NIAID scientists report inventions to OTD by submitting Employee Invention Reports (EIRs). The EIRs are reviewed by OTD and, with the

assistance of the NIAID Technology Evaluation Advisory Committee (TEAC), are evaluated for the purpose of filing domestic and foreign patent applications. In fiscal year (FY) 2003, TEAC reviewed 27 intramural EIRs and recommended that a patent application be filed on 22 of them. NIAID currently has 342 active U.S. patent properties, including 168 issued patents and 174 pending patent applications.

NIAID had a total of 245 active license agreements in FY 2003 for both patented inventions and biological materials. These licenses generated about \$10.3 million in royalty income, which was first used to pay NIAID inventors their share according to Federal law and NIH policy. The Institute also distributed royalty income to intramural laboratories to support research projects and equipment acquisition that otherwise would not have been accomplished with appropriated funds. The remaining royalties were used to pay OTD's entire operating budget, including patent prosecution fees, OTD staff salaries, associated office expenses, and overhead charged by OTT.

In FY 2003, a total of 192 MTAs, 12 CTAs, 59 CDAs, 5 CRADAs, 14 M-CRADAs, and 21 other agreements, not including the screening agreement related to severe acute respiratory syndrome (SARS) discussed below, were executed and negotiated by OTD. NIAID extramural divisions referred technology transfer issues to OTD on 5 contracts, and OTD NIAID scientists performed research under 33 CRADAs and 40 M-CRADAs in FY 2003. The following table provides a history of NIAID's patent, license, and CRADA activities.

NIAID Technology Transfer Activities

Fiscal Year	Pending Patents	Issued Patents	Licenses in Effect	Active CRADAs
1994	85	65	84	29
1995	96	71	101	31
1996	95	84	120	42
1997	128	91	131	71
1998	154	83	155	95
1999	169	94	195	74
2000	229	100	196	86
2001	194	125	190	93
2002	147	139	197	85
2003	174	168	245	71

Technology Transfer Highlights

OTD supported NIAID's response to SARS by drafting an agreement for use in a collaboration between the NIAID Division of Microbiology and Infectious Diseases (DMID) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to provide resources to screen possible anti-SARS proprietary compounds. This screening agreement has been provided to 190 companies, of which more than 40 requested that the screening agreement be renegotiated by OTD. In addition to this screening agreement, OTD negotiated and completed at least 13 other SARS-related agreements.

In FY 2003, OTD negotiated or facilitated the following public-private partnerships.

Evaluation of Adenoviral Encoding Proteins Associated With SARS (GenVec)

Recombinant adenoviral vectors have been widely investigated in recent years as a gene delivery system for gene therapy and vaccination. Recombinant adenoviral vectors offer a promising strategy for development of a candidate SARS vaccine that could be effective

in humans. Investigators at the Vaccine Research Center (VRC), NIAID, the NIH, and GenVec, Inc. (GenVec) will collaborate to evaluate and develop adenoviral vectors expressing modified SARS genes. The collaboration will evaluate adenovectors for potential application, such as a SARS preventive vaccine. VRC will provide GenVec with several modified SARS genes, and GenVec will construct and produce recombinant adenovectors that express SARS genes, using the GenVec adenovector and cell line system. The overall goal is to provide VRC with advanced vector technologies suitable for rapid advancement toward clinical trial.

Analysis of the Immune Response to Hepatitis C Virus (Innogenetics)

Under this CRADA, investigators in the Hepatitis Viruses Section, Laboratory of Infectious Diseases, Division of Intramural Research at NIAID, and Innogenetics will perform basic and applied studies of the immune response to hepatitis C virus (HCV) in nonhuman primates in order to determine how to modify the host response to HCV for therapeutic and immunoprophylactic benefit.

Use of Quantum Dots for Improved Cellular Classification in Flow Cytometry (Quantum Dot Corporation)

Under this CRADA, investigators in the Immunology and Flow Cytometry Core of NIAID's VRC and Quantum Dot Corporation will aim to adapt quantum dots for use in detailed characterization of the function and types of immune cells that respond to pathogens and vaccines. The quantum dots are semiconductor nanocrystals with unique fluorescent properties that may significantly aid in the identification of specific properties of these cells using flow cytometry.

Oligonucleotide Control Sets for Microarray Applications (Invitrogen Corporation)

The purpose of this CRADA is to develop oligonucleotide sets of standards for use as a universal reference for interpreting and reporting microarray and other expression investigative research tools. The outcome of this project should result in two complementary standard sets that can be used for researchers: (1) oligonucleotide probe sets for use by facilities that produce custom or spotted DNA microarrays, and (2) premixed cocktails of target RNA standards and hybridization controls for researchers who perform the sample labeling and hybridization of

microarrays. It is envisioned that these standards would benefit public health by facilitating the use of microarrays in biomedical research areas, including infectious diseases and genetic research as well as other research fields.

A Study of the Mechanism of Action of the Anti-HIV Compound, PA-457 (Panacos, Inc.)

NIAID and Panacos Pharmaceuticals, Inc., are collaborating under this CRADA to study the HIV inhibitory mechanism of action of Panacos Pharmaceuticals' proprietary compound PA-457. The parties will employ state-of-the-art biochemical and structural biology techniques to carry out their research program.

New CRADAs

During FY 2003, NIAID scientists entered into the following five new CRADAs:

Collaborator

GenVec, Inc.

Investigator

Phillip Gomez III, Ph.D., M.B.A.
Vaccine Research Center

Title

Evaluation of Adenoviral Encoding Proteins
Associated With SARS

Collaborator

Innogenetics

Investigator

Robert H. Purcell, M.D.
Laboratory of Infectious Diseases

Title

Analysis of the Immune Response to Hepatitis
C Virus

Collaborator

Invitrogen Corp.

Investigators

Thomas Kindt, Ph.D.
Michael Wilson, Ph.D.
Research Technologies Branch, Division of
Intramural Research

Title

Oligonucleotide Control Sets for Microarray
Applications

Collaborator

Panacos, Inc.

InvestigatorEric Freed, Ph.D.
Laboratory of Molecular Microbiology**Title**A Study of the Mechanism of Action of the
Anti-HIV Compound, PA-457**Collaborator**

Quantum Dot Corp.

InvestigatorMario Roederer, Ph.D.
Vaccine Research Center**Title**Use of Quantum Dots for Improved Cellular
Classification in Flow Cytometry**CRADAs in Effect, FY 2003****Collaborator**

Achillion Pharmaceuticals

InvestigatorJohn Inman, Ph.D.
Laboratory of Immunology**Title**Development of Optimized Inhibitors of Protein
Zinc Finger Domains**Collaborator**

American Cyanamid

InvestigatorBrian Murphy, M.D.
Laboratory of Infectious Diseases**Title**Development of Safe and Effective Live
Attenuated Vaccines for Respiratory Syncytial
Virus Subgroups A and B and Parainfluenza
Viruses Type 1, 2, and 3**Collaborator**

Biospace.com

InvestigatorLaurence Wolfe, Ph.D.
Office of Technology and Information Systems**Title**Development of an Electronic Procurement
System for Commodity Identification, Product
and Service Acquisition, and Budget Tracking**Collaborator**

Chiron

InvestigatorH. Clifford Lane, M.D.
Laboratory of Immunoregulation**Title**Research and Development of IL-2 as a
Treatment for HIV Infection

Collaborator

Ciphergen Biosystems

Investigators

John Kehrl, M.D.

Tae-Wook Chun, Ph.D.

Laboratory of Immunoregulation

Title

Identification and Characterization of Novel Non-Cytolytic Antiviral Factors Derived From CD8+ T Cells of HIV-Infected Individuals Using the ProteinChip® System

Collaborator

Connaught Technology Corp.

Investigator

Warren Strober, M.D.

Laboratory of Clinical Investigation

Title

Development of Vectored Vaccines and Therapeutics for the Prevention and Treatment of AIDS

Collaborator

Crucell

Investigator

Phillip Gomez III, Ph.D., M.B.A.

Vaccine Research Center

Title

Development of an Improved Recombinant Adenovirus Vector for Vaccination Against the Ebola Virus

Collaborator

Genetics Institute

Investigator

Ethan Shevach, M.D.

Laboratory of Immunology

Title

Analysis of Gene Expression in Immunoregulatory T Cells that Co-Express the CD4 and CD25 Surface Markers

Collaborator

Genetics Institute

Investigators

Stephen Straus, M.D.

Warren Strober, M.D.

Peter Mannon, M.D.

Ivan Fuss, M.D.

Laboratory of Clinical Investigation

Title

A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding, Safety Study of Two Parallel Dose Levels of Subcutaneously Administered Human Monoclonal Antibody to Interleukin-12 (J695) in Patients With Active Crohn's Disease

Collaborator

Genetics Institute

Investigator

Thomas Wynn, Ph.D.

Laboratory of Parasitic Disease

Title

Development of IL-13 Antagonism as a Treatment for Fibrosis in Schistosomiasis

