Kudos to NIH Technology Transfer Efforts

Prepared by
Office of Technology Transfer
National Institutes of Health
U.S. Department of Health & Human Services

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Table of Contents

2012

National Institutes of Health | Inventors on NIH Patents Issued in FY 2012
Congratulations to Inventors on NIH Patents Issued in FY 2012 1

Licensing Executives Society | Industry-University-Government Interface Sector | ”Deals of Distinction Award™”
Facilitating Access to HIV Treatment in Developing Countries 6

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
Sound Attenuation Canopy 7
Treatment of Niemann-Pick Disease Type-C with 2-hydroxypropyl-β-cyclodextrin 8
AAV Technology: Delivery Vehicle of Choice for Gene Therapy 10

Federal Laboratory Consortium | Mid-Atlantic Region Award | Outstanding Technology Transfer Professional
Richard Rodriguez, Director, Division of Technology Development and Transfer, NIH Office of Technology Transfer 11

Federal Laboratory Consortium | Mid-Atlantic Region Award | Representative of the Year
Dr. Thomas Stackhouse, Associate Director, Technology Transfer Center, National Cancer Institute 12

Federal Laboratory Consortium | Mid-Atlantic Region Award | State and Local Economic Development
Chief Science Officer Development Training Certificate Program (“CSO Boot Camp”) Team 13

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
An Interactive Software Package for the Analysis of Microarray Data 15
Development of Eribulin, a Potent Anti-Cancer Agent from a Marine Sponge 17
Use of Therapeutic Antibodies as a Novel Treatment for Multiple Sclerosis 18
Vibro-Tactile Stimulation Device and Method for Swallowing Disorders 20

2011

National Institutes of Health | Inventors on NIH Patents Issued in FY 2011
Congratulations to Inventors on NIH Patents Issued in FY 2011 22

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
Use of Therapeutic Antibodies as a Novel Treatment for Multiple Sclerosis 26

Federal Laboratory Consortium | Mid-Atlantic Region Award | Outstanding Technology Transfer Professional
Laurie Arrants, Director, Technology Transfer Office, National Institute of Neurological Disorders and Stroke 28

Federal Laboratory Consortium | Mid-Atlantic Region Award | State and Local Development
National Cancer Institute 29

Federal Laboratory Consortium | Mid-Atlantic Region Award | Technology Transfer Professional Rookie of the Year
Dr. Samuel Bish, Licensing and Patenting Manager, NIH Office of Technology Transfer 30

Table of Contents

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
A Lifesaving Diagnostic Test for Cancer Patients 31

Federal Laboratory Consortium | National Award | STEM Award
2010 STEM Postdoc Conference Committee 32

2010

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
A Life-Saving Diagnostic Test for Cancer Patients 33
High-Speed Counter Current Chromatography 34
Identification and Development of Agents to Treat Glioblastoma and Other Tumors Over-expressing Nuclear Receptor CoRepressor 35
Novel Protein-Like Therapeutics for Treatment of Cancer 36
Therapeutic Antibodies for the Treatment of Cancer 37
Therapeutic Immunotoxins for the Treatment of T Cell Malignancies 38

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Cell Line Bank for Cancer Research 39
Innovative Techniques and Reagents for Improved Genetic Engineering 41
PROSTVAC, a Therapeutic Vaccine for Treating Prostate Cancer 42

Federal Laboratory Consortium | National Award | Laboratory Director of the Year
Dr. Robert Wiltrout, Director, Center for Cancer Research, National Cancer Institute 43

2009

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
Cell Line Bank for Cancer Research 44
Innovative Techniques and Reagents for Improved Genetic Engineering 46

Federal Laboratory Consortium | Mid-Atlantic Region Award | Laboratory Director of the Year
Dr. Robert Wiltrout, Director, Center for Cancer Research, National Cancer Institute 48

Federal Laboratory Consortium | Mid-Atlantic Region Award | Outstanding Technology Transfer Professional
Karen Maurey, Director, Technology Transfer Center, National Cancer Institute 51

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Mast Cell Line for Research on Allergies and Inflammatory Diseases 53

Licensing Executives Society | Industry-University-Government Interface Sector | ”Deals of Distinction Award™”
Development of Sodium Nitrite as a Repurposed Pharmaceutical Agent 54

U.S. Department of Health and Human Services | Green Champions Award | Environmental Stewardship
Green Team Efforts — NIH Office of Technology Transfer 55

Table of Contents

2008

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
Select100™ Multi-Specimen Loader and Image Acquisition System 56

2007

Biotechnology Industry Organization | BIO 2007 Innovation Corridor "Best Poster" Award
Novel Protein for Development of a Chlamydial Vaccine 57

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
Targeted Treatments for Chronic and Painful Diseases 58

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Gardasil™: A New Era in Cancer Prevention 59

2006

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Kepivance®: Improving the Quality of Life for Cancer Patients 60

2005

Federal Laboratory Consortium | Mid-Atlantic Region Award | Excellence in Technology Transfer
Accelerated Magnetic Resonance Imaging (T-SENSE) 61
Kepivance®: Improving the Quality of Life for Cancer Patients 62
Parvovirus B19 Diagnostic Test Kit 63
Taxus® Express2™: Bypassing By-pass Surgery with Paclitaxel-Coated Stents 64

1999

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Drs. Jon G. Wilkes and Dwight Miller, National Center for Toxicological Research, FDA 65

1997

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Dr. R. Michael Blaese, National Human Genome Research Institute 65

1993

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer
Dr. Joseph Pitha, National Institute on Aging 65

Table of Contents

1992

Federal Laboratory Consortium | National Award | Excellence in Technology Transfer

Dr. W. French Anderson, National Heart Lung and Blood Institute 65

Congratulations to Inventors on NIH Patents Issued in FY 2012

CC- CLINICAL CENTER

Ingmar Bitter
Marek Franaszek
Gheorghe Iordanescu
Alan Remaley
Ronald Summers
Robert Van Uitert

NCI - NATIONAL CANCER INSTITUTE

Gosse Adema
Keli Agama
Rando Allikmets
Smitha Antony
Ettore Appella
Cassio Baptista
Susan Bates
Jay Berzofsky
Robert Blumenthal
Michael Bustin
R. Andrew Byrd
Lydie Cassard
Deb Chatterjee
Tai Cheuk
Mike Citro
David Covell
Sandeep Dave
Michael Dean
Frank DeRosa
Nallathamby Devasahayam
Dimiter Dimitrov
Mark Dudley
Igor Espinoza-Delgado
Barbara Felber
Yang Feng
Carl Figdor
William Figg
David Fitzgerald
Daniel Fowler
Erin Gardner
Atul Goel
Paul Goldsmith
Ronald Gress
Koichi Hagiwara
Curtis Harris
James Hartley
Vincent Hearing
Melinda Hollingshead
Jeanne Hou
Joseph Hrabie
Konrad Huppi
Patrick Hwu
Hidekazu Ikeuchi
Jeff Isenberg
Sahar Javanmard
Jane Jensen
Unsu Jung
Syed Kashmiri
Yutaka Kawakami
Frederic Kaye
Larry Keefer
Javed Khan
Shioko Kimura
Dennis Klinman
Takefumi Komiya
Janusz Koscielniak
Andrei Koslov
Murali Krishna
Henry Krutzsch
Reiko Kurotani
Larry Kwak
Rejean Lapointe
Lance Liotta
Hong Lou
Katrina Marinda
Victor Marquez
James McMahon
Arpita Mehta
Paul Meltzer
Susan Mertins
James Mitchell
Richard Morgan
Toshiyuki Mori
Robert Moschel
David Munroe
Makoto Nagashima
Sang-kon Oh
Barry O'Keefe
Joost Oppenheim
Pasquale Pagliaro
Claudia Palena
Maria Parkhurst
Thierry Passeron
Ira Pastan
Geoffrey Patton
Gary Pauly
George Pavlakis
Yves Pommier
Yossef Raviv
Nicholas Restifo
Paul Robbins
David Roberts
Steven Rosenberg
Andreas Rosenwald
Mark Roth
Jeffrey Rubin

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2012

NCI - NATIONAL CANCER INSTITUTE

Lawrence Samelson
Takashi Sato
Aaron Schetter
Marco Schito
Jeffrey Schlom
Thomas Schneider
Kalavathy Sitaraman
Sergey Smulevitch
Louis Staudt
Sankaran Subramanian
Vivian Takafuji
Bruce Tan
Nadya Tarasova
Kwong-Yok Tsang
Aykut Uren
Mathias Viard
Bahu Rao Vishnuvajjala
Xin Wei Wang
Allan Weissman
Wyndham Wilson
David Wink
George Wright
John Wunderlich
Chang-yun Xiong
Yuji Yamaguchi
De Yang
Yili Yang
Zhiya Yu
Sam Zaremba
Mei-yun Zhang
Zhongyu Zhu

NEI — NATIONAL EYE INSTITUTE

Karl Csaky
Fransico De Monasterio
Lourdes Ponce

NHGRI – NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Francis Collins
Maria Eriksson

NHLBI – NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Marcelo Amar
H. Bryan Brewer
Stephen Demosky
John Derbyshire
Michael Guttman
June-Hong Kim
Ozgur Kocaturk
Arnold Kristof
Robert Lederman
Warren Leonard
Rodney Levine
Katherine Malinda
Elliot Mcveigh
Joel Moss
Edward Neufeld
Gregorino Paone
Rosanne Spolski
John Stonik
James Taylor
Fairwell Thomas

NIA – NATIONAL INSTITUTE ON AGING

Bira Arya
Alexei Bagrov
Maire Doyle
Josephine Egan
Olga Fedorova
Edward Lakatta
Dan Longo

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2012

NIAID – NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Robert Alexander
Ghalib Alkhatib
Edward Berger
Joseph Blaney
Christopher Broder
Byron Caughey
Bimal Chakrabarti
Robert Chanock
Zhaochun Chen
Christophe Combadiere
Frank DeLeo
Barna Dey
Suzanne Emerson
Yu Feng
Elizabeth Fischer
Ivan Fuss
Kathryn Hanley
Frank Heller
Yasutaka Hoshino
Dana Hsu
Chih-chin Huang
John Inman
John Jenkins
Albert Kapikian
Paul Kennedy
Stanislava Kocianova
Franklin Koh
Peter Kwong
John La Montagne
Ching-juh Lai
Stephen Leppla
Victor Lobanenkov
Dmitiri Loukinov
John Mascola
Mahtab Moayeri
Roger Moore
David Morens
Herbert Morse
Brian Murphy
Philip Murphy
Gary Nabel
Daniel O'Brien
Gilad Ofek
Akio Ohta
Michael Otto
Susette Priola
Elena Pugacheva
Robert Purcell
Judit Quasney
Michail Sitkovsky
Warren Strober
Kanta Subbarao
Nancy Sullivan
Min Tang
Jovanka Voyich
Cuong Vuong
Rong Wang
Stephen Whitehead
Richard Wyatt
Ling Xu
Zhi-yong Yang
Yufeng Yao
Tongqing Zhou

NIAMS – NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Catherine Ettinger
Wan-Ju Li
Peter Lipsky
Rocky Tuan

NIBIB – NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Paul Smith
Edward Wellner

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2012

NICHD – EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Zuzana Kossaczka
Bai Lu
John Mcdonald
Anil Mukherjee
John Robbins
Rachel Schneerson
Shousun Szu
Roger Woodgate
Feng Zheng
Gary Zhongjian Zhang
Weiguo Zhang

NIDA — NATIONAL INSTITUTE ON DRUG ABUSE

Peter Grundt
Amy Newman

NIDCD — NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Dennis Drayna
Un-kyung Kim

NIDCR – NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Ioannis Bossis
John Chiorini
John Cisar
Giovanni Di Pasquale
Andrew Doyle
Mark Hoon
Hynda Kleinman
M Rosovitz
Nicholas Ryba
Michael Schmidt

NIDDK – NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Kenneth Jacobson
Yoonkyung Kim
Edgar Lewis
Eduardo Padlan
Delia Ramirez
Joseph Shiloach
Mariusz Szkudlinski
Bruce Weintraub
Wei Yang

NIEHS – NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

MIchelle Block
Po-See Chen
Jau-Shyong Hong
Lawrence Lazarus
Guorong Li
Giia-Shuen Peng
Liya Qin
Wei Zhang

NIMH – NATIONAL INSTITUTE OF MENTAL HEALTH

Stephen Huffaker
Joel Kleinman
Edward Unsworth
Daniel Weinberger

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2012

NINDS – NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Jozef Duyn
Jill Heemskerk
Alan Koretsky
Hellmut Merkle
Shumin Wang

Facilitating Access to HIV Treatment in Developing Countries

The 2012 Deals of Distinction™ Award was presented to the National Institutes of Health (NIH) along with the University of Illinois at Chicago (UIC), who jointly own one patent family, and to Gilead Sciences (Gilead) for license agreements granted to the Medicines Patent Pool, a newly established initiative of UNITAID, an international organization established to grant licenses for the generic manufacture and purchase of drugs against HIV/AIDS, malaria, and tuberculosis. The award, one of the most prestigious for technology transfer, was given to NIH at the Licensing Executives Society Annual Meeting on October 17th in Toronto, Canada.

NIH and Gilead are the first licensors to join the Pool and will pave the way for additional public and private patent holders to help improve the availability of medicines in developing countries. The patents licensed by NIH/UIC relate to the protease inhibitor class of HIV medicines, which are used to treat drug-resistant HIV infection or patients with high viral loads, as best exemplified to date by the drug darunavir.

The Medicines Patent Pool, established by UNITAID in July 2010, is the first of its kind for HIV medicines. The primary objective of the Medicines Patent Pool is to improve access to affordable, appropriate HIV medicines in developing countries through the voluntary licensing of critical intellectual property from pharmaceutical companies. By streamlining licensing processes for the production of generic versions of patented HIV medicines for distribution and sale in the developing world, the Pool aims to serve as a one-stop shop that will speed up the pace at which newer medicines reach patients, and will help bring prices down by encouraging competition among multiple producers. It will also spur innovation, helping to facilitate the development of needed new HIV medicine formulations for children and of 'fixed-dose combinations' that combine several medicines into one pill, thereby simplifying treatment for patients.

In making the award the model partnership between the NIH, UIC, Gilead Sciences and the Medicines Pool was cited by the Licensing Executives Society as "an innovative endeavor in facilitating access to HIV treatment in developing countries" and one that "showcases the success of public-private partnerships to improve availability of medicine".

Sound Attenuation Canopy

High sound levels in work settings can have negative effects on worker concentration and productivity. Even offices separated by walls and doors transmit sound between them. As office buildings optimize space, the allotment for each person, office, or work area often decreases. With more office workers in a given area, localized noise levels are increasing beyond optimal levels for worker productivity.

Some gains in controlling unwanted sound transmission can be made either by addressing the composition or construction of the walls and doors that separate adjacent spaces, or sealing voids or penetrations that could transfer sound with insulation. These conventional approaches still do not deliver the degree of sound attenuation often desired in a work setting, as most noise travels from office to office through the space above the suspended interior ceiling, called a plenum, now common in modern office and laboratory buildings.

The National Institute of Allergy and Infectious Diseases (NIAID) Office of Research Operations (ORO) was confronted with this sound transmission problem while developing new office and laboratory space for its employees. The problem was solved by the invention of the Sound Attenuation Canopy (SAC), an inexpensive, green, simple, passive, low-cost invention that diffuses the transmission of sound from one office or laboratory to another. NIAID, as an Institute within the National Institutes of Health (NIH), supports NIH's mission to foster creative discoveries, innovative research strategies, and their applications as a basis for protecting and improving health. The SAC directly affects human health by improving workers' working conditions and productivity.

The NIAID Office of Technology Development advised ORO regarding the intellectual property protection process and, together with one of the inventors, identified a potential licensee. The NIH Office of Technology Transfer successfully negotiated a nonexclusive license with Transwall, a manufacturer of demountable architectural wall systems. The technology currently is used in an existing NIAID leased building and will be installed in a NIAID facility currently under construction. Installation and use in other federal offices and laboratory buildings is anticipated. The licensee concurrently is actively marketing the technology.

Awardees:

NIH - National Institute of Allergy and Infectious Diseases
Judit A. Quasney
Michael H. Piziali

NIH - Office of Technology Transfer
Michael Shmilovich

Treatment of Niemann-Pick Disease Type-C with 2-hydroxypropyl-β-cyclodextrin

Currently, there are no FDA-approved therapies for Niemann-Pick disease type-C1 (NPC). NPC is a rare lethal genetic lysosomal storage disorder that results in an accumulation of cholesterol in the liver and spleen and eventually leads to neurodegeneration. 2-hydroxypropyl-β-cyclodextrin (HPβCD) is a cyclodextrin typically used by the pharmaceutical industry as an excipient. Studies of NPC in animal models have shown that HPβCD can reduce the biochemical burden associated with NPC, improving neurological pathology, decreasing neurological dysfunction, and increasing lifespan.

Development of an FDA approvable treatment for NPC has been advanced by the transfer of a proprietary formulation of HPβCD and access to the FDA drug master file from Janssen Research & Development, LLC (J&J/Janssen) to the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH).

Both NICHD and NCATS are recipients of material and technical support from J&J/Janssen. The company is providing its properietary FDA-approved formulation of HPβCD for use in both preclinical and clinical studies. J&J/Janssen's HPβCD is made by a high-yield process; it is very well-characterized and has an FDA drug master file (DMF). In addition, this material was administered to two NPC patients in September 2010 under a "compassionate use" investigational new drug (IND) after the FDA granted HPβCD orphan drug status in May 2010. So the participation of J&J/Janssen in this project is critical to its success.

Along with the material, J&J/Janssen is providing access to its DMF and toxicology expertise in support of an IND to be filed by NICHD. It is anticipated that, in the upcoming clinical trial, J&J/Janssen will also provide analytical laboratory support to the clinical trial to determine HPβCD metabolite levels in samples of patient biofluids.

Importantly, J&J/Janssen is allowing NIH to reformulate its HPβCD and redistribute it to the academic collaborators as necessary to ensure the success of the project.

The result of this technology transfer effort was the rapid accumulation of preclinical results in support of an IND application to the FDA for the use of HPβCD for treating NPC by intracerebroventricular (ICV) therapeutic administration. The further efforts of the collaborating parties will represent the best effort to advance FDA approval of a treatment for NPC.

Awardees:

NIH - Eunice Kennedy Shriver National Institute of Child Health and Human Development
Dr. Forbes D. Porter
Nicole Yanjanin
John Heiss

(continued)

Treatment of Niemann-Pick Disease Type-C with 2-hydroxypropyl-β-cyclodextrin

Awardees:

NIH - National Human Genome Research Institute
- **Bill Paven**

NIH - National Center for Advancing Translational Sciences
- **Dr. Christopher P. Austin**
- **Dr. John McKew**
- **Dr. Elizabeth Ottinger**
- **Lili Portilla**
- **Dr. Juan Jose Marugan**
- **Dr. Wei Zheng**
- **Dr. Nuria Carillo-Carrasco**
- **Xin Xiu**
- **Pramod Terse**

NIH - National Cancer Institute
- **Dr. Alan E. Hubbs**

J&J Pharmaceutical Research & Development, LLC
- **Dr. Steven Silber**
- **Dr. L. Mark Kao**
- **Ilona Scott**

AAV Technology: Delivery Vehicle of Choice for Gene Therapy

Adeno-associated viruses (AAVs) are attractive delivery vectors in the field of gene therapy. A team from the National Institutes of Health (NIH) developed AAV5-based vectors for delivering gene therapy products into parts of human bodies. Gene therapy is on the brink of becoming a common medical practice; however, developing safe and effective gene therapy products has been challenging. One major issue has been finding a delivery vector to target the diseased tissues in the body without devastating side effects. An AAV is a small virus that infects humans but is not known to cause disease and causes only a very mild immune response. These features make AAV an attractive delivery vector for gene therapy. In fact, the AAV-based vectors developed at the NIH present a popular choice for gene therapy.

The AAV5 technology has been out-licensed extensively by the NIH Office of Technology Transfer (OTT). One example was a recent exclusive and nonexclusive combination license for the commercial development of AAV5-based gene therapy products. Under this agreement, Amsterdam Molecular Therapeutics (AMT) will have exclusive rights to develop treatments for a restricted number of disease indications, but nonexclusive rights to develop treatments for other diseases. As such, NIH OTT not only allows sufficient incentive for the expedited therapeutic development of AAV5 technology by one licensee, but also ensures the continued availability of AAV technology widely to future commercial partners. In support of the NIH's public health mission, NIH OTT also agreed to reduce royalties when AMT collaborates with acadmic institutions on therapies for ultra orphan indications.

This is just one approach that NIH OTT uses under its license agreements to provide incentives for companies targeting rare and neglected diseases, which broadens the application of NIH technologies to meet public health needs. The technology transfer effort of the NIH OTT has maximized the return on publicly funded research, and commercialization of the scientific discovery of AAV5 technology has advanced the public health mission of the NIH and will provide directe benefit to patients worldwide.

Awardees:

NIH - National Heart Lung and Blood Institute
Dr. Robert Kotin
Dr. John A. Chiorini

Richard Rodriguez

As Director of the Division of Technology Development and Transfer (DTDT) in the National Institutes of Health (NIH) Office of Technology Transfer (OTT), Richard Rodriguez has provided a high degree of leadership and vision instrumental to enhancing the transfer of innovative technologies developed by NIH and Food and Drug Administration (FDA) scientists to industrial partners. His efforts have enabled new biomedical products to reach the consumer, as well as unique biological materials to be made available for use as research tools by the private sector.

Rodriguez has done an exceptional job managing DTDT by improving systems and automating work processes. Under his leadership, DTDT has implemented a paperless work process for patenting and liensing activities using a SharePoint adaptation that automates the entire process and workflow. Centralized storage fosters a more open, collaborative environment, which facilitates the ease of document review, processing, and reassignment to other individuals. The net result is an efficient and flexible system for processing much of OTT's internal work, and an improvement in quality and timeliness that allows staff to reappropriate the time saved to focus on critical activities, such as patent prosecution management and licensing negotiations.

Rodriguez has also played an important role in developing new model agreements for licensing NIH and FDA inventions to startup companies and nonprofits. The new Model Nonprofit License Agreement was announced at a White House Conference on Science, Technology, and Innovation for Global Development as part of the President's "Startup America" initiative. The new license expedites the transfer of NIH and FDA patents for drugs and biologics under terms that are favorable to companies in the startup phase. To date, OTT has received 19 startup license applications and executed three option agreements and one startup Patent License Agreement.

Due to budget constraints, OTT has been unable to fill the position of General Medicine Branch Chief. As many Branch activities are mediated through the Branch Chief, this position is important to the success of the Branch. Rodriguez has served as Acting Branch Chief for more than 18 months. He sets an excellent example by shouldering the additional burden while continuing his many and diverse duties as DTDT Director. While he has juggled these two roles far longer than expected, his efficiency, accessibility and positive attitude have served the General Medicine Branch well, and it is functioning at an outstanding level.

Rodriguez has shown the important leadership skills that have energized those working for him and improved broader relationships within and outside OTT. He is creative, inspires trust, exhibits originality, and is decisive as needed. He communicates a clear message, delegates to promote team development, and works with his Branch chiefs to allow them to achieve their potential.

Dr. Thomas Stackhouse

Tom Stackhouse, Ph.D., is Associate Director of the Technology Transfer Center at the National Cancer Institute (NCI). The Center serves as the focal point for the implementation of legislation relating to collaborative agreements and inventions for the NCI, including the Frederick National Laboratory of Cancer Research. Dr. Stackhouse oversees the satellite office located in the Frederick National Laboratory of Cancer Research, which provides a full range of technology transfer servics to NCI's scientists located in Frederick.

Dr. Stackhouse is the NCI's Alternate laboratory Representative to the FLC. He served on the FLC Executive Board for two terms as a Member-at-Large, as well as on the Recognition, State and Local Government, and Education and Training committees. For the past two years, he has been responsible for advanced training courses at the FLC's annual meeting. In this capacity he has helped member laboratories and other meeting attendees learn about a variety of topics, including Deemed Export and Export Control, Software Licensing, and the America Invents Act. He has also served as Vice-Chair of the Education and Training Committee, assisting with assembling instructors for basic and intermediate training sessions at the national meeting.

As a member of the FLC Executive Board, Dr. Stackhouse offered the perspective of a problem-solving professional who could reconcile diverse points of view and propose workable solutions. His many years of experience as a scientist, technology transfer professional, and a seasoned supervisor enable him to approach situations in a multifaceted manner, taking all stakeholders' interests into account while making decisions.

Dr. Stackhouse is not only active at the national level, but also at the regional level for the Mid-Atlantic Region (MAR). For the past six years, he has served on the MAR's Planning Committee, where his contributions have helped shape the annual regional conference and supported many regional initiatives. He and his staff are also active leaders on the Washington, D.C. metro area's planning team, which is responsible for MAR activities in the area.

In addition to FLC activities, Dr. Stackhouse shares his expertise through direct interactions with other federal laboratories. He devises strategies and oversees activities that maximize the commercialization of NCI's inventions to improve public health and provide a return on investment. NCI's patent portfolio currently has several thousand patents and patent applications, and the licensing of this portfolio by the NIH Office of Technology Transfer generated over $60 million of royalty income in FY11.

Chief Science Officer (CSO) Development Training Certificate Program Team "CSO Boot Camp"

In the Mid-Atlantic Region, Maryland is in an enviable position with regard to biotechnology-related resources that encourage and support entrepreneurial efforts. Academic institutions, a federal laboratory, a committed county department of economic development, and a unique small business have developed an effective consortium to leverage these resources. The potential for human capital to support this entrepreneurial growth is further augmented by the number of graduate and post-doctoral programs available in the region. Ironically, a significantly steady decrease in the availability of academic positions for new graduate and post-graduate-level scientists has created an additional talent resource pool for new and existing biotechnology companies. Despite these significant human capital resources, traditional academic graduate and post-graduate training do not focus on teaching the business leadership and management skills required to attain successful industry scientist-level positions. This confluence of circumstances was the catalyst for the formation of a unique and highly synergistic consortium to remedy this situation.

Together, the NIH Office of Technology Transfer, Montgomery College, the Foundation for Advanced Education in the Sciences (FAES) Graduate School at NIH, Montgomery County Department of Economic Development, and Human Workflows, LLC, combined forces to develop a novel training certificate program focused on teaching academic scientists the business leadership and management skills necessary to be successful in industry. The program consists of a 36-credit house, 12-week course that teaches academic and research scientists the business skills valued by industry.

Unlike more traditional generic business management offerings, the modules of this "CSO Boot Camp" on leadership, negotiation, line management, finance, project management and communication have been customized to emphasize how each of these skill sets impacts scientists functioning in industry. The result is the development of scientist leaders who can fast-track in industry positions regardless of whether they choose management or research, and a pipeline that provides the highly skilled workforce necessary to staff and propel important science and technology businesses into the future.

With the first CSO course having been completed in 2011, it is too soon to definitively determine the practical impact of the Boot Camp on the careers of the participants and the companies that hired them. However, feedback from the students has been unanimously positive; in fact, their sole criticism was that the course was too short. Externally, there is significant interest in the program outside of Montgomery County, Md., where the course is currently being taught. As a result of this interest, efforts are underway to leverage leading-edge online technologies available at Montgomery College to further develop the CSO course into an online program that can be deployed both synchronously and asynchronously. The ultimate measure of the impact of the CSO programs will be the placement records of graduates of the proram and their success in those positions.

(continued)

Chief Science Officer (CSO) Development Training Certificate Program Team "CSO Boot Camp"

Awardees:

Montgomery County Development of Economic Development
Fizie Haleem

Human Workflows, LLC
Randall K. Ribaudo

NIH - Office of Technology Transfer
Mojdeh Bahar

Foundation for Advanced Education in the Sciences Graduate School at NIH
Steven Ferguson

An Interactive Software Package for the Analysis of Microarray Data

The emergence of bioinformatics tools, which integrate molecular biology and genomics with computer-based information technology, is bringing about a revolution in our understanding of the molecular mechanisms underlying normal and dysfunctional biological processes. The microarray is one such tool that caused a paradigm shift in the manner in which researchers collect and analyze genetic data. Microarrays allow researchers to monitor the whole genome in a single experiment thus enabling researchers to obtain a picture of the complex and orchestrated interactions that exist among thousands of genes simultaneously.

Since many biologists are not trained in computer programming and statistical analysis, they often have difficulty translating microarray data into meaningful biological conclusions. The technology in this nomination describes a comprehensive desktop software package invented by Dr. Richard Simon and colleagues of the National Cancer Institute's (NCI) Biometric Research Branch (BRB). The software performs sophisticated and powerful calculations that allow scientists to analyze their microarray data by discovering biologically significant patterns in gene expression data. The package, known as BRB-Array Tools, is widely recognized as the most statistically sound package available for the analysis of microarray data.

BRB-Array Tools has been transferred using mechanisms designed to facilitate broad dissemination of the software to a variety of users. After conferring with NCI's TTC on the most effective strategy to accomplish this goal, a model for distribution was developed and implemented in less than a month in which the software could be downloaded from the BRB site at no cost to users from academic and non-profit institutions and to commercial users for a reasonable, one-time fee. Requestors from non-profits are required to click through to accept the terms of an online Software Transfer Agreement (STA) while commercial entities are directed to NIH's Office of Technology Transfer (OTT) where they are required to negotiate a one-time, perpetual, non-exclusive license.

Prior to the successful implementation of the technology transfer mechanisms that allowed for web-based distribution, very few institutions at NIH adopted systems that allowed for online request of materials and online execution of the necessary technology transfer agreement. Today, a number of technology transfer offices are exploring online methods of documenting transfer of materials.

This technology transfer effort represents a successful experiment in providing researchers with powerful tools to analyze complex information in the most efficient manner possible. BRB-Array Tools has been the subject of over 13,000 Software Transfer Agreements to government agencies, universities, and research institutions in 66 countries as well as 35 non-exclusive licenses to commercial entities. BRB-Array Tools is continuously being developed and improved by Dr. Simon and as its utility becomes more evident to individuals in the field, more technology transfer mechanisms will be put in place to accommodate the growing demand.

(continued)

An Interactive Software Package for the Analysis of Microarray Data

Awardees:

NIH - National Cancer Institute
Dr. Richard Simon
Robert Wagner

NIH - Office of Technology Transfer
Michael Shmilovich

Development of Eribulin, a Potent Anti-Cancer Agent from a Marine Sponge

Natural products have formed the basis of traditional medicine systems for thousands of years and have been the single most productive source of leads for the development of cancer drugs. This nomination describes the discovery of halichondrin B, a compound isolated from a species of marine sponge, and the subsequent preclinical and clinical research and development of a related synthetic compound into the novel cancer drug Eribulin.

A variety of technology transfer methods were put in place to facilitate involvement of the parties necessary to bring halichondrin B to market and to overcome various obstacles that were encountered along the way. After halichondrin B was isolated by Japanese scientists from Eisai Inc. in 1986, NCI accepted the compound for initial preclinical testing and made it the original test case for the NCI 60 cell line screen. During this testing, halichondrin B's unique mechanism of action as a microtubule destablizer was elucidated.

After realizing the compound had tremendous potential as an anticancer agent, NCI prioritized its development and began to explore methods to generate sufficient quantities for further preclinical and clinical testing. A Letter of Collection (LOC) was put into place between NCI and the New Zealand government to harvest the species of sponge that yields halichondrin B. After discovering that one metric ton of sponges would only yield 300 mg of the compound, it became clear that the development of synthetic analogs would be the most viable option for further development of the compound. Supported by grants from NCI, Harvard researchers developed synthetic methods and licensed the synthetic methodologies and patents to Eisai, who subsequently developed many synthetic analogues to halichondrin B.

Eisai then negotiated a screening Material Transfer Agreement (MTA) with NCI under which NCI performed studies comparing the anticancer activity of the synthetic analogues with that of the parent compound. These studies demonstrated that the synthetic analogs were as safe and effective as the parent and provided strong rational for the product's continued development. In 2004, Eisai and NCI entered into a Clinical Trials Cooperative Research and Development Agreement (CRADA) to finalize preclinical studies and initiate early phase 1 clinical trials to evaluate the safety of the synthetic analog in patients with cancer. These studies resulted in FDA priority approval of Eribulin on November 15, 2010 for the treatment of patients with metastatic breast cancer. This technology transfer effort has been of critical importance as there are limited treatment options for women with aggressive forms of late-stage breast cancer who have already received other therapies. The CRADA term was extended and the parties currently have plans to explore development of the synthetic analog of halichondrin B for treatment of other types of tumors.

Awardees:

NIH - National Cancer Institute
Dr. Sherry Ansher
Dr. David Newman

Use of Therapeutic Antibodies as a Novel Treatment for Multiple Sclerosis

Multiple sclerosis (MS) is a disease of the central nervous system in which the immune system attacks the brain and spinal cord, typically resulting in muscle weakness, problems with vision and coordination, pain, and in some patients, cognitive impairments. The disorder affects approximately 400,000 people in the U.S. and more than 2.5 million people worldwide. Patients with relapsing forms of MS are currently treated with one of three FDA-approved interferon beta agents or with glatiramer acetate. Unfortunately, each of these treatments is not effective in a substantial number of patients. Therefore, there is an urgent need to develop new and more effective treatments for MS, especially for those MS patients that fail to respond or respond only partially to standard immunotherapy.

Drs. Bielekova, Martin, and McFarland of the National Institute of Neurological Disorders and Stroke (NINDS) of the NIH discovered that daclizumab, a humanized antibody to the interleukin-2 receptor alpha chain (IL-2Rα) is effective in treating MS. Daclizumab was first developed in the lab of Dr. Waldmann and approved in the U.S. for preventing organ transplant rejection. The NIH investigators led a small clinical trial of patients with MS who did not respond to interferon-beta alone and found that adding daclizumab improved patient outcome. Patients who received the combined therapy had a 78 percent reduction in new brain lesions and a 70 percent reduction in total lesions, along with other significant clinical improvements. Daclizumab was also very well tolerated. Based on this trial the NIH investigators anticipated that daclizumab and other anti-IL-2Rα antibodies would be useful either as combination therapy or stand-alone treatment in MS and patent applications disclosing these findings were filed by the NIH.

The technology is exclusively licensed to Abbott (formerly Facet Biotech/PDL) who in collaboration with Biogen Idec has initiated and is currently enrolling patients for a Phase III study with a subcutaneous formulation of daclizumab intended for monthly administration. The licensee has recently concluded a study that enrolled 230 patients with MS which confirmed that using daclizumab as an add-on therapy helped patients whose symptoms had relapsed while they were taking interferon-beta. Dr. Bielekova has led several small scale clinical trials at the NIH that have lead to the conclusion that daclizumab monotherapy is effective in most patients who experienced persistent MS disease activity with interferon-beta therapy. While Drs. Bielekova, Martin, McFarland and Waldmann helped the transfer of this technology from bench to bedside by conducting clinical trials and disseminating the results of their findings, the technology transfer professionals at the NIH helped transfer this valuable technology to biopharmaceutical companies to ensure that FDA approved therapies are developed that can further help in treating MS worldwide.

Awardees:

NIH - National Institute of Neurological Disorders and Stroke
Dr. Bibiana Bielekova
Dr. Roland Martin
Dr. Henry McFarland

NIH - National Cancer Institute
Dr. Thomas Waldmann

(continued)

Use of Therapeutic Antibodies as a Novel Treatment for Multiple Sclerosis

Awardees:

NIH - National Institute of Neurological Disorders and Stroke
NIH - National Cancer Institute
Dr. Melissa Maderia
Dr. Martha Lubet

NIH - National Cancer Institute
Dr. Charlotte McGuinness
Thomas Close

NIH - Office of Technology Transfer
Dr. Surekha Vathyam
Mojdeh Bahar
Richard Rodriguez

Vibro-Tactile Stimulation Device and Method for Swallowing Disorders

The transferred technology is a non-invasive, intensive, swallowing retraining device that combines sensory stimulation with motor retraining to rehabilitate swallow function, initially targeted for dysphagia patients. Dysphagia is a common disorder that creates difficulty swallowing. Patients at risk of choking on fluid or food face a risk of life-threatening aspiration pneumonia and may need to be fed through a tube. Dysphagia may occur as a result of stroke, brain injury, tumor removal, or neurodegenerative disease with associated high medical care costs as well as decreased quality of life and social opportunity. The prevalence of dysphagia is likely to increase in the U.S. as the population ages.

The overall purpose of the technology is to provide a new system for daily self-training of swallowing that is less costly and potentially more effective than options currently available. The device provides triggering of the reflexive component of swallowing synchronous with volitional retraining throughout the day in a patient's own environment. This can augment or replace current approaches to rehabilitation that depend upon the patient having access to speech pathologists for a limited intervention of only a few hours a week.

Following discussions with multiple companies and a CRADA for comparison to an implanted system, the technology was licensed to Passy-Muir, Inc., a small, privately owned company based in Irvine, California with a worldwide reputation for the delivery of high quality medical devices for voice and swallowing. Its product line includes non-mechanical swallowing and speaking valves for adults and children. Passy-Muir was granted rights to the technology under an exclusive license with the National Institutes of Health.

The nominees were intricately involved in the transfer process. Christy L. Ludlow, Ph.D., formerly at the Laryngeal and Speech Section of the NINDS at NIH, was the main inventor of the technology. Dr. Ludlow has extensive knowledge and experience studying vibratory stimulation as a trigger for swallowing. Laurie Arrants, M.S., the Technology Development Coordinator for NINDS, was a steadfast champion of the technology within NINDS and for years advised Dr. Ludlow about positioning the device for commercialization and marketed the technology. Heather Gunas, J.D., M.P.H., a Technology Transfer Specialist at NIH, negotiated numerous, related agreements including a CRADA; she also conducted a direct marketing campaign to multiple companies which included Passy-Muir. Dr. Ludlow, supported by Ms. Gunas and Arrants, worked diligently to show Passy-Muir that its ongoing distribution, training programs, and target patient population were suited perfectly for the device. Passy-Muir then negotiated an exclusive license with Michael Shmilovich, J.D., and Susan Ano, Ph.D., both from the Division of Technology Development and Transfer, OTT, NIH. The two worked with the company to develop realistic milestones based on the developmental and regulatory pathway required for marketing.

Awardees:

NIH - National Institute of Neurological Disorders and Stroke
Dr. Christy Ludlow

(continued)

Vibro-Tactile Stimulation Device and Method for Swallowing Disorders

Awardees:

NIH - National Institute of Neurological Disorders and Stroke
Heather Gunas
Laurie Arrants

NIH - Office of Technology Transfer
Michael Shmilovich
Dr. Susan Ano

Congratulations to Inventors on NIH Patents Issued in FY 2011

CC- CLINICAL CENTER

Marek Franaszek
Jiang Li
King Li
Ziv Neeman
Ronald Summers
Bradford Wood

NCI - NATIONAL CANCER INSTITUTE

Stefan Ambs
Nese Atabey
Sook-Hee Bang
Todd Barry
Susan Bates
Tapan Bera
Jay Berzofsky
John Beutler
Brenda Boersma-Maland
Donald Bottaro
Michael Boyd
Diane Breckenridge
Terrence Burke
Natasha Caplen
Bryce Chackerian
Yoon Cho-Chung
Mike Citro
David Covell
Frank Cuttitta
Frank DeRosa
Dimiter Dimitrov
Marcin Dyba
Ted Elsasser
Michael Emmert-Buck
Barbara Felber
Yang Feng
William Figg
David Fitzgerald
Yang Gao
Alessio Giubellino
Sharon Glynn
Kenichi Hanada
Curtis Harris
Lee Helman
Stephen Hewitt
Mitchell Ho
Melinda Hollingshead
Joseph Hrabie
Cary Hsu
Tomoko Ise
Stas Kahl
Preeya Kapur
Syed Kashmiri
Larry Keefer
Javed Khan
Dennis Klinman
Henry Krutzsch
Byungkook Lee
Michael Lerman
Steven Libutti
William Marston Linehan
Paul Liu
Philip Lorenzi
Douglas Lowy
Ilya Lyakhov
Crystal Mackall
Alfredo Martinez
Chiara Mazzanti
Mariam Mckee
Daniel McVicar
Susan Mertins
Luis Montuenga
Richard Morgan
Robert Moschel
Makoto Nagashima
Satoshi Nagata
Leonard Neckers
Danielle Needle
Michael Nickerson
Barry O'Keefe
Ira Pastan
Geoffrey Patton
Gary Pauly
George Pavlakis
Sandra Pike
Ruben Pio
Margherita Rosati
Steven Rosenberg
Andreas Rosenwald
Jeffrey Rubin
Joseph Saavedra
Elliott Schiffmann
John Schiller
Jeffrey Schlom
Laura Schmidt
Thomas Schneider
Kenneth Snader
Louis Staudt
William Stetler-Stevenson
Mary Stracke
Nadya Tarasova
Jorge Toro
Giovanna Tosato
Kwong-Yok Tsang
Maria Turner
Leon van den Broeke

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2011

NCI - NATIONAL CANCER INSTITUTE

James Vincent
Bahu Rao Vishnuvajjala
Thomas Walsh
Qiong Wang
Michelle Warren
David Waterhouse
Guangping Wei
Jun Wei
John Weinstein
Wyndham Wilson
David Wink
Laiman Xiang
Xia Xu
James Yang
Qin Yang
Lei Yao
Teizo Yoshimura
Berton Zbar
Regina Ziegler

NHGRI – NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Mauricio Arcos-Burgos
Lawrence Brody
Brian Capell
Francis Collins
Maximilian Muenke

NHLBI – NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Anthony Aletras
Christelle Bourgeois
S Narasimhan Danthi
John Derbyshire
Neal Epstein
Shahin Hassanzadeh
Daniel Herzka
Paul Hwang
Yoichiro Ito
Ju-Gyeong Kang
Parag Karmarkar
Robert Lederman
Warren Leonard
Omar Mian
Elliot McVeigh
Joel Moss
Willmar Patino
Rosanne Spolski
Linda Stevens
Adrian Wiestner
Steve Winitsky

NIA – NATIONAL INSTITUTE ON AGING

Arya Biragyn
Nigel Greig
Harold Holloway
Qian-sheng Yu

NIAAA – NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Gary Murray

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2011

NIAID – NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Oral Alpan
Yasmine Belkaid
Ursula Buchholz
Jens Bukh
Alexander Bukreyev
Bimal Chakrabarti
Robert Chanock
Zhaochun Chen
Peter Collins
Suzanne Emerson
Yasutaka Hoshino
Peter Jahrling
Tirumalai Kamala
Shaden Kamhawi
Albert Kapikian
Wing-pui Kong
Stephen Leppla
Shi-hui Liu
Paolo Lusso
Polly Matzinger
Herbert Morse
Bernard Moss
Brian Murphy
Gary Nabel
Robert Purcell
Jose Ribeiro
David Sacks
Alexander Schmidt
Mario Skiadopoulos
Nancy Sullivan
Michael Teng
Jesus Valenzuela
Stephen Whitehead
Thomas Wynn
Zhi-yong Yang

NIAMS – NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Catherine Ettinger
Peter Lipsky
John O'Shea

NIBIB – NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Nicole Morgan
Paul Smith
Edward Wellner

NICHD – EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Richard Blye
Douglas Brenneman
Niamh Cawley
Jean Grivel
Hyun Kim
Yoke-peng Loh
Leonid Margolis
Edward Mertz
James Mills
Catherine Spong
Constantine Stratakis
James Sullivan

NIDCR – NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Bruce Baum
Thomas Bugge
Mark Hoon
Nicholas Ryba

(continued)

Congratulations to Inventors on NIH Patents Issued in FY 2011

NIDDK – NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Carole Bewley Clore
Kenneth Jacobson
Eduardo Padlan
Harvey Pollard
S. Stoney Simons
Susanna Tchilibon

NIEHS – NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Perry Blackshear
Joan Graves
Deborah Stumpo
Darryl Zeldin

NIGMS – NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Faith Pangilinan

NIMH – NATIONAL INSTITUTE OF MENTAL HEALTH

Silvia Buervenich
F Castellanos
Robert Innis
Gonzalo Laje
Neva Lazarous
Husseini Manji
Francis McMahon
David Neville Jr
Victor Pike
Edward Unsworth
Yi-Liu Yuan
Sami Zoghbi

NINDS – NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Roscoe Brady
John Hallenbeck
Christine Kaneski
Stefanie Kluepfel-Stahl
George Nascimento
Raphael Schiffmann
Sang-Hoon Shin
Alfonso Silva
Maria Spatz
Hidetaka Takeda
Hideaki Wakita

NLM – NATIONAL LIBRARY OF MEDICINE

Tao Tao

OD – OFFICE OF THE DIRECTOR

Sharon Greenblum

Use of Therapeutic Antibodies as a Novel Treatment for Multiple Sclerosis

Multiple sclerosis (MS) is a disease of the central nervous system in which the immune system attacks the brain and spinal cord, typically resulting in muscle weakness, problems with vision and coordination, pain, and, in some patients, cognitive impairments. The disorder affects approximately 400,000 people in the U.S. and more than 2.5 million people worldwide. Patients with relapsing forms of MS are currently treated with one of three FDA-approved interferon-beta agents or with glatiramer acetate. Unfortunately, each of these treatments is not effective in a substantial number of patients. Therefore, there is an urgent need to develop new and more effective treatments, especially for those MS patients who fail to respond or respond only partially to standard immunotherapy.

A team from the National Institute of Neurological Disorders and Stroke (NINDS) discovered that daclizumab, a humanized antibody to the interleukin-2 receptor alpha chain (IL-2Rα) approved in the U.S. for preventing organ transplant rejection, is effective in treating MS. They led small clinical trial of MS patients who did not respond to interferon-beta alone and found that adding daclizumab improved patient outcome. Patients who received the combined therapy had a 78-percent reduction in new brain lesions and a 70-percent reduction in total lesions, along with other significant clinical improvements. The daclizumab was also very well tolerated. Based on this trial, the NINDS team anticipated that daclizumab and other anti-IL-2Rα antibodies would be useful either as combination therapy or stand-alone treatment in MS, and patent applications disclosing these findings were filed by the National Institutes of Health (NIH).

The technology is exclusively licensed to Abbott (formerly Facet Biotech/PDL) which, in collaboration with Biogen Idec, has initiated and is currently enrolling patients for a Phase III study. The licensee has recently concluded a study that enrolled 230 patients with MS, which confirmed that using daclizumab as an add-on therapy helped patients whose symptoms had relapsed while they were taking interferon-beta. Several other small-scale clinical trials at NIH have led to the conclusion that daclizumab monotherapy is effective in most patients who experienced persistent MS disease activity with interferon-beta therapy. While the team helped the transfer of this technology from bench to bedside by conducting clinical trials and disseminating the results of their findings, the technology transfer professionals at NIH helped transfer this valuable technology to biopharmaceutical companies to ensure the development of Food and Drug Administration (FDA)-approved therapies that can help treat MS worldwide.

Awardees:

National Institute of Neurological Disorders and Stroke
Dr. Bibiana Bielekova
Dr. Roland Martin
Dr. Henry McFarland
Dr. Melissa Maderia
Laurie Arrants
Dr. Charlotte McGuinness

(continued)

Use of Therapeutic Antibodies as a Novel Treatment for Multiple Sclerosis

Awardees:

National Cancer Institute
Dr. Thomas Waldmann
Thomas Close

NIH Office of Technology Transfer
Dr. Surekha Vathyam
Mojdeh Bahar
Richard Rodriguez

Laurie Arrants
Director, Technology Transfer Office, NINDS

As Director of the Technology Transfer Office at the National Institutes of Health's (NIH) National Institute of Neurological Disorders and Stroke (NINDS), Laurie Arrants has provided the leadership and vision that have been instrumental in facilitating transfer of the innovative research carried out by the NINDS scientists to industrial partners and collaborators. She has demonstrated novel and creative methods to accomplish the transfer of numerous technologies and services on behalf of NINDS, as well as the entire NIH community. She is recognized agency-wide for her efforts to promote efficiencies and enhance collaborative efforts, and has demonstrated leadership in promoting the best practices for technology transfer. Because of her efforts, NINDS investigators are well-informed about the commercialization process, provided with guidance concerning regulatory issues, and assured that proper agreements are utilized to most effectively advance their science.

Ms. Arrants is widely considered to be an expert in technology transfer, and her advice and input are sought by all levels at NIH and across the federal laboratory community. She is also active in the technology transfer community. She has served as a Member-at-Large on the Executive Board of the Federal Laboratory Consortium for Technology Transfer (FLC), a Fundamentals Training Instructor at FLC National meetings, and a vital member of the Mid-Atlantic Region and the Region's Planning Committee.

Ms. Arrants is currently serving as Vice Chair of the NIH/FDA Technology Development and Transfer Committee (TDTC). As a member of the TDTC, she worked to increase access to shared technology transfer data, helped to improve procedural functions that provide cost savings to NIH, and provided valuable input on improving marketing strategies. She is also a recipient of the NINDS Individual Merit Award, the HHS Special Act or Service Award, the NCI Customer Service Award, and the NCI Technology Transfer Service Award.

Ms. Arrants' willingness to take on the difficult jobs and ask the difficult questions has made her one of the most respected technology transfer professionals at NIH. Her desire to provide the best service to NINDS through strong advocacy and innovative thinking is unparalleled. She is always willing to extend herself personally, think creatively, and consider new and different approaches to long-held ideas.

National Cancer Institute

The Mid-Atlantic Region State and Local Economic Development Award recognizes successful initiatives that involve partnership between state or local economic development groups and federal laboratories for economic benefit in the region.

The FLC Mid-Atlantic Region (FLC-MAR) has actively engaged academia and state and local economic development organizations around the region in fostering technology development and technology transfer. Two groups in particular stand out in this effort: the FLC/Southeastern Virginia planning group and the FLC/Washington Metro planning group, which focuses on Maryland, Washington DC, and northern Virginia.

Technology innovation is one of the key economic drivers of local economies and originates from a variety of sectors within a region. In order to harness the maximum impact of a region's technological capabilities, it is necessary to foster an atmosphere of collaboration among these sectors. The FLC-MAR has been actively involved in organizing forums for state and local governments, federal technology-based agencies, universities, industry, and economic development agencies to showcase the various partnering opportunities, technologies and services available from each sector.

During 2010-2011, the FLC-MAR organized three forums designed to take full advantage of the vast technology resources available in the region. These forums were created to encourage broad involvement by relevant sectors of the local community and, at the same time, to take full advantage of the technology strength of the respective areas in the Mid-Atlantic Region. All of these events provided an interactive forum highlighted by participation from all relevant stakeholders. Local universities and economic development agencies were well-represented, and they were given the opportunity to seek or provide assistance for various technology-related initiatives. This strategy had a synergistic effect, in that problems faced by members of one sector could be addressed by technologies or solutions from another. The FLC planning groups have been able to establish and sustain strong, positive networking partnerships with a range of academic and economic development organizations in support of mutual goals. Specifically, federal labs are combining their technology development with commercialization efforts by academia and the support of business development by the private sector to foster technology and economic growth.

Awardees:

NIH Office of Technology Transfer
Mojdeh Bahar

National Cancer Institute
Charles Salahuddin
Dr. Thomas Stackhouse

Dr. Samuel Bish
Licensing and Patenting Manager, NIH Office of Technology Transfer

The structure and function of the Office of Technology Transfer (OTT) at the National Institutes of Health (NIH) require new Licensing and patenting managers to be involved in all aspects of technology transfer, specifically technology valuation, patent prosecution, license negotiation, marketing of technologies, and the review of Cooperative Research and Development Agreements (CRADAs).

Since joining OTT less than three years ago, Dr. Samuel E. Bish has already excelled in all of the above-mentioned functions. He is currently handling a patent docket of more than 200 cancer technologies concentrated on cancer immunotherapeutics, and he has drafted and executed a wide number and variety of licenses. He has worked diligently on these agreements on behalf of the NIH, and has demonstrated excellent negotiation skills in bringing them to completion. Through these achievements he has demonstrated superior analytical, communication, and interpersonal skills — unusual skill sets for someone who has only fairly recently become a technology transfer practitioner.

With regard to his licensing activities, Dr. Bish has been presented with some complex and challenging situations. In two cases, he worked on deals for licenses that had been terminated. He successfully negotiated new licenses for the same intellectual property and, in doing so, handled complex issues of co-ownership, patent prosecution reimbursement, and CRADA subject invention determination. In both scenarios, Dr. Bish persevered and brought the negotiations to a close, resulting in two licenses. In accomplishing this, Dr. Bish demonstrated his ability to be a tough negotiator with unparalleled attention to detail. As to patent matters, Dr. Bish manages a rather large and complex portfolio of cancer immunotherapy inventions coming from some of the most senior and prestigious investigators in the field.

In addition to performing his own tasks, Dr. Bish educates others about technology transfer. For example, he participated in an interview with the NIH Office of Intramural Training and Education (OITE), answering questions about transitioning from research to technology transfer. He also participated in a similar forum at the University of Maryland, Department of Cell Biology and Molecular Genetics Graduate Student Association.

Dr. Bish is a hard-working, diligent team player who excels at dealing with challenging situations. He is a sublime multi-tasker. What has impressed both his colleagues in OTT, as well as the scientists and company professionals with whom he works, is his can-do, positive attitude — which makes working with him a true pleasure!

A Lifesaving Diagnostic Test for Cancer Patients

Most people are aware that anti-cancer treatments often have negative side effects, but patients are willing to tolerate these side effects for the potential life-saving effects of the treatment. However, some patients treated with the anti-cancer drug 5-Fluorouracil (5-FU) will have fatal reactions typically caused by cardio-toxicity. A life-saving diagnostic test to identify cancer patients who may experience 5-FU toxicity has been developed by scientists at the National Cancer Institute (NCI). Thus, it is possible to avoid 5-FU toxicity by using this diagnostic screening test prior to the administration of 5-FU.

The diagnostic test is based on screening for a mutation in the dihydropyrimidine dehydrogenase (DPD) gene. DPD is involved with the degradation of 5-FU, and it has been shown that patients exhibiting 5-FU toxicity have low DPD activity levels. In 1994, Dr. Frank Gonzalez and his colleague at NCI determined the molecular basis (a splicing mutation) for the DPD deficiency observed in patients with 5-FU toxicity and developed a method to detect the mutation. Since then, this discovery has been translated into multiple commercial products that are used to detect the mutation and allow healthcare providers to offer optimal anti-cancer treatment.

5-FU is used for the treatment of multiple cancers, including breast and colon cancers. In the United States, approximately 275,000 cancer patients receive 5-FU annually. It is estimated that 3% of those patients develop some degree of toxic reaction. Patients suffering toxic reactions are difficult and expensive to treat further. Approximately 15% of those developing a toxic reaction will die as a result of exposure to 5-FU. More than 1,300 patients in the United States die each year as a result of 5-FU toxicity. These deaths are all potentially avoidable if patients are screened prior to the administration of 5-FU using the diagnostic test developed by NCI.

This technology has been licensed nonexclusively to several licensees. The transfer of this technology through these nonexclusive licenses has enabled the wide dissemination of this test in the United States and Europe. As a result of these multiple licenses, many more people around the globe can forego being treated by a drug that may do more harm than good. The wide dissemination of this life-saving diagnostic test promotes the NIH mission of improving public health.

Awardees:

National Cancer Institute
Dr. Frank Gonzalez

Universidad de Extremadura (Spain)
Dr. Pedro Fernandez-Salguero

NIH Office of Technology Transfer
Dr. Betty Tong
Mojdeh Bahar

2010 STEM Postdoc Conference Committee

The STEM Award recognizes the efforts of an FLC laboratory employee or team that has demonstrated outstanding work in support of science, technology, engineering, and mathematics (STEM) education during the past year.

The annual STEM Postdoc Conference and Career Fair matches Washington, D.C. area postdoctoral fellows with local companies looking for highly qualified science, technology, engineering or mathematics (STEM) talent. The conference provides a content-rich agenda, including keynote addresses by technology leaders and entrepreneurs, panels highlighting traditional and nontraditional career opportunities, and resume consultants to provide feedback on effective resume writing. The centerpiece of the event is always the career fair. At the 2010 conference, attendees met with over 40 companies, and a number of the attendees scored interviews for possible employment.

The Conference Planning Committee is composed of representatives from federal agencies, economic development organizations, and private industry. A number of the committee members have served for multiple years because they believe strongly that the conference serves the valuable educational and economic development function of building strong relationships between the region's federal laboratories and its private companies, and in sustaining a highly educated and trained workforce through this enrichment and networking opportunity.

In its 5-year history, the conference has attracted 2,250 postdoctoral fellows and 151 recruiting companies. A number of companies have derived enough value from the conference that they have participated in subsequent ones.

Awardees:

NIH Office of Technology Transfer
Steven Ferguson
Mojdeh Bahar

National Institute on Alcohol Abuse and Alcoholism
Srinagesh Koushik

A Life-Saving Diagnostic Test for Cancer Patients

Most people are aware that anti-cancer treatments often have negative side effects, but patients are willing to tolerate these side effects for the potential life-saving effects of the treatment. However, some patients treated with the anti-cancer drug 5-Fluorouracil (5-FU) will have fatal reactions typically caused by cardio-toxicity. A life-saving diagnostic test to identify cancer patients who may experience 5-FU toxicity has been developed by scientists at the National Cancer Institute (NCI). Thus, it is possible to avoid 5-FU toxicity by using this diagnostic screening test prior to the administration of 5-FU.

The diagnostic test is based on screening for a mutation in the dihydropyrimidine dehydrogenase (DPD) gene. DPD is involved with the degradation of 5-FU, and it has been shown that patients exhibiting 5-FU toxicity have low DPD activity levels. In 1994, Dr. Frank Gonzalez and his colleague at NCI determined the molecular basis (a splicing mutation) for the DPD deficiency observed in patients with 5-FU toxicity and developed a method to detect the mutation. Since then, this discovery has been translated into multiple commercial products that are used to detect the mutation and allow healthcare providers to offer optimal anti-cancer treatment.

5-FU is used for the treatment of multiple cancers, including breast and colon cancers. In the United States, approximately 275,000 cancer patients receive 5-FU annually. It is estimated that 3% of those patients develop some degree of toxic reaction. Patients suffering toxic reactions are difficult and expensive to treat further. Approximately 15% of those developing a toxic reaction will die as a result of exposure to 5-FU. More than 1,300 patients in the United States die each year as a result of 5-FU toxicity. These deaths are all potentially avoidable if patients are screened prior to the administration of 5-FU using the diagnostic test developed by NCI.

This technology has been licensed nonexclusively to several licensees. The transfer of this technology through these nonexclusive licenses has enabled the wide dissemination of this test in the United States and Europe. As a result of these multiple licenses, many more people around the globe can forego being treated by a drug that may do more harm than good. The wide dissemination of this life-saving diagnostic test promotes the NIH mission of improving public health.

Awardees:

National Cancer Institute
Dr. Frank Gonzalez

Universidad de Extremadura (Spain)
Dr. Pedro Fernandez-Salguero

High-Speed Counter Current Chromatography

The pool of potential medicinal candidates found in natural products is vast. One section of one plant can contain thousands of potential candidate compounds. Natural products research has become increasingly interesting to pharmaceutical companies engaged in new drug discovery. As a result, a device is needed that will extract candidate compounds more efficiently and cost-effectively.

Dr. Yoichiro Ito of the National Heart Lung and Blood Institute (NHLBI) designed the rotors, coils, and systems for high-speed counter current chromatography. The complete device optimizes the separation and purification of high molecular weight biomolecules using a salt gradient applied in a spiral flow membrane. The channels are compartmentalized into upper and lower rotary discs. A sample containing compounds to be purified is introduced in a buffered solution into the lower channel flowing in one direction while the salt flows in the other. The concentration of salt permeates the membrane and precipitates the large biomolecules on the other side.

Dr. Martha Knight of NHLBI initiated a Cooperative Research and Development Agreement (CRADA) with Peptide Technologies, Inc. (PTC), which conducted research on the device to purify and separate peptides and proteins. Once the CRADA with PTC ended, Dr. Knight eventually facilitated a transfer of the technology to CC Biotech, which licensed the device. A number of entities have approached CC Biotech for purchase and sublicensing of the technology, including Pfizer; the University of Rio de Janeiro, Brazil; and Kinjo Gakuji University in Nagoya, Japan.

Awardees:

National Heart Lung and Blood Institute
Dr. Yoichiro Ito

CC Biotech, LLC
Dr. Martha Knight

Identification and Development of Agents to Treat Glioblastoma and Other Tumors Over-expressing Nuclear Receptor CoRepressor

The National Institute of Neurological Disorders and Stroke (NINDS) and Lixte Biotechnology Holdings, Inc. (Lixte) are collaborating to identify and develop agents that target the Nuclear Receptor CoRepressor (N-COR) pathway. Dr. Zhengping Zhuang's laboratory at NINDS has determined that several kinds of tumors, including glioblastomas and medulla blastomas, over-express N-CoR.

Dr. Zhuang discussed this discovery with Dr. John S. Kovach shortly before Dr. Kovach decided to start a new biotechnology company. After the company, Lixte Biotechnology Holdings, Inc., was founded, a Cooperative Research and Development Agreement (CRADA) between NINDS and Lixte was executed to develop agents to treat glioblastoma.

Lixte developed and provided agents to Dr. Zhuang so he could determine if the agents inhibited the growth of tumor cells growing in vitro. Several of the agents had the desired activity, and two, designated LB-100 and LB-102, were selected for further studies. LB-100 and LB-102 are also effective inhibiting the growth of the tumor cells in a mouse model of glioblastoma (growth of a human glioblastoma tumor injected into mice). Preliminary studies indicate that LB-102 might be used in combination with other cancer chemotherapeutics to treat patients with glioblastoma multiforme, neuroblastoma, and other cancers. Lixte and NINDS have conducted preliminary toxicity studies and pharmacokinetic studies on LB-102. Lixte plans to continue these studies and hopes to submit an IND to the FDA for treatment of patients with glioblastoma multiforme in the near future.

Patents related to the treatment on central nervous systems cancers (such as glioblastomas and medulloblastomas) with some of the agents studied in the CRADA were filed, and Lixte has licensed NINDS' rights to these patents.

Awardee:

National Institute of Neurological Disorders and Stroke
Dr. Zhengping Zhuang

Novel Protein-Like Therapeutics for Treatment of Cancer

Cancer is caused by the improper regulation of cascading signals, or pathways, within the cell. One of the most prevalent means of fighting cancer involves the development of small molecule drugs and biologics that target and bind various proteins to disrupt certain pathways. The Hedgehog pathway is involved in embryonic development and is activated in many different tumor types. Smoothened (SMO) is a protein that plays an integral role in this pathway.

A technology developed by the National Cancer Institute (NCI) describes novel compounds that disrupt the Hedgehog pathway by inhibiting activity of the SMO protein. This disruption has the effect of reducing cell growth of the numerous types of tumors that use this pathway. These inhibitors belong to class of drugs known as peptidomimetics (PMDs). PMDs are synthetic drugs created by altering naturally occurring proteins.

Separate technologies being developed by NCI are nanoparticles that can be prepared using a procedure that incorporates PMDs. The resulting PMD nanoparticle delivery vehicle can permeate tumors and deliver the PMDs to cancer cells. This technology platform overcomes many of the specificity and stability issues associated with small molecules and protein-based drugs.

Transfer of this technology involved a Cooperative Research and Development Agreement (CRADA) with Calidris Therapeutics, a startup company which has based its entire product development strategy on the NCI technologies. Calidris is also in the process of exclusively licensing PMDs for all cancer types, as well as the nanoparticle methodology. This CRADA/licensing approach allows for continued development of the technology under the CRADA, while the license will allow Calidris to secure background rights in the technology and help to attract potential investors.

The potential benefit of this technology transfer effort extends beyond the development of a single therapeutic. The parties are attempting to establish the framework for the creation of a new therapeutic field and a new generation of drugs that are highly specific, potent, and applicable to a multitude of diverse diseases. The inventors refer to these new therapeutics as “synthetic biologicals” because they possess the high specificity and reduced side effects associated with many protein therapeutics.

With the inventors’ active assistance, NCI has made efforts to develop the technology for a variety of healthcare applications. Future efforts will involve continued implementation of technology transfer mechanisms designed to maximize the technologies’ impact on global health. The success already realized from this technology transfer promises a breadth of advances in the health field, and makes it clear that technology transfer efforts to establish new collaborative research efforts will be essential.

Awardees:

National Cancer Institute
- **Dr. Nadya Tarasova**
- **Dr. Michael Dean**
- **Dr. Sergei Tarasov**
- **Dr. Hong Lou**

Therapeutic Antibodies for the Treatment of Cancer

The term “cancer” is used to describe a collection of several diseases that are caused by the aberrant growth of cells and the invasion of these cells into other tissues, where they disrupt normal organ function. Cancers are commonly treated by surgical removal of the cancerous tissue, followed by a regimen of conventional chemotherapy or radiation therapy. Unfortunately, these conventional therapies lack specificity for cancer cells, leading to undesirable side effects that result from the non-specific killing of essential normal cells. Recent efforts in developing new treatments for cancer involve the use of monoclonal antibodies that recognize cell surface proteins that are preferentially expressed on cancer cells. This is believed to increase the effectiveness of treatments while reducing unpleasant side effects by specifically attacking only the cancer cells while avoiding essential normal cells. Indeed, there are now several successful monoclonal antibody therapies for the treat¬ment of cancer, including Avastin® and Herceptin®.

The transferred technology, developed at the National Cancer Institute (NCI), involves the development of monoclonal antibodies to the cell surface protein known as mesothelin. Mesothelin is preferentially expressed on the cells of a number of different cancers, including mesothelioma and ovarian and pancreatic cancers, suggesting that it is an excellent target for the creation of a new anti-cancer antibody. After initially isolating a first-generation monoclonal antibody to mesothelin, the NCI optimized the antibody for increased binding affinity, increased selectivity and decreased non-specific toxicity, ultimately resulting in the identification of an antibody called SS1. The humanized version of SS1, MORAb-009, is currently being developed by researchers at NIH and Morphotek, Inc., a U.S. biopharmaceutical company, by means of an exclusive commercialization license. The license was executed in December 2005, and the licensee has worked diligently in its attempts to commercialize the invention. A Phase II clinical trial studying the ability of MORAb-009 to treat pancreatic cancer was recently completed. If clinical trials are successful, MORAb-009 may help cancer patients who might otherwise have no treatment options.

Awardees:

National Cancer Institute
Dr. Ira Pastan
Dr. Kai Chang
Dr. Mark Willingham
Dr. Partha Chowdhury

Therapeutic Immunotoxins for the Treatment of T Cell Malignancies

Abnormal T lymphocyte (T cell) function, including tumor formation in T cells, can lead to a wide variety of diseases. Over 100 million people worldwide suffer from T cell autoimmune disorders of varying severity, such as lupus and graft-versus-host disease, and the incidence of T cell-mediated cancers, including lymphomas and leukemias, has risen over the past decade. These diseases can be deadly, and not all patients respond to standard therapies. New treatment options and more advanced therapies are needed for patients with T cell-mediated diseases to increase their chances of survival and improve their quality of life.

The transferred technology describes T-cell targeting immunotoxins developed in the laboratory of Dr. David Neville, Jr. at the National Institute of Mental Health (NIMH). The immunotoxin proteins consist of two portions: a targeting antibody that directs the immunotoxin to T cells and an exotoxin aimed at destroying the targeted T cells. These immunotoxins could be potentially useful in treating any disease or abnormality caused by T cells. The transferred technology also involves a high-yield, low-cost immunotoxin expression system whereby functional immunotoxins can be produced in mutant yeast strains.

The development of these immunotoxin technologies was realized through an extensive collaborative research effort. During the early stages of the technology, Dr. Neville and NIMH established collaborations with two prestigious academic institutions and a major commercial partner through a four-way Cooperative Research and Development Agreement (CRADA). Later, another well-known nonprofit institution made the CRADA a five-way collaboration to help with late preclinical and clinical studies. Very early in the clinical testing, the commercial partner terminated the CRADA and the license. Without the commercial contributions, it appeared that development of this promising therapy would stall before its medical potential could be realized.

In March 2010, NIH transferred rights to the immunotoxin intellectual property to Angimmune, LLC, through an exclusive license. After retiring from 48 years of federal service, Dr. Neville co-founded Angimmune to further develop the immunotoxins he invented during his federal career. Under the direction of Dr. Neville, Angimmune initiated new clinical studies with the lead immunotoxins and showed their effectiveness in clinical trial patients. Without Dr. Neville's passion to realize the therapeutic potential of this technology through his inventive federal research and in his licensing efforts at Angimmune, clinical research of this technology would have ceased, ending the hope of a future marketed drug.

Awardees:

National Institute of Mental Health
Dr. David Neville, Jr.

NIH Office of Technology Transfer
Dr. Samuel Bish

Cell Line Bank for Cancer Research

Cell lines are important biomedical tools that have revolutionized the way researchers study diseases. Human tumor cell lines can be used as in vitro model systems of cancer that are able to simulate how the disease behaves in the body. The National Cancer Institute (NCI) has approximately 439 human tumor cell lines that have an important application as research tools to study a variety of cancers. The majority of the cell lines were cultured from lung cancer tissue, but they can be used to study many tumor types.

The cell line bank, which began in 1976, is the result of exhaustive efforts by NCI scientists to provide the research community with comprehensive biological tools to study several cancer types. These cell lines contain a mutation that makes the cells sensitive to the presence of growth-inhibiting drugs, and they are valuable in identifying compounds with a therapeutic potential against cancer. Scientists can use the cell lines to screen thousands of compounds for anti-cancer activity. Five of the cell lines were made a part of the NCI 60 cell line screen, the most extensively profiled set of cancer cells in existence.

Transfer of these cell lines to the research community involved a variety of mechanisms, including consolidating them into one umbrella Invention Report in 2007. This aggregation allowed researchers easier access to any of the 400 plus lines contained in the invention without having to negotiate separate agreements for each line.

In order to transfer the cell lines to nonprofit entities, 63 Material Transfer Agreements (MTAs) were negotiated by NCI's Technology Transfer Center. Additionally, thousands of MTAs for the cell lines have been executed by American Type Culture Collection, a repository for biological materials. The cell lines were distributed to for-profit entities through 17 Biological Material Licenses negotiated by the National Institutes of Health's (NIH) Office of Technology Transfer. Four Commercial Evaluation Licenses were used to grant the nonexclusive right to evaluate the technology's commercial potential. In addition, nine licenses are currently being negotiated.

Although the technology is a research tool, significant tangible benefits have already been realized from its transfer. These cell lines have been the subject of more licenses than any other biological material at NCI and have netted approximately $350,000 in royalties that will be used to further NIH's mission. Several of the cell lines have each been cited in over 100 publications and numerous patents. In fact, numerous etiologic lung cancer genes published over the past two decades were either discovered or validated using these cell lines. Significant breakthroughs have resulted from the transfer of this technology, and it appears there is wide potential for future research and further opportunities for technology transfer.

Awardees:

National Cancer Institute
Dr. Frederic J. Kaye

(continued)

Cell Line Bank for Cancer Research

Awardees:

University of Texas - Southwestern Medical School
Dr. Adi F. Gazdar
Dr. John Minna

Harvard Medical School
Dana-Farber Cancer Institute
Dr. Bruce E. Johnson

Innovative Techniques and Reagents for Improved Genetic Engineering

The development of restriction enzyme technology in the 1970s was a breakthrough in genetic engineering. For the first time, scientists were able to cut DNA at specific sites and insert sequences with matching ends. However, the technology was limited to insertion at particular sites in the host vector, and the size of the inserted DNA quickly became a limiting factor. The National Cancer Institute's (NCI) solution is a technology that consists of three specialized bacterial strains and seven plasmids, developed around a genetic system in E. coli that was harnessed into an enabling platform technology, allowing for highly efficient, rapid, and direct manipulation of larger DNA sequences (up to 100kb) than previously enabled by conventional molecular biology methods. This system, called recombineering, has revolutionized genetic engineering techniques, including the modification of genes on bacterial artificial chromosomes (BACs) and the generation of conditional knockout mice.

The research community has enthusiastically received this technology, and over 1,100 non-profit researchers thus far have received the materials. The technology transfer efforts initially focused on the negotiation of individual Material Transfer Agreements with each recipient. However, growing interest created the need for a simple and streamlined process, leading to deposit of the materials in the NCI's Preclinical Repository in 2007 and making the NIH Simple Letter Agreement available online. This has greatly expedited transfer of the materials. In addition, the inventors have three issued patents and several applications pending, and the technology has been nonexclusively licensed to 18 commercial entities.

The NCI team continues to develop the technology, making improvements to the initial bacterial strains that have resulted in a "second generation" set. The laboratory continues to use the technology in research on gene regulation and initiation of transcription and translation, and it has been the subject of over 125 publications by both the inventors and outside investigators. Other diverse uses of the technology include stem cell research, genetic studies in model organisms, creation of research tools such as transgenic mice and specialized imaging vectors, and high-throughput screening.

Awardees:

National Cancer Institute
Dr. Donald Court
Ms. Nina C. Constantino
Dr. Neal G. Copeland
Dr. Nancy A. Jenkins
Dr. Hilary M. Ellis
Dr. E-Chiang Lee
Dr. Soren Warming
Dr. Daiguan Yu
Dr. Simanti Datta

PROSTVAC, a Therapeutic Vaccine for Treating Prostate Cancer

Prostate cancer is the most common non-skin cancer of males in the U.S., and is responsible for more deaths than any other cancer, except lung cancer. Cancer vaccines, which harness the body's immune system to identify and destroy cancer cells, have emerged as a promising new approach to fighting prostate cancer. One approach to cancer vaccination involves identifying antigens from cancer cells and immunizing cancer patients against those antigens to stimulate the body's immune cells to attack and kill the cancer cells.

This technology describes PROSTVAC, a therapeutic vaccine developed by Dr. Jeffrey Schlom and his colleagues that induces a specific, targeted immune response that attacks prostate cancer cells. PROSTVAC was initially developed by the NCI through a Cooperative Research and Development Agreement (CRADA) and license partnership with another company. Once the CRADA ended, NCI then worked diligently to enable PROSTVAC development to continue. BN ImmunoTherapeutics (BNIT), a small U.S.-based vaccine pharmaceutical company, was selected as the commercial partner.

The collaboration has led to the development of a therapeutic vaccine with the potential to revolutionize how researchers and physicians fight prostate cancer. Numerous clinical trials have shown that in addition to having a very good safety profile, PROSTVAC appears to be an effective option for the treatment of advanced prostate cancer. Data from a multi¬center, randomized Phase 2 study of 125 patients with metastatic prostate cancer showed that individuals treated with PROSTVAC increased overall survival by 8.5 months compared to the control group. This promising data will be used to improve all aspects of the technology, including safety, efficacy, and clinical trial design.

A variety of clinical studies are ongoing and being planned to develop PROSTVAC to the point where it can benefit the general public suffering from prostate cancer. A Phase 3 study for FDA approval is scheduled to begin this year.

Awardee:

National Cancer Institute
Dr. Jeffrey Schlom

Dr. Robert Wiltrout
Director, Center for Cancer Research, National Cancer Institute

Dr. Robert Wiltrout is Director of the National Cancer Institute's (NCI) Center for Cancer Research (CCR), which is home to more than 250 scientists and clinicians conducting intramural research at NCI. The Center is organized into over 50 branches and laboratories, each grouping scientists with complementary interests. CCR's investigators are basic, clinical, and translational scientists who work together to advance our knowledge of cancer and AIDS, and to develop new therapies against these diseases. CCR investigators collaborate with scientists at the more than 20 other institutes and centers of the National Institutes of Health (NIH), as well as with extramural scientists in academia and industry.

Each year, the Center stimulates and supports new technology development worldwide by sending in excess of several thousand shipments of research materials, including newly developed transgenic animal models, cell lines, plasmids, vectors, software/ databases and state-of-the-art research tools, to numerous industrial and academic research programs and centers. Dr. Wiltrout's efforts have resulted in NCI's continued technology transfer advances. He provided oversight of the Center's intellectual property and technology transfer portfolio, and supported the infrastructure necessary to ensure continued new and creative collaborations. In FY 2008, the Center had over 275 active clinical trials, more than 120 active Cooperative Research and Development Agreements (CRADAs), and 120 new commercial licenses, which increased the Center's net income to $36 million.

Dr. Wiltrout has a strong belief in the importance of building strong scientific partnerships with public and private institutions, and he strives to accelerate the movement of scientific discoveries to the marketplace for the ultimate benefit of public health. To this end, Dr. Wiltrout has created several initiatives to maximize partnerships and stimulate communication across the Center's 53 laboratories and clinical branches, as well as serve as a focal point for high impact collaborations. Through these partnerships, the Center has been able to develop cancer therapeutics and treatments to improve the quality of life for cancer and HIV/AIDS patients.

Dr. Wiltrout serves as the principal investigator on four highly successful CRADAs with industry and is actively pursuing three additional CRADA opportunities. Under his leadership and oversight, more than 30 clinical and basic research protocols to develop valuable research and clinical agents have been approved. These industrial collaborations will contribute directly to the development of novel clinical compounds with the potential for positive impacts on public health.

Cell Line Bank for Cancer Research

Cell lines are important biomedical tools that have revolutionized the way in which researchers study diseases. Human tumor cell lines can be used as in vitro model systems of cancer that are able to simulate the manner in which the disease behaves in the body. This technology describes approximately 439 human tumor cell lines that have important application as research tools to study a wide variety of cancers. The majority of the cell lines were cultured from lung cancer tissue, but they can be used to study many tumor types.

The cell line bank, which began in 1976, is the result of exhaustive efforts by NCI scientists to provide comprehensive biological tools to study several cancer types. These cell lines contain a mutation that makes the cells sensitive to the presence of growth-inhibiting drugs and are valuable in identifying compounds with therapeutic potential against cancer. Scientists can use the cell lines to screen thousands of compounds for anti-cancer activity. Five of the cell lines described in the technology were made a part of the NCI 60 cell line screen, the most extensively profiled set of cancer cells in existence.

Transfer of these cell lines to the research community involved a variety of mechanisms. In order to facilitate transfer of the technology, all cell lines were consolidated into one umbrella Invention Report in 2007. This aggregation allowed researchers easier access to any of the 400 plus lines contained in the invention without having to negotiate separate agreements for each line.

In order to transfer the cell lines to non-profit entities, 63 Material Transfer Agreements were negotiated by NCI's Technology Transfer Center. Additionally, thousands of MTAs for the cell lines have been executed by American Type Culture Collection. The technology was distributed to for-profit entities through 17 Biological Material Licenses negotiated by NIH's Office of Technology Transfer. Four Commercial Evaluation Licenses were used to grant the nonexclusive right to evaluate the technology's commercial potential. Additionally, nine licenses are currently being negotiated.

Although the technology is a research tool, significant tangible benefits have already been realized from its transfer. These cell lines have been the subject of more licenses than any other biological material at NCI and have netted approximately $350,000 in royalties that will be used to further NIH's mission. Several of the cell lines have each been cited in over 100 publications and in numerous patents. In fact, numerous etiologic lung cancer genes published over the past two decades were either discovered or validated using these tumor cell lines. Significant breakthroughs have resulted from the transfer of this technology and it appears there is still wide potential for future research and further opportunities for technology transfer.

Awardees:

National Cancer Institute
Dr. Frederic J. Kaye

(continued)

Cell Line Bank for Cancer Research

Awardees:

University of Texas - Southwestern Medical School
Dr. Adi F. Gazdar
Dr. John Minna

Harvard Medical School
Dana-Farber Cancer Institute
Dr. Bruce E. Johnson

Innovative Techniques and Reagents for Improved Genetic Engineering

The development of restriction enzyme technology in the 1970s was a breakthrough in molecular biology research. For the first time, scientists were able to cut DNA at specific sites, and insert sequences with matching ends. However, the technology was limited to insertion at particular sites in the host vector, and the size of the inserted DNA quickly became a limiting factor.

Through the research of Dr. Donald Court and colleagues at the National Cancer Institute's Center for Cancer Research, a set of recombination-mediated genetic engineering, or "recombineering," reagents was developed. Three specialized bacterial strains and seven plasmids were developed, based upon a genetic system in E. coli that was harnessed into a powerful platform technology allowing for highly efficient and rapid genomic manipulation in comparison to previous techniques. Additionally, much larger DNA sequences (up to 100kb) can be inserted. Besides improving standard molecular biology research, this technique is used to generate Bacterial Artificial Chromosomes (BACs) and conditional knockout mice.

The research community has enthusiastically received this technique, and 795 non-profit researchers have received the materials thus far. The technology transfer efforts initially focused on the negotiation of individual Material Transfer Agreements with each recipient. Growing interest created the need for a simple and streamlined process, leading to the deposit of the materials in the NCI's Preclinical Repository in 2007 and making the NIH Simple Letter Agreement available online. This has greatly expedited the transfer of the materials. Additionally, the inventors have three issued patents and several applications pending, and the technology has been non-exclusively licensed to 18 commercial entities.

Dr. Court and his colleagues continue to develop the technology, making improvements to the initial bacterial cell lines resulting in a "second generation" set that, together with a selection plasmid construct, added the functionality of positive/negative selection and are specifically designed for BAC generation. His laboratory continues to use the technology in research on gene regulation and initiation of transcription and translation, and it has been the subject of a number of publications by both the inventors and outside investigators. Other projects utilizing recombineering are diverse and have included stem cell research, genetic studies in model organisms, creating research tools such as transgenic mice and specialized imaging vectors, and high-throughput screening.

The investigators are credited for not only discovering and developing this revolutionary technology, but also for seeing a need for widespread distribution within the research community and seeking out the technical support and technology transfer mechanisms needed to provide these materials as broadly as possible. They also anticipated recipients wanting to access unpublished information regarding protocols and experimental design techniques in order to use these materials, and have made this technical know-how available through their Recombineering Website.

Awardees:

National Cancer Institute
Dr. Donald Court

(continued)

Innovative Techniques and Reagents for Improved Genetic Engineering

Awardees:

National Cancer Institute
- **Ms. Nina C. Constantino**
- **Dr. Neal G. Copeland**
- **Dr. Nancy A. Jenkins**
- **Dr. Hilary M. Ellis**
- **Dr. E-Chiang Lee**
- **Dr. Soren Warming**
- **Dr. Daiguan Yu**
- **Dr. Simanti Datta**

Dr. Robert Wiltrout
Director, Center for Cancer Research, National Cancer Institute

Over the past 29 years, Dr. Wiltrout has contributed as a scientist and leader to the Center for Cancer Research by supporting the infrastructure necessary to ensure continued new and creative collaborations that result in successful technology development and transfer to the Center's industrial partners. Last year, the CCR had over 275 active clinical trials, more than 126 active Cooperative Research and Development Agreements with industry, and 120 new commercial licenses. The Center's technologies continue to bring in an increasing amount of royalty income to the institute through licenses. Last year, the net income increased significantly to $36 million. CCR's technologies can be found in over 200 licensed products including many successful FDA approved products.

Dr. Wiltrout has a strong belief in the importance of building strong scientific partnerships with public and private institutions and strives to accelerate the movement of scientific discoveries to the market place for the ultimate benefit of public health. Through these partnerships, the Center has been able to develop cancer therapeutics, and treatments to improve the quality of life for cancer and HIV/AIDS patients. The research conducted by the staff of the Center for Cancer Research is at the forefront of the NCI's intramural effort to reduce suffering and death due to cancer, and thereby promote national public health. Dr. Wiltrout strives to ensure that the CCR continues to provide a unique environment in which basic research discoveries can be effectively translated into new technological or clinical applications in a timely fashion. Through these initiatives the CCR researchers are collectively able to work with collaborative partners to best drive the Center's discoveries from the bench, to early phase clinical studies, and through FDA approval using the Center's cutting-edge technologies—functional imaging, genomics, proteomics, and new approaches to drug development.

Dr. Wiltrout has personally been involved in ensuring that the employees of the Center are well informed and engaged in matters relating to technology transfer. New Center investigators, staff scientist, staff clinicians, fellows, and graduate students are required to fulfill their obligation to take a NIH online technology transfer training for intramural researchers. In addition, he has required that the Center's Labs and Branches participate in the NCI Technology Transfer Center's outreach and information meetings. Dr. Wiltrout has also provided a forum at senior management Lab and Branch Chief Meetings for technology transfer management to make presentations and discuss new technology transfer topics impacting the Center as well as current needs and technology transfer challenges and future opportunities.

Dr. Wiltrout has dedicated himself to ensure that funds allotted to support patent filings are carefully used to maximize the benefit and impact for new technology development. He personally reviewed Center's Patent Portfolio in consultation with the NCI's Technology Transfer Branch and the NIH Office of Technology Transfer. He approved abandonment recommendations of unlicensed patented inventions that individually had high future projected costs, short patent terms, and minimal prospects of licensing with a large cost savings for the NCI. Dr. Wiltrout has strategically supported the reinvestment of NCI royalty dollars to support those projects and initiatives that will have a broader and positive impact on the development new

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Dr. Robert Wiltrout
Director, Center for Cancer Research, National Cancer Institute

technologies for the benefit of public health. Dr. Wiltrout has also ensured that individual technology transfer accomplishments are recognized and rewarded within the Center for those individuals who have made commendable contributions to the Center's technology transfer endeavors for that year.

Dr. Wiltrout believes in the importance of supporting the training and in recognizing the accomplishments of the next generation of well trained and informed scientific leaders. Under the direction of Dr. Wiltrout, in any year, there are more than 1,000 individuals actively participating in CCR supported training endeavors.

Dr. Wiltrout has participated in and supported efforts to encourage the Center's researchers to collaborate with industry. He has also begun a process to reengineer, streamline, and optimize the clinical protocol review process within the Center making it an ideal place for industry to conduct important clinical trials. Dr. Wiltrout, as the Director for the Center for Cancer Research, oversees the clinical research portfolio which has several hundred active clinical trials.

Dr. Wiltrout has been highly recognized for his technology transfer accomplishments and track record for the Center. In addition to his achievements, he actively pursues his independent basic and clinical research interests resulting in employee invention reports, patents, and successful CRADA collaborations with industry. He is named as an inventor on several government-assigned patents in the area of immune response and hematopoietic regulation.

Under the direction of Dr. Wiltrout, there has been tremendous efforts and resources in the support of building the Immunology Center of Excellence which has a collective impact across the research community at the NIH and extramurally. Dr. Wiltrout has also devoted significant time and resources to the creation of the Cancer and Inflammation Program that has been highly interactive in collaboration with both intramural and extramural community. Another major initiative that Dr. Wiltrout has been directly involved is the new Chemical Biology Program with DCTD.

Dr. Wiltrout continued with his impressive track record of contributions to technology transfer advances of the National Cancer Institute in the 2008/9 fiscal year. He worked closely with his senior staff and Technology Transfer Center staff expanding the newly established novel CRADA mechanism that allows for the Center to efficiently work with industrial collaborators. Under this CRADA collaboration, Dr. Wiltrout, as Director, actively serves as the principal investigator on a broader scope collaboration for a compound or class of compounds which is reviewed and approved by the NIH CRADA Subcommittee. Under this new "umbrella CRADA" mechanism, after the initial approval and review, the principal investigator/Center Director and appropriate company officials have the authority to approve additional studies that are in the scope of the existing research plan by executing an approved research plan without the need for negotiating and executing a new CRADA. The process has been extremely beneficial to building more significant collaborations and reducing the time required to initiate research. The universal CRADA represents a new paradigm for industry and government developmental collaborations.

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Dr. Robert Wiltrout
Director, Center for Cancer Research, National Cancer Institute

In 2009, Dr. Wiltrout has been actively involved in the CCR's universal CRADAs. He serves as the principal investigator on four highly successful CRADAs with industry and is actively pursuing three additional universal CRADA opportunities. Under his direction, the CCR investigators have gained rapid access to multiple novel pharmaceutical compounds for further basic research and clinical development.

Dr. Wiltrout's continued leadership and oversight of the CCR's technology portfolio as well as his individual research accomplishments have substantially benefited the technology development initiatives of the NCI.

Karen Maurey
Director, Technology Transfer Center, National Cancer Institute

As Director of the Technology Transfer Center (TTC) at the NIH National Cancer Institute (NCI), Karen Maurey has provided the leadership and vision that has been instrumental in facilitating the transfer of the innovative research carried out by the NCI scientists to industrial partners and collaborators. Her efforts have enabled unique biological materials to be made available for use as research tools by the private and public sectors as well as new biomedical products to reach the consumer.

During the time Ms. Maurey has been directing the efforts of the TTC, three new products with innovative NCI technologies licensed from NIH have received FDA approval. These include Gardasil®, a new vaccine to protect against cervical cancer, Prezista™, a novel protease inhibitor for the treatment of HIV-1 in patients who are non-responsive to existing antiretroviral therapies, and Kepivance™, a human keratinocyte growth factor protein used to decrease the incidence and duration of severe mouth sores in patients with hematologic cancers who receive myelotoxic therapy. Two of the three, Gardasil® and Kepivance™, were recipients of the FLC Awards for Excellence in Technology Transfer.

TTC provides a complete array of services to support the NCI technology development activities, including the negotiation of transactional agreements between the NCI and outside parties; review of employee invention reports (EIRs); recommendations to the NIH's Office of Technology Transfer concerning filing of domestic and foreign patent applications; proposing and implementing innovative development strategies and academic and industry partnerships for NCI technology; advising and assisting NCI extramural grantees and contractors with issues related to grantees' and contractors' intellectual property developed with NIH support.

Ms. Maurey oversees the work of 50 technology transfer specialist and support staff who handle the technology transfer needs for all of NCI's intramural research labs and branches and all of NCI's extramural programs. This oversight includes the laboratories located at the NCI satellite campus in Frederick, Maryland. The NCI-Frederick campus consists of staff from both NCI and a system of contracts and is the only designated Federally Funded Research and Development Center (FFRDC) within HHS.

Ms. Maurey provided oversight for establishing the intellectual property parameters and guidelines for several key NCI initiatives which have been handled through the NCI-Frederick campus, including the Full-Length cDNA Initiative, the Chemical Genomics Initiative, the Proteomics Initiative, and the NCI's Alliance for Nanotechnology in Cancer.

The NCI TTC handles an enormous workload with remarkable effectiveness and efficiency. During FY08 (on behalf of just the NCI laboratories), the TTC managed a docket of over 170 active Cooperative Research and Development Agreements (CRADAs); submitted 148 EIRs; and executed 44 new CRADAs, over 1,800 Material Transfer Agreements, and 22 Clinical Trial Agreements. In FY08, the NCI CRADA program brought in $6.67 million in CRADA funds. In addition, Ms. Maurey's office acts as a Competitive Service Center for 10 other NIH institutes, providing similar technology transfer services to these clients.

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Karen Maurey
Director, Technology Transfer Center, National Cancer Institute

Under her leadership, her office undertook an outreach program to the NCI intramural labs and scientists. TTC staff is assigned to each lab to provide advice and guidance, negotiate agreements, answer questions, and keep the scientists informed of technology transfer policy and requirements. TTC staff participates in meetings, discussions, and conferences, as appropriate, to stay apprised of and monitor the scientists' needs. These efforts have led to a greatly enhanced appreciation of technology transfer issues by the scientists and concomitant increased cooperation between the TTC staff and the NCI labs.

Ms. Maurey is widely considered an expert in technology transfer and her advice and input are sought by all levels at NIH. Her leadership in implementing the new NIH publication policy at NCI was vital to its acceptance among researchers. Karen's contributions to the development of the new NIH policies and procedures for materials from human subjects were insightful and incisive. She was also instrumental in reviewing and revising the PHS model CRADAs so that they more accurately reflect the new ways that NIH collaborates with industry. Additionally, her office developed an umbrella CRADA with a large pharmaceutical company that has expedited the approval of the CRADAs and, thus, accelerated the research in important new cancer drug research. In collaboration with the Maryland Technology Development Corporation (TEDCO), Ms. Maurey's office held a highly successful Technology Transfer and Federal Marketplace event to showcase to industry new NCI technologies focused on cancer therapeutics and diagnostics. Over 30 companies participated in the event and heard presentations from the Director of NCI, distinguished scientists, Ms Maurey, and others.

She has served on the PHS Technology Transfer Policy Board, the NIH Public-Private Partnership Implementation Group, the PHS Technology Development and Transfer Committee, the NIH Technology Transfer Working Group, and the Catapult Advisory Group. Ms Maurey has been an invited speaker on numerous occasions, including a science writers' seminar on public/private partnerships in cancer research, the FLC, the Center of Excellence in Immunology, and the 2006 NIH Tenure Track Investigator Retreat: Educating Investigators on the Tenure Process. She co-authored an article on intellectual property issues related to AIDS vaccine development and also teaches at the NIH Technology Transfer University and is a course co-instructor in the NIH Foundation for Advanced Education in the Sciences (FAES) Graduate School "Certificate In Technology Transfer" program.

Ms. Maurey is a recipient of two Individual NIH Merit Awards, one Group NIH Merit Award, and several Federal Technology Transfer Awards. Ms Maurey's leadership and interpersonal skills have enhanced working relationships both internally and externally that have been extremely important to NIH achieving its technology transfer mission. Her desire to provide the best service to NCI through strong partnerships with all components of the NIH is unparalleled. Karen's willingness to extend herself personally, think creatively, and consider new and different approaches to long held ideas make her a well respected and much admired technology transfer professional and colleague.

Mast Cell Line for Research on Allergies and Inflammatory Diseases

Reactive mast cells are the culprit in allergic diseases and have also been implicated in other diseases ranging from autoimmune disorders to cancer to atherosclerosis. These immune sentinel cells normally defend against parasites and bacteria, but sometimes they overreact to harmless intruders, such as pollens or plant oils, releasing granules loaded with inflammation-inciting molecules, such as histamine, as well as various proteases and cytokines that cause allergic and inflammatory reactions.

Mast cell research has been hampered by its reliance on primary cultures of human or murine mast cells. Establishing primary cultures is a costly, time-consuming affair that takes 6 to 8 weeks and yields a limited number of cells. A longtime milestone in allergy and inflammatory medicine has been realized by a National Institute of Allergy and Infectious Diseases team, which developed a new mast cell line derived from human mast cell leukemia tissue. Named LAD2, this line closely resembles normal mast cells in the human body. The availability of this immortalized mast cell line ensures a continuous supply of human mast cells, yielding reproducible data that is more easily compared between different labs.

The LAD2 cell line represents a potent tool for understanding the normal functions of mast cells within the human body and identifying the mechanisms of a variety of diseases. Research utilizing this cell line promises to lead to the development of novel therapies to combat allergic diseases. Since its availability in 2001, the cell line has been made widely available to the research community via Material Transfer Agreements, resulting in more than 60 publications from laboratories worldwide. It has also been a licensing success, with the execution of more than 30 licenses with biotechnology and pharmaceutical companies.

With this cell line, scientists are analyzing the molecular mechanisms used by allergens and anti-inflammatory agents to aggravate or suppress mast cell activity. Projects include identifying the molecular mediators triggered by allergens, designing tests to identify new allergens, and developing compounds to treat inflammations caused by mast cells. With this new human cell line, scientists can save time, effort, and expense to advance allergy and inflammation research.

Awardees:

National Institute of Allergy and Infectious Diseases
Dr. Arnold S. Kirshenbaum
Dr. Dean D. Metcalfe
Dr. Cem Akin

Development of Sodium Nitrite as a Repurposed Pharmaceutical Agent

"Intellectual property (IP) development and the licensing of IP is an essential component of innovation in our knowledge-based economy. Each year, major IP deals between companies help drive innovation and ensure that new products continue to reach businesses and consumers." The National Institutes of Health (NIH) is pleased to announce that it has received the "Deals of Distinction Award™" along with Hope Pharmaceuticals and Aires Pharmaceuticals from the Licensing Executive Society (LES). This award was announced at the 2009 annual LES Meeting in San Francisco on October 21st and was awarded in the Industry-University-Government Interface Sector. The award for this category is a group of licensing agreements for the development of sodium nitrite as a repurposed pharmaceutical agent potentially effective against a number of serious medical conditions. The NIH, supported by four university collaborators, was able complete exclusive license agreements with Hope Pharmaceuticals (for infused delivery) and Aires Pharmaceuticals (for inhaled delivery) to develop new treatments for conditions not well-managed by existing therapies.

The license agreements were based upon the discovery by four NIH institutes (National Institute of Neurological Disorders and Stroke, National Heart Lung & Blood Institute, Clinical Center, and National Institute of Diabetes and Digestive and Kidney Diseases) and four universities (Loma Linda University, Louisiana State University, University of Alabama, and Wake Forest University) that low, physiological and non-toxic concentrations of sodium nitrite could be used in disease indications such as pulmonary hypertension, ischemia-reperfusion injury, hemolytic disease, hemoglobinopathies (including sickle cell disease) and cerebral vasospasm. Sodium nitrite is currently only available to patients by intravenous delivery for the treatment of cyanide poisoning.

The final license agreements are a testament to the willingness of all sides to work together with the hope that their efforts will culminate in new safe and effective treatments for significant diseases.

Green Team Efforts
NIH Office of Technology Transfer

The Office of Technology Transfer (OTT) implemented office-wide efforts in recycling, energy reduction and creating a paperless office. OTT procured recycling bins for paper, batteries, mail packages, printer toner, glass and plastic. When drafting documents, the office uses old paper and, when possible, prints on both sides of the paper before recycling. During the most recent office renovation, OTT installed motion-sensing light switches to all its renovated office spaces.

To the extent possible, OTT has become a paperless office. This effort includes scanning tens of thousands of documents and making them available electronically on the data management system, using electronic signatures on license agreements and memorandums, sending documents electronically and using an online document-sharing portal that facilitates paperless information sharing.

The office also initiated internal education programs in recycling and energy consumption reduction. These efforts have led to a significant reduction in paper and toner use and costs, as well as a drastic improvement of the environment.

Select100™ Multi-Specimen Loader and Image Acquisition System

Over the last 15 years, the application of computers to microscopes has significantly enhanced the level of automation that is possible once a specimen has been inserted into the microscope. A long-standing bottleneck has been the automated delivery of multiple specimens into an electron microscope, and overcoming this has presented researchers with significant challenges. The Select100™, described in this Nomination, is an automated specimen-loading system that permits sequential examination of as many as 100 specimens on any modern transmission electron microscope capable of computerized operation.

The Select100™ provides an unprecedented level of automation as well as a 10-fold increase in specimen throughput. It is now possible to screen a large number of specimens using transmission electron microscopy without user intervention.

The Select100™ was invented by Dr. Sriram Subramaniam, Chief of the Biophysics Section in the Laboratory of Cell Biology of the National Cancer Institute. Following the conceptualization of the technology, a Cooperative Research and Development Agreement (CRADA) was executed between NCI and Gatan, Inc., the world's leading manufacturer of instrumentation and software for electron microscopy. Software development was led by NCI, and the construction of the Select100™ was led by Gatan. The CRADA was extended twice to accommodate unexpected innovations. The Select100™ is now commercially available through Gatan. The success of this CRADA has resulted in discussions about future collaborations between NCI and Gatan.

The level of automation provided by the Select100™ has made a significant impact on the throughput of specimens that can be examined every day, leading to a more comprehensive screening for research in several technological disciplines. The improvements made possible by this technology have been disseminated throughout the scientific community at numerous conferences and through co-authored publications. There are also ongoing efforts to improve the design of the system and to facilitate market expansion of the Select100™. The increases in data throughput enabled by the Select100™ can be expected to drive further innovation in the speed of image processing. For example, the Select100™ could enable personalized medicine, in which drugs are tailored to an individual's genetic profile. Given the unprecedented improvements in existing technology that have resulted from the CRADA between NCI and Gatan, there are additional benefits from future research opportunities, collaboration, and technology transfer.

Awardee:

National Cancer Institute
Dr. Sriram Subramaniam

Novel Protein for Development of a Chlamydial Vaccine

The poster presented by Anna Z. Amar, Technology Development Associate, National Institute of Allergy and Infectious Diseases (NIAID), NIH – for a Novel Protein for Development of a Chlamydial Vaccine – was awarded "Best Poster" at the BIO 2007 Convention.

The technology developed by Harlan D. Caldwell, Ph.D, Chief and Senior Investigator of the Laboratory of Intracellular Parasites, Rocky Mountain Laboratory, NIAID, relates to a novel chlamydial protein, termed polymorphic membrane protein D (PmpD) that can be used to develop a vaccine against all chlamydial serovariants that cause important human diseases, including sexually transmitted infection (STI) and blinding trachoma. The antigenically common PmpD is a target of protective neutralizing antibodies and, therefore, could be developed and used as a single univalent vaccine to prevent both chlamydial STI and trachoma.

Chlamydia trachomatis isolates consist of 15 different serovariants that cause STI and blinding trachoma. Chlamydia is the leading cause of bacterial STI with an estimated 10 million new cases per year in the US alone. Infection of females can result in tubal factor infertility. Trachoma is the leading cause of preventable blindness in the developing world with an estimated 200 million individuals being afflicted by the disease. Trachoma has recently been identified as one of the world's most important neglected infectious diseases. Control of both STI and trachoma by antibiotic intervention is not effective. Hence there is an urgent need for a safe and effective vaccine against both chlamydial STI and trachoma. Polymorphic membrane protein D is a novel chlamydial pan-neutralizing antigen that is the only known common neutralizing target shared by all human chlamydial isolates. These unique biological and antigenic properties make PmpD a highly valued target for the generation of a univalent vaccine that potentially could protect against all chlamydial serovariants that cause both STI and blinding trachoma.

The market value of a vaccine capable of preventing chlamydial STI is expected to be $3-5 billion per year. This could rise to $10 billion or more by the year 2010 as the only current treatment, antibiotic intervention, is negatively affecting natural immunity, thereby leading to an anticipated increase in the prevalence of chlamydial STI.

Currently there is no vaccine for the prevention of human chlamydial diseases. This technology represents the first antigen that could be developed as a univalent recombinant protein, DNA or infectious vectored vaccine capable of protecting against all human chlamydial serovariants.

Targeted Treatments for Chronic and Painful Diseases

The researchers have developed a group of compounds useful in treating a wide variety of diseases, many of which are chronic and painful for those afflicted. These compounds, known as adenosine A3 receptor agonists, are small molecules that bind to adenosine A3 receptor and induce their biological activity. The adenosine A3 receptors are embedded in cell surfaces and are important for communicating the need for a cell to initiate activity in response to adenosine detected outside the cell. Adenosine is important in the body's response to chronic or acute tissue stress or cell damage. Because the four subtypes of adenosine receptors are located in different tissues, they tend to be tissue- and disease- specific, making them both very valuable in drug development and challenging for identifying molecules that will bind to them with the desired affinity and specificity. The first selective adenosine A3 receptor agonist and also the most selective such agonists have been designed by NIDDK researchers to stimulate this receptor subtype exclusively and, therefore, have very focused biological activity. For example, certain of these small molecules activate adenosine A3 receptors to provide cerebroprotective, cardioprotective, and anti-inflammatory effects and to shrink tumor cells.

The development of receptor-specific adenosine A3 receptor agonists of high affinity at NIDDK has enabled current clinical trials and pre-clinical studies by NIDDK's licensee and CRADA partner, Can-Fite Biopharma, Ltd. for treatment of rheumatoid arthritis, dry eye syndrome, and psoriasis, with very encouraging results. Rheumatoid arthritis is a chronic disease of unknown cause affecting 2.1 million Americans. It can lead to long-term joint damage, resulting in chronic pain, loss of function and disability. Dry eye syndrome is an extremely common condition, the cause of which remains unclear, and is thought to affect approximately 60 million Americans. Psoriasis is a lifelong skin disease affecting approximately 7.5 million Americans, about 10 percent to 30 percent of whom also develop psoriasis arthritis, which causes pain, stiffness and swelling in and around the joints. Other autoimmune inflammatory diseases are under study and in pre-clinical trials in an effort to bring comfort to other patients and alleviate other chronic and painful diseases through use of the technology. Its use is also being evaluated in pre-clinical studies for cancers.

Awardee:

National Institute of Diabetes and Digestive and Kidney Diseases
Dr. Kenneth A. Jacobson

Gardasil™: A New Era in Cancer Prevention

Human papilloma virus (HPV) is the most common sexually transmitted infection in the United States. The Centers for Disease Control and Prevention estimates that about 6.2 million Americans are infected with genital HPV each year and that over half of all sexually active men and women become infected at some time in their lives. While most HPV infections are cleared by the body's own defense system and do not lead to cancer, virtually all cases of cervical cancer are linked to HPV infection. On average, there are 9,700 new cases of cervical cancer and 3,700 deaths attributed to HPV in the United States each year. Worldwide, cervical cancer is the second most common cancer in women, and is estimated to cause over 470,000 new cases and 233,000 deaths each year.

Nearly two decades ago, researchers at the NCI, part of the National Institutes of Health (NIH), showed that a structural protein from the surface of an HPV serotype causally linked to the development of cervical cancer can self-assemble into virus-like particles (VLPs) that stimulate protective immune responses to HPV without causing infection. The NIH facilitated translation of this discovery into a commercial human vaccine by overseeing the patenting of the VLP technology and licensing it to Merck and Glaxo-SmithKline (GSK).

The resulting vaccines trigger the immune system to produce protective antibodies that bind the virus, thereby thwarting viral infection of cervical cells and subsequent cancers. Clinical trials of Gardasil™, the Merck vaccine, demonstrated 100% protection against the development of precancerous cervical lesions and nearly complete protection against the development of genital warts. In June 2006, the Food and Drug Administration approved Gardasil™ for the prevention of cervical pre-cancer, cancer, and genital warts. A GSK vaccine (Cervarix™) that is also based on NCI's VLP technology has been submitted for regulatory approval in Europe.

HPV vaccination is expected to translate into public health benefits in the U.S. by complementing existing cervical cancer screening, and reducing the medical care followup and invasive procedures associated with abnormal Pap smears as well as related health care costs. In poorly resourced regions of the world, HPV immunization may prevent several hundred thousand cancers annually, many of which affect relatively young women. The vaccine may offer far greater benefits in the developing world because the burden of disease is greatest and other preventive approaches to cervical cancer are limited or nonexistent.

Awardees:

National Cancer Institute
Dr. John T. Schiller
Dr. Douglas R. Lowy
Dr. Reinhard Kimbauer

Kepivance®: Improving the Quality of Life for Cancer Patients

Cancer is the second largest cause of mortality in the U.S., but researchers have made tremendous progress in developing new and effective treatments to reduce these mortalities. The National Cancer Institute's 2015 challenge goal is to turn cancer from a killer into a chronic disease in the next ten years. Thus far, progress in the fight against cancer has come at a heavy price in the form of devastating side effects. While meant to kill cancer cells, most cancer drugs also destroy normal tissue.

Mucositis (painful sores and ulcers in the lining of the mouth) is a common complication of chemotherapy and/or radiation, affecting approximately 80% of patients who undergo this intensive treatment prior to bone marrow transplantation. In this condition, the cells lining the mouth and throat are damaged, making the patients' everyday activities, such as eating, drinking, swallowing and talking, difficult or impossible. They require longer hospitalization, high doses of painkillers, and intravenous feeding. Prior to Kepivance®, there was no treatment for this condition.

This invention describes the use of Palifermin, a recombinant human keratinocyte growth factor (KGF) that can be used to reduce the incidence and duration of oral mucositis in cancer patients. Dr. Jeffrey Rubin and his collaborators at the National Institutes of Health (NIH) discovered the original molecule, realized its importance, and filed for patent protection in 1989. Amgen was then chosen as a commercial partner to develop a useful therapeutic with this molecule, because they had worked with other growth factors such as PDGF and G-CSF. Convinced that KGF would fit well in Amgen's product development strategy, NIH granted them an exclusive license to the invention in 1992.

Approved by the Food and Drug Administration in 2004 and sold under the brand name Kepivance®, this is a first-of-its-kind medicine that directly and effectively addresses the issue of a cancer patient's quality of life, and it is bound to inspire other drug developers to introduce such valuable products. Currently, this drug benefits approximately 11,000 adult Americans with hematologic malignancies who undergo bone marrow transplantation each year. As other indications are pursued and the medical community realizes the value provided to their patients by this treatment, the number of people benefiting from Kepivance® is bound to multiply. First-of-a-kind drugs generally see a delayed but rather dramatic upswing in usage as practitioners become more comfortable prescribing them and as new uses are developed.

Awardees:

National Cancer Institute
Dr. Jeffrey S. Rubin
Dr. Paul W. Finch
Dr. Stuart Aaronson

Accelerated Magnetic Resonance Imaging (T-SENSE)

This new, accelerated magnetic resonance imaging (MRI) method reduces the total imaging time for lengthy scans. The method may be used for imaging dynamic events such as heart motion or brain activity. The technology exploits the spatial and temporal correlation of magnetic resonance signals by combining parallel imaging and temporal filtering to achieve a new MRI technique referred to as (TSENSE). The TSENSE method has a higher degree of artifact suppression using parallel imaging and temporal filtering. This discovery provides a robust, accelerated imaging method that tolerates body motion or change in scan plane without the need to reacquire additional reference images. Prior to this discovery, it was difficult to obtain clear images with motion during patient scans, and has enabled the use of parallel imaging acceleration for real-time applications where the scan plane orientation is frequently changed. This improvement has general applicability to imaging various activities in human, (e.g. blood flow, brain activity and heart motion) in a shorter period of time, thus reducing scan time for patients and reduced artifacts that can lead to misdiagnosis of magnetic resonance scans.

Awardees:

National Heart Lung and Blood Institute
Dr. Peter Kellerman
Dr. Elliot McVeigh

Kepivance®: Improving the Quality of Life for Cancer Patients

Thus far the progress in our fight against cancer has come at a heavy price in the form of devastating side effects. While they are meant to kill cancer cells, most cancer drugs also destroy normal tissues. Mucositis (painful sores and ulcers in the lining of the mouth) is a common complication of chemotherapy and/or radiation, affecting approximately 80% of patients who undergo this intensive treatment prior to bone marrow transplantation. In this condition, the cells lining the mouth and throat are damaged, making the patients' everyday activities, such as eating, drinking, swallowing and talking, difficult or impossible. They require longer hospitalization, high doses of narcotics such as morphine, and intravenous feeding.

With the discovery of a recombinant human keratinocyte growth factor (KGF), trade name Kepivance®, there now is an effective treatment for this condition. Approved by the FDA in 2004, Kepivance®, this is a first of its kind of medicine that directly and effectively addresses the issue of a cancer patient's quality of life. Currently this drug benefits approximately 11,000 adult Americans with hematologic malignancies who undergo bone marrow transplantation each year, and its use is projected to increase as it is used in conjunction with other cancer treatments.

Awardees:

National Cancer Institute
Dr. Jeffrey S. Rubin
Dr. Paul W. Finch
Dr. Stuart Aaronson

Parvovirus B19 Diagnostic Test Kit

This development is the first and only FDA approved diagnostic test kit for parvovirus B19. Parvovirus B19 infection in pregnancy is often overlooked simply because most infected pregnant women are asymptomatic or have only mild manifestations, such as slight itching. However, pregnant women (in the first and second trimesters) with the B19 infection can give rise to serious fetal complications during pregnancy. Up to 50% of women are susceptible to parvovirus B19 infection. The B19 infection may result in anemia, pregnancy miscarriage and/or other problems. Early diagnosis of B19V infection will identify those at risk and may allow for early intervention therapy, thereby improving fetal survival. Patients who are immuno-compromised and others may also develop chronic B19 infection that previously has been difficult to diagnose. This new test kit will make diagnosis much easier and more reliable.

Awardees:

National Heart Lung and Blood Institute
Dr. Neal Young
Dr. Sachiko Kajigaya

Taxus®Express2™: Bypassing By-pass Surgery with Paclitaxel-Coated Stents

Taxus® Express2™ has the potential to benefit many of the victims of cardiovascular disease, which causes 40% of all deaths in the US. After a heart attack, patients often undergo an invasive by-pass surgery or a less invasive angioplasty procedure to open up the clogged artery. In the latter procedure, a tiny mesh-like device called a stent is inserted into the artery to keep it propped open. However, in many of the stent placement cases, the body reacts to this foreign object with scar tissue formation and the artery narrows again. Taxus® Express2™ is a medical device in which a cancer drug commonly known as Taxol® is imbedded into the interior of the stent. The drug is enclosed in a timed-release polymer so that it is dispensed into the tissue slowly and this prevents the re-blocking (restenosis) of the artery that is being treated. This device has dramatically reduced restenosis rates in patients treated with stents to just 3 to 6 percent, meaning far fewer return visits to the catheterization lab or operating room for cardiac patients.

Awardees:

National Institute of Aging
Dr. Steven J. Sollott

Madison County (NY) Department of Health
Dr. James Kinsella

1999

For the development of an indicator device to detect food quality.

Awardees:

Food and Drug Administration
Dr. Jon G. Wilkes
Dr. Dwight W. Miller

1997

For the development of gene therapy as a clinically useful procedure for training genetic diseases.

Awardee:

National Human Genome Research Institute
Dr. R. Michael Blaese

1993

In recognition of pioneering research and development and an unsurpassed commitment to transferring NIH/NIA technology to benefit mankind.

Awardee:

National Institute on Aging
Dr. Joseph Pitha

1992

In recognition of pioneering research and development that has brought NIH technology from the theoretical realms of the laboratory to clinical applications.

Awardee:

National Heart Lung and Blood Institute
Dr. W. French Anderson