Kudos to NIH Technology Transfer Efforts

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

April 2016

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Discovery to Commercialization: New Immunotherapy for Rare Childhood Cancer, Neuroblastoma

On March 10, 2015, the U.S. Food and Drug Administration (FDA) approved Unituxin™ (dinutuximab) as part of first-line therapy for pediatric patients with high-risk neuroblastoma, a rare cancer that most often occurs in young children. This approval was the result of a collaborative effort among the National Cancer Institute (NCI), the Children's Oncology Group, and United Therapeutics Corporation (UTC) for the first approved therapy for pediatric high-risk neuroblastoma. Dinutuximab (or monoclonal antibody ch14.18) binds to a ganglioside commonly expressed on the surface of neuroblastoma tumor cells. This binding triggers an immune response that kills the cancer cells.

The NCI Technology Transfer Center (TTC) played an important role in this discovery-to-commercialization story--from its concerted efforts to find and identify a partner strongly committed to moving this important treatment through commercialization and FDA licensure processes to negotiation of a Cooperative Research and Development Agreement (CRADA), and several other technology transfer agreements necessary to support this commercialization effort.

NCI's Biopharmaceutical Development Program (BDP) played an instrumental role in supporting this project over the years. Specifically, ch14.18 was produced under NCI contracts/subcontracts and provided for NCI-funded clinical studies through the BDP. The BDP worked directly with NCI, the FDA, and Health Canada on issues of patient safety and product characterization. NCI BDP's Regulatory Affairs group worked extensively with NCI's Cancer Therapy Evaluation Program (CTEP), the FDA, and Health Canada to develop regulatory submissions and ensure their submission in a timely manner.

A CRADA allowed the transfer of NCI BDP's evolving drug production process to UTC, the company that would take the product to licensure. The agreement also supported data transfer from NCI's Division of Cancer Treatment and Diagnosis clinical trials to UTC, which was needed for FDA approval of ch14.18 as a treatment in children with high-risk neuroblastoma.

Children with neuroblastoma will benefit from this collaboration, and the drug development pathway blazed by dinutuximab will likely be followed in the future to develop other novel agents directed against pediatric cancer therapeutic targets.

Awardees:

NIH - National Cancer Institute
- **Dr. Sherry Ansher**
- **Dr. Jan Casadei**
- **Dr. Karen Muszynski**
- **Dr. Malcolm Smith**
- **Donna Bialozor**

Leidos Biomedical Research, Inc.
- **Beverly Keseling**

United Therapeutics Corporation
- **Dr. L. Mary Smith**

Development of First Immunotherapy to Treat Chordoma

Cancer vaccines harness the immune system to identify and destroy cancer cells, and are a promising new approach to fighting cancer. In contrast to preventative vaccines, cancer vaccines identify antigens from cancer cells and immunize cancer patients against those antigens to stimulate the body's immune cells to attack and kill the cancer cells. The National Cancer Institute (NCI) has developed investigational cancer vaccines that induce a specific, targeted immune response against cancer cells expressing the brachyury protein. The discovery may be the first medical treatment for chordoma, a rare cancer with no alternative medical therapy.

Brachyury is a type of genetic on-switch, also known as a transcription factor. It is a driver of a process associated with cancer progression and resistance to therapy. Brachyury is an attractive vaccine target because it is not generally found in normal tissues, but is abnormally found in many cancers and chordoma, a difficult-to-treat bone cancer. When brachyury is expressed in tumor cells, it enhances their invasiveness and induces resistance to chemotherapy and radiation.

Before NCI's discovery, brachyury was deemed "undruggable" because of challenges associated with developing therapies targeting transcription factors. The first NIH patent application covering brachyury as a cancer vaccine was filed in 2007. Since then, the invention has attracted significant commercial interest.

NCI is currently developing brachyury vaccines through Cooperative Research and Development Agreements (CRADAs) and license partnerships with GlobeImmune, Inc.; Bavarian Nordic; and Etubics Corporation, respectively. These collaborations led to the rapid translation of investigational therapeutic vaccines with the potential to revolutionize how researchers and physicians treat many cancers.

NCI's collaborations led to the creation of new intellectual property and licensing activities. Currently, there are several issued patents and pending patent applications. NCI's commitment to collaborate with multiple partners is helping to exploit the discovery's full potential. The rapid translation and clinical development of brachyury vaccines has been well-served by careful management of a complex technology transfer process.

Awardees:

NIH - National Cancer Institute
- **Dr. James Gulley**
- **Dr. Christopher Heery**
- **Dr. Claudia Palina**
- **Dr. Jeffrey Schlom**
- **Kevin Brand (formerly of NIH)**
- **Dr. Michael Pollack**

NIH - Office of Technology Transfer
- **Dr. Kevin Chang**
- **Dr. Sabarni Chatterjee**
- **Mojdeh Bahar (formerly of NIH)**

First FDA Approval: Combination Therapy for Rare Childhood Cancer, Neuroblastoma

On March 10, 2015, the Food and Drug Administration (FDA) approved Unituxin™ (dinutuximab) as part of first-line therapy for pediatric patients with high-risk neuroblastoma, a rare cancer that most often occurs in young children. This approval was the result of a collaborative effort between the National Cancer Institute (NCI), the Children's Oncology Group, and United Therapeutics Corporation (UTC) for the first approved therapy for pediatric high-risk neuroblastoma. Dinutuximab (or monoclonal antibody ch14.18) binds to a ganglioside commonly expressed on the surface of neuroblastoma tumor cells. This binding triggers an immune response that kills the cancer cells.

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Children with neuroblastoma will benefit from this collaboration, and the drug development pathway blazed by dinutuximab will likely be followed in the future to develop other novel agents directed against pediatric cancer therapeutic targets.

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- **Donna Bialozor**
- **Dr. Karen Muszynski**
- **Dr. Sherry Ansher**
- **Dr. Malcolm Smith**
- **Dr. Jan Casadei**

United Therapeutics Corporation
- **Dr. L. Mary Smith**

Leidos Biomedical Research, Inc.
- **Beverly Keseling**

Novel Therapeutics to Treat Niemann-Pick C Disease and Other Lysosomal Disorders

Niemann-Pick disease, type C (NPC) is a lethal, neurodegenerative disorder that affects children. Presently, no therapies for NPC are approved by the Food and Drug Administration (FDA). Several studies have suggested the potential use of 2-hydroxypropyl-β-cyclodextrin (HPBCD) to treat NPC, but the critical studies and data required for an Investigative New Drug (IND) application to evaluate HPBCD were not available. A multi-institute scientific and clinical team of National Institutes of Health (NIH) intramural researchers and clinicians in a unique collaboration with several academic institutes, industry partners, and patient advocacy groups has generated extensive data to establish safe, effective dosing for the delivery of HPBCD directly into the central nervous system of NPC patients.

The goal of this technology transfer effort is to effectively transfer the valuable preclinical and clinical assets to a private partner who can further develop and commercialize the technology to the benefit of NPC patients. The nominees, each with varied specific expertise but a total commitment to the project goals, worked as a cohesive and effective team to achieve the goals of the project while satisfying the needs and aspirations of other stakeholders.

The goals were realized on December 10, 2014, when NIH signed a unique exclusive license, which for the first time included, along with patent rights, the transfer of an IND, U.S. and European orphan drug designations. In addition, the National Center for Advancing Translational Sciences (NCATS) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) signed a joint Cooperative Research and Development Agreement (CRADA) with Vtesse, Inc., a company dedicated to developing drugs for the unmet medical needs of patients suffering from severe and life-threatening lysosomal disorder diseases, including NPC.

The result of this technology transfer effort was a commitment from the industry partner to undertake pivotal clinical trials and commercialization, and also to collaboratively conduct preclinical discovery and development of other novel drugs for NPC and other lysosomal storage diseases. This technology transfer makes it possible for the patients and patient families affected by these devastating disorders to hope for an effective cure in the near future.

Awardees

NIH - National Center for Advancing Translational Sciences
- **Lili Portilla**
- **Dr. Krishna Balakrishnan**
- **Dr. Charles Niebylski**
- **Dr. Elizabeth Ottinger**
- **Dr. Wei Zheng**
- **Dr. Juan Marugan**

NIH - Eunice Kennedy Shriver National Institute of Child Health and Human Development
- **Dr. Forbes Porter**

(continued)

Novel Therapeutics to Treat Niemann-Pick C Disease and Other Lysosomal Disorders

Awardees:

NIH - National Cancer Institute
Dr. Alan Hubbs

NIH - Office of Technology Transfer
Dr. Suryanarayana Vepa
Fatima Sayyid
Richard Rodriguez

Vtesse, Inc.
Dr. Bernardus Machielse
Dr. Ravi Venkataramani

Development of First Immunotherapy to Treat Chordoma, a Rare Bone Cancer

Cancer vaccines harness the immune system to identify and destroy cancer cells, and are a promising new approach to fighting cancer. In contrast to preventative vaccines, cancer vaccines identify antigens from cancer cells and immunize cancer patients against those antigens to stimulate the body's immune cells to attack and kill the cancer cells. The National Cancer Institute (NCI) has developed investigational cancer vaccines that induct a specific, targeted immune response against cancer cells expressing the brachyury protein. The discovery may be the first medical treatment for chordoma, a rare cancer with no alternative medical therapy.

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NIH - National Cancer Institute
- **Dr. Michael Pollack**
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- **Dr. Claudia Paline**
- **Dr. Christopher Heery**
- **Dr. James Gulley**
- **Dr. Jeffrey Schlom**

NIH - Office of Technology Transfer
- **Dr. Sabarni Chatterjee**
- **Mojdeh Bahar (formerly of NIH)**
- **Dr. Kevin Chang**

NIH International Technology Transfer Mentoring Program

Medical research to combat disease is now a global effort and one that now requires an international technology transfer effort to see that new discoveries from research are effectively developed and commercialized to reach patients. While the United States in general, and the National Institutes of health (NIH) in particular, have long led the way in effective biomedical technology transfer, such is not the case with new or younger transfer programs at research institutions outside the US, especially those in emerging and middle-income countries. In the International Technology Transfer Mentoring Program, mentoring opportunities of up to 90 days are provided to scientists, managers and other qualified technology transfer personnel with a background in the fields of law, business, or life sciences by a trans-NIH staff lead by the Office of the Director's Office of Technology Transfer. This program has enabled international visitors to combine their legal, business, or life science background with training and experience in the technology transfer field to become more efficient and effective technology transfer officers at their own home research institutions.

International research institutions participating in the mentoring program are responsible for the travel & living expenses of their staff; there is no NIH funding dedicated to support this program or its participants. While the program is open to all technology transfer officers from research institutions or agencies outside the US, preference is given to those from emerging and middle income countries. The international research institutions participating in the technology transfer mentoring program in FY15 were:

- Ethiopian Public Health Institute (Ethiopia)
- Saudi Food & Drug Authority (Saudi Arabia)
- University Scoiola Superiore Sant'Ann (Italy)
- Ege University (Turkey)
- University of Edinburgh (Scotland)
- University of the West Indies (Jamaica)
- Istanbul Sehir University (Turkey)
- King Abdullah International Medical Research Center (Saudi Arabia)
- King Abdulaziz City for Science and Technology (Saudi Arabia)
- Middle Eastern Technical University (Turkey)
- Turin Polytechnic (Italy)
- University of Calabria (Italy)

Prior year participants in the program have included research institutions from Chile, Mexico, Qatar, China, India, France, UK, Croatia, Czech Republic, Argentina and Kenya.

During their stay the international visitors interacted with NIH staff in the areas of patenting, licensing, marketing, international technology transfer and technology transfer policy. They also had meetings and discussions with other federal agencies, such as the Food & Drug Administration and the Patent & Trademark Office and attended FLC events where possible. Each international visitor concluded their stay with a seminar presentation to the NIH community about biomedical development, research collaboration and technology transfer in their region.

(continued)

NIH International Technology Transfer Mentoring Program

Awardees:

NIH - National Heart, Lung and Blood Institute
- **Brian Bailey**

NIH - National Cancer Institute
- **Vio Conley**
- **Michael Currens**
- **Charles Salahuddin**
- **Luis Salicrup**

NIH - National Institute of Allergy and Infectious Diseases
- **Haiqing Li**
- **Mukul Ranjan**

NIH - National Institute of Diabetes and Digestive and Kidney Diseases
- **Agnes Rooke**

NIH - Office of Technology Transfer
- **Steven Ferguson**
- **Uri Reichman**
- **Alex Taylor**
- **Dr. Betty Tong**
- **Tracy White**

Congratulations to FY-2015 NIH Patent Recipients

CC— CLINICAL CENTER

Michael Iadarola
Joseph Kovacs
Patrick Murray
Daniel Sweeney
Bradford Wood
Sheng Xu
Adrian Zelazny

NCATS — NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

Christopher Austin
Matthew Boxer
James Inglese
Jian-kang Jiang
Juan Marugan
Noel Southall
Craig Thomas
Steven Titus
Wei Zheng

NCI — NATIONAL CANCER INSTITUTE

Suresh Ambudkar
Miriam Anver
Inglill Avis
Sivasubramanian Baskar
Susan Bates
Richard Beers
Christina Bergamaschi
Jay Berzofsky
John Beutler
Michael Bishop
Josip Blonder
Heidi Bokesch
Terrence Burke
John Cardellina
Weizao Chen
Murali Cherukuri
Nachimuthu Chinnasamy
Joon-Yong Chung
Suhman Chung
Mike Citro
Carol Clayberger
Thomas Conrads
John Cook
Nina Costantino
Donald Court
Michael Currens
Frank Cuttitta
Simanti Datta
Sandeep Dave
Michael Dean
Frank DeRosa
Nallathamby Devasahayam
Michael Difilippantonio
Dimiter Dimitrov
Mark Dudley
Tom Ebersole
Barbara Felber
Yang Feng
William Figg
David Fitzgerald
Wilmarie Flores-Santana
Kaori Fujita
Jeff Gildersleeve
Marian Grade
Sergei Gulnik
Jens Habermann
Gordon Hager
Akinobu Hamada
Curtis Harris
Vincent Hearing
Curtis Henrich
Stephen Hewitt
James Hodge
Thomas Hofer
Izumi Horikawa
Joseph Hrabie
Cary Hsu
Yi-Hisang Huang
Aki Iwai
Elaine Jaffe
Junfang Ji
Xinhua Ji
Donald Johann
Randall Johnson
Piotr Kaczmarek
Udai Kammula
Larry Keefer
Javed Khan
Jung-Hyun Kim
Yeong Kim
Dennis Klinman
Natalay Kouprina
Robert Kreitman
Alan Krensky
Vladimir Larionov

(continued)

Congratulations to FY-2015 NIH Patent Recipients

NCI — NATIONAL CANCER INSTITUTE

Byungkook Lee
Min-Jung Lee
Stuart LeGrice
George Lenz
Qian Li
Zhitao Li
William Marston Linehan
Hong Lou
Douglas Lowy
Christophe Marchand
Justin Maxhimer
James McMahon
James Mitchell
Hiroaki Mitsuya
Makoto Nagashima
Megumi Nakano
Leonard Neckers
George Nelson
Dianne Newton
Michael Nickerson
Vladimir Noskov
Barry O'Keefe
Sang-kon Oh
Masanori Onda
Claudia Palena
Yanlil Pang
Thierry Passeron
Ira Pastan
Diana Pastrana
George Pavlakis
Bo Peng
Alan Perantoni
Liyanage Perera
Yves Pommier
Douglas Price
Avraham Rasooly
Karlyne Reilly
Nicholas Restifo
Thomas Ried
Paul Robbins
Marjorie Robert-Guroff
David Roberts
Jeffrey Roberts
Robert Robey
Steven Rosenberg
Joseph Saavedra
David Salomon
John Schiller
Jeffrey Schlom
Laura Schmidt
Bradley Scroggins
Dominic Scudiero
Gary Shaw
Genbin Shi
Robert Shoemaker
Suneet Shukla
Tristan Sissung
Michael Smith
Carole Sourbier
Alex Sparreboom
Louis Staudt
Diana Stavreva
Sriram Subramaniam
Sankaran Subramanian
Nadya Tarasova
Masaki Terabe
Laurent Thibaut
Joshua Thomas
Jorge Toro
Jane Trepel Neckers
Kwong-Yok Tsang
Thomas Turbyville
Maria Turner
Antonio Valentin
Timothy Veenstra
Rebecca Voltan
Thomas Waldmann
Xin Wei Wang
Michelle Warren
Bih-Rong Wei
Jun Wei
John Weldon
Jennifer Wilson
Wyndham Wilson
David Wink
Cheryl Winkler
George Wright
Taro Yamashita
Li Yang
Berton Zbar
Ling Zhang
Zhu Zhongyu

NEI — NATIONAL EYE INSTITUTE

Juan Amaral
Brian Brooks
Chaiki Fujimoto
Igal Gery
Jiahn-Dar Huang
Jung Wha Lee
Lourdes Ponce
Ignacio Rodriguez
William Samuel

(continued)

Congratulations to FY-2015 NIH Patent Recipients

NHGRI — NATIONAL HUMAN GENOME RESEARCH INSTITUTE

David Adams
Francis Collins
William Gahl
Marjan Huizing
Riko Klootwijk
Eirini Manoli

NHLBI — NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Marcelo Amar
Robert Balaban
Richard Cannon
Richard Childs
Christian Combs
Nanae Harashima
Yoichiro Ito
Sachiko Kajigaya
Jay Knutson
Elliot Mcveigh
Vinay Pai
Alan Remaley
Yoshiyuki Takahashi
Sumithira Vasu
Han Wen

NIA — NATIONAL INSTITUTE ON AGING

Darrell Abernethy
Bira Arya
Farideh Beigi-abhari
Khalid Chakir
Maire Doyle
Josephine Egan
Juan Espinoza
Geppino Falco
Nigel Greig
Harold Holloway
Sung-Lim Lee
Dan Longo
Weiming Luo
Manuela Monti
Lioudmila Sharova
Ilaria Stanghellini
David Tweedie
Irving Wainer
Qian-sheng Yu
Michal Zalzman
Weizhong Zhu

NIAID — NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Jesse Arbuckle
Joseph Blaney
Bimal Chakrabarti
Robert Chanock
Zhaochun Chen
Jeffrey Cohen
Peter Collins
Frank DeLeo
Li Ding
Patricia Earl
Suzanne Emerson
Doran Fink
Elizabeth Fischer
Ivo Francischetti
Ivan Fuss
Regis Gomes
David Greenberg
Steven Holland
Haijing Hu
Peter Jahrling
Reed Johnson
Shaden Kamhawi
Albert Kapikian
Atsushi Kitani
Stanislava Kocianova
Thomas Kristie
Joseph Kubofcik
Ching-juh Lai
Stephen Leppla
Yu Liang
Peter Mannon
Adriana Marques
Louis Miller
Mahtab Moayeri
Bernard Moss
Brian Murphy
Sheila Nolan
Thomas Nutman
Akio Ohta

(continued)

Congratulations to FY-2015 NIH Patent Recipients

NIAID — NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Michael Otto
Jason Paragas
Lesley Pesnicak
Alexander Pletnev
Jan Preiss
Robert Purcell
Joseph Putnak
Jose Ribeiro
Ethan Shevach
Mario Skiadopoulos
Frida Stock
Warren Strober
Nancy Sullivan
Jesus Valenzuela
Jodi Vogel
Jovanka Voyich
Stephen Whitehead
Yimin Wu
Linda Wyatt

NIAMS — NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Peter Lipsky
Francoise Meylan
Richard Siegel
Yun-Jeong Song

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

Zuzana Biesova
Diana Blithe
Richard Blye
Jerry Keith
Hyun Kim
Zuzana Kossaczka
Joanna Kubler-Kielb
Min Lee (non-inventor POC)
Andrea Lisco
Darrell Liu
Fathy Majadly
Leonid Margolis
Christopher Mocca
Lynnette Nieman
Forbes Porter
John Robbins
Tracey Rouault
Rachel Schneerson
Shousun Szu
Christophe Vanpouille

NIDA — NATIONAL INSTITUTE ON DRUG ABUSE

Qing Rong Liu
Thomas Spande

NIDCR — NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Ioannis Bossis
Peter Burbelo
John Chiorini
John Cisar
Stan Gronthos
Hynda Kleinman
Masako Miura
Pamela Robey
Byoung-Moo Seo

(continued)

Congratulations to FY-2015 NIH Patent Recipients

NIDDK — NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Hugo Garraffo
Marvin Gershengorn
Wei Huang
Kenneth Jacobson
Jeffrey Kopp
Susanne Neumann
Bruce Raaka
Alan Schechter
Joseph Shiloach
Dilip Tosh
Herman Yeh

NIEHS — NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Michelle Block
Stavros Garantziotis
Jau-Shyong Hong
Guorong Li
Liya Qin

NIMH — NATIONAL INSTITUTE OF MENTAL HEALTH

Wayne Drevets
Newlin Morgan
Yi-Liu Yuan

NINDS — NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Bibiana Bielekova
Stephen Dodd
John Hallenbeck
Mark Hallett
Ianessa Humbert
Alan Koretsky
Christy Ludlow
Henry Mcfarland
Christopher Poletto
Maria Spatz
Hidetaka Takeda
Hideaki Wakita

Congratulations to FY-2015 CDC Patent Recipients

CDC — CENTERS FOR DISEASE CONTROL AND PREVENTION

Edwin Ades
Cesar Albarino
Larry Anderson
Nikkol Atwell-Melnick
Alison Basile
Bernard Beall
Brian Bird
Joseph Caba
George Carlone
Arnold Castro
Gwong-Jen Chang
Bean Chen
Nancy Cox
Wayne Crill
Kelly Curtis
Shannon Dalton
Inger Damon
Joshua Devos
Prasson Diwakar
Ruben Donis
Dean Erdman
Patricia Fields
Collette Fitzgerald Leaumont
Thomas Folks
David Frazer
J. Geraldo Garcia-Lerma
Jon Gentsch
Robert George
Roger Glass
Duane Gubler
Lia Haynes
Walid Heneine
Vincent Hill
Mary Hoelscher
Robert Janssen
Baoming Jiang
Scott Johnson
Danny Jue
Marcia Kalish
Jacqueline Katz
Claire Kinney
Richard Kinney
Alexander Klimov
Thomas Ksiazek
Pramod Kulkarni
Yu Li
Xiaoyan Lu
Joseph Martinez
Walter McKinney
John McQuiston
Jothikumar Narayanan
Clement Ndongmo
Stuart Nichol
Robert Otten
Sherry Owen
Christopher Pan
Chou-Pong Pau
Jan Pohl
Conrad Quinn
GowriSankar Rajam
Donna Rudolph
Charles Rupprecht
Jean-Francois Saluzzo
Suryaprakash Sambhara
Jacquelyn Sampson
Anthony Sanchez
Jarad Schiffer
Vera Semenova
Julile Skinnner
Todd Smith
Stephen Soroka
Kansas Sparks
Sandra Steiner
Pavel Svoboda
William Switzer
Kathleen Tatti
Jennifer Thomas
Kathleen Thurman
Maria-Lucia Tondella
Nicholas Wagar
Huiying Wang
Yuhuan Wang
Agnes Warner
Bryan Wimer
Jonas Winchell
Xianfu Wu
Chunfu Yang
Shengke Zeng
Hui Zhao
Zhiyong Zhou

Congratulations to FY-2015 FDA Patent Recipients

FDA — FOOD AND DRUG ADMINISTRATION

Pierre Alusta
Richard Beger
Ira Berkower
Dan Buzatu
Eric Calvo
Edward Cox
Alain Debrabant
Robert Duncan
Barry Falgout
Carl Frasch
Hana Golding
Koji Kawakami
Surender Khurana
Dennis Kopecko
Ryan Kretzer
Che-Hung Robert Lee
Lewis Markoff
Hira Nakhasi
Yangmin Ning
Bruce Pearce
Raj Puri
Angamuthu Selvapandiyan
Randal Tucker
Jon Wilkes
De Qi Xu
Hiroshi Yamada

The Breast Cancer Startup Challenge

The National Cancer Institute (NCI), in partnership with the nonprofit Center for Advancing Innovation (CAI) and the Avon Foundation for Women, launched The Breast Cancer Startup Challenge, a first-of-a-kind, international, university-based competition. Through the creation of startup companies, it represents a new model to accelerate the transfer of federally funded inventions to the marketplace, specifically focused on increasing the volume of developing emerging breast cancer technologies.

In 2013, NCI entered into a Partnership Intermediary Agreement (PIA) with CAI to evaluate and offer recommendations to market the NCI patent portfolio. An outcome of that effort was the idea to create a business startup challenge to move certain technologies forward. Breast cancer was selected as the challenge focus, and a three-way collaboration agreement was developed to implement the challenge by NCI, CAI, and the Avon Foundation.

Nine patented technologies from NCI's intramural research program that show great promise to advance the treatment, diagnosis, and prevention of breast cancer were simultaneously transferred to launch ten new startup companies in 2014 under the Challenge. NCI's patented inventions include therapeutics, diagnostics, prognostics, and one device, vaccine, delivery system and health IT invention.

The Challenge's federally funded inventions, startups, and lead inventors are:

1. **Diagnostic from Biopsies with Software Analysis**
   Radial Genomics, University of Cambridge
   Dr. Thomas Misteli, NCI

2. **Immunotherapy Using Modified Self Tumor Cells**
   PCV Therapeutics, Washington University in Saint Louis
   Dr. Dennis Klinman, NCI

3. **Human Monoclonal Antibody Based Cancer Therapies**
   Mesopharm Therapeutics, Stanford University
   Dr. Mitchell Ho, NCI

4. **Immunotherapy Using Granulysin Activated Monocytes**
   Orpheden Therapeutics, Northwestern University
   Dr. Alan Krensky, Northwestern University (formerly NCI)

5. **Anti-cancer Toxin**
   Oncolinx, Rutgers University
   Dr. Nadya Tarasova, NCI

6. **Versatile Delivery Method for Cancer Therapeutics**
   Bespoke Therapeutics, Wake Forest University
   Dr. Stanislaw J. Kaczmarczyk, NCI
   Dr. Deb Chatterjee, NCI

(continued)

The Breast Cancer Startup Challenge

7. **Genomic-based Diagnostic Assay**
   Heragen, Unversity of California, Berkeley
   Dr. Steven Libutti, Albert Einstein College of Medicine (formerly NCI)

8. **Tissue-based Diagnostic Assay**
   ProVivoX, McGill University
   Dr. Steven M. Hewitt, NCI

9. **Diagnostic Kit for Therapy Benefit Prediction**
   Taxor Diagnostics, Tulane University
   Dr. Sherry Yang, NCI

Additional Awardees:

Avon Foundation Breast Cancer Crusade
Dr. Marc Hurlbert

CAI - Center for Advancing Innovation
Rosemarie Truman

NCI - National Cancer Institute
Karen Maurey
Dr. Thomas Stackhouse

NIH - Office of Technology Transfer
Richard Rodriguez
Jennifer Wong

A Low-Cost Tissue Microarrayer Instrument to Support Improved Cancer Diagnoses

A tissue microarray (TMA) is an important technique used by pathologists to accurately analyze tissue samples. It is a means of aggregating tissue samples in an organized grid fashion for high throughput analysis. Automated TMAs are commercially available, but they are expensive ($16,000-$230,000) and require specialized training and experience to apply the technology. This recently transferred technology from the National Cancer Institute (NCI) addresses the high instrumentation cost and specialized training barriers of existing commercial tissue microarrays, and offers a simplified, manual, low-cost tissue alternative for use in clinical and research settings to validate the immunohistochemical (IHC) assays for cancer diagnosis.

The NCI team was led by Dr. Stephen Hewitt, a research pathologist who first conceived this invention in response to his observation that the community needed a simpler and more affordable instrument for the discovery and validation of biomarkers to ultimately improve cancer research and diagnosis. Once patented, the NCI Technology Transfer Center identified that the advancement of the technology could be well-served by the Small Business Innovation Research Technology Transfer (SBIR-TT) program, and subsequently recommended it as one of the first NCI technologies for the program. The technology was released as a contract topic for the SBIR-TT and was awarded to a small company, Micatu, Inc. Micatu completed Phase I of the award, and was later awarded Phase II grant funding in June 2014.

The transfer of this NCI technology highlights the use of the SBIR-TT mechanism to transform a patented NCI invention into a commercialized product. The commercialization of this instrument provides researchers and pathology laboratories with access to a technology that was not previously accessible because of technical complexity and significant cost. From Dr. Hewitt's original 2003 drawing, a high-quality, precision instrument with functional and speed capabilities rivaling automated instruments that cost from 8 to 30 times as much is being realized. The "Microarray," likened to a "histology lab in a box," operates without power, making it accessible in the field. Through the vision of Dr. Hewitt and the engineering know-how of Micatu, the result of this technology transfer is an affordable, turnkey instrument that gives investigators the ability to construct their own TMAs rather than having to go to a core service laboratory.

Awardees:

NIH - National Cancer Institute
Dr. Stephen Hewitt
Dr. Greg Evans
April Franks
Dr. John Hewes

NIH - Office of Technology Transfer
Tedd Fenn

Interleukin-2 Receptor Gamma Deficient Mice, Widely Used Research Tools

In 1995, Dr. Warren J. Leonard of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), reported the creation of an interleukin-2 receptor gamma chain (IL-2Rg) deficient mouse. His lab also demonstrated earlier that mutations in the gene encoding IL-2Rg result in X-linked severe combined immunodeficiency (XSCID) and that IL-2Rg is a subunit common to multiple cytokine receptors. The IL-2Rg-deficient mice created by Dr. Leonard provide a unique animal model, the first of its kind, to study XSCID and other immune deficiencies. In addition, the mouse model can also be used as a parent to create new mutant mice harboring double or even triple mutations for the studies of a wide variety of human diseases. NIH obtained a patent for Dr. Leonard's technology in 1999.

Since 1998, Dr. Leonard's technology had been licensed to five commercial entities by the NIH Office of Technology Transfer. Among the parties, The Jackson Laboratory (JAX), a nonprofit biomedical research institution, presented as the most significant and active licensee. JAX is the source for more than 7,000 strains of genetically defined mice for the worldwide research community. Its initial agreement in 1998 provided for royalty-free distribution of the mice to nonprofit laboratories, while corporate laboratories were required to license from NIH. In 2005, it signed an Inter-institutional Agreement with the NIH for a new mutant strain derived from Dr. Leonard's IL-2Rg-deficient mice, with amendments to the agreement made in 2009 and 2010.

Dr. Betty B. Tong, Senior Licensing and Patenting Manager; Steve M. Ferguson, Deputy Director, Licensing and Entrepreneurship; and Thomas Clouse, former Licensing and Patenting Manager, all of the NIH Office of Technology Transfer, negotiated these agreements. Thanks to their efforts, JAX has been able to continually provide its new mutant mice to an estimated 500 users in academic and industry labs. In addition, there are two other new mutant strains derived by JAX from Dr. Leonard's IL-2Rg-deficient mice. They are available as new tools for research and drug discover.

Besides the benefits to the research community, the 2009 JAX agreement also added language to include new mutant mice strains derived by JAX that carry the IL-2Rg mutant allele based on Dr. Leonard's patent. With the execution of the 2009 agreement and its amendments, the amount of royalty payments made to the NIH by licensees now exceeds $2 million, with significant increases the past five years.

Awardees:

NIH - National Heart, Lung, and Blood Institute
Dr. Warren Leonard

NIH - Office of Technology Transfer
Dr. Betty Tong
Steven Ferguson
Thomas Clouse (currently of the National Cancer Institute)

Deep Transcranial Magnetic Stimulation Coil and Therapy System

In April 2013, President Obama unveiled the "BRAIN" initiative, which called on the scientific community to better understand the human brain in an effort to treat, prevent, and cure neurological diseases. For example, anxiety, depression, substance abuse, and post-traumatic stress are a few pervasive neuropsychiatric diseases that afflict more than 150 million people in developed countries, and approximately 15 million of those are in the U.S.

A joint effort from the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Drug Abuse (NIDA) developed a unique H-coil configuration for a deep therapeutic transcranial stimulation (dTMS) system. This dTMS system is capable of delivering magnetic fields to the deep brain, where it stimulates the limbic system, an important area of the brain modulated by dopamine and implicated in multiple neurological and neuropsychiatric disorders.

Dr. Abraham Zanger, who originally developed the technology at NIDA, left NIH and cofounded the company Brainsway, to which NIH exclusively licensed patents covering the H-coil design and its implementation in therapeutically stimulating the deep brain. the company later engaged the NINDS Technology Transfer Office to put in place a clinical collaboration, the purpose of which was to study the uses of its dTMS system for treating Parkinson's disease. In this technology transfer transaction, the inventor was able to license from the federal government the technology in which he had played a crucial development role; find market-experienced people with whom to start a company; find multiple national research organizations to collaborate with, including re-engaging with his original collaborators at NIH to initiate a clinical research protocol; and, ultimately market a device that received clearance from the Food and Drug Administration (FDA) under a 510K application.

In July 2011, FDA approval was awarded for the treatment of specific depression disorders, and approval is pending for a variety of other neuropsychiatric disorders. The dTMS system has also been approved in Europe (under the CE mark) for use in treating all forms of clinical depression, bipolar disorder, post-traumatic stress disorder (PTSD), schizophrenia, smoking cessation, Parkinson's disease, neuropathic pain, Alzheimer's disease, and autism. Ongoing studies include the use of dTMS in a variety of substance addictions, Tourette's syndrome, obestiy, anorexia nervosa, ADD/DHD, and stroke rehabilitation. Currently, the system is in use at more than 15 hospitals and care facilities throughout the U.S.

Awardees:

NIH - National Institute of Neurological Disorders and Stroke
Dr. Mark Hallett

NIH - National Cancer Institute
Heather Gunas

Ben-Gurion University
Dr. Abraham Zangen

(continued)

Deep Transcranial Magnetic Stimulation Coil and Therapy System

Awardees:

Brainsway, Inc.
Dr. Yiftach Roth
Uza Sofer

NIH - Office of Technology Transfer
Michael Shmilovich

Discovery to Market

New research discoveries from federal intramural laboratories typically reach the market via transfer of the underlying technology to private companies for further development and commercialization. This technology transfer process at the Department of Health and Human Services (HHS) and the Department of Defense (DOD) has been assisted by MBA students from Johns Hopkins University's (JHU) Carey Business School in a year-long "Discovery to Market" (D2M) technology transfer course, in which students conduct feasibility studies to determine how discoveries and inventions could be launched as commercial products. The National Institutes of Health (NIH) and the U.S. Army Medical Research and Material Command's (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC) have successfully used partnership agreements with this local academic institution to enhance their own productivity, while also providing practical student experiences relating to entrepreneurship, biomedical innovation, and medical product development.

In the D2M program, MBA students at Carey Business School, after learning the fundamentals of technology commercialization and entrepreneurship, gain access to review cutting-edge biomedical technologies in the commercialization pipeline at NIH and USAMRMC technology transfer offices (TTOs). The MBA teams then evaluate the technology to identify the value proposition of the invention, a market feasibility analysis. TTO licensing associates and scientists from the research institutions receive the analysis and specific action items, including potential licensing opportunities, to better manage the innovations—from finding new commercial partners to dropping technologies with poor commercialization prospects—thus saving money. With its focus on practical experience and outcomes, D2M has become very popular with MBA students as well as TTO licensing staff and scientists.

Because they are the "client" for the business analysis conducted by the MBA student teams, technology licensing associates at the laboratories have found the reports very useful. When reports for the technologies show insufficient commercial opportunity or other unsurmountable problems, the reports can be used as justification for dropping further technology transfer activities for a given case, saving the laboratory from further patent expenses.

When the reports from the MBA students are positive, the technology licensing associate receives an "action plan" with specific activities identified. These have resulted in additional research collaborations for the laboratories or new licensing partners for the underlying technology.

Awardees:

NIH - Office of Technology Transfer
Steven Ferguson

U.S. Army Telemedicine and Advanced Technology Research Center
Ronald Marchessault, Jr.

(continued)

Discovery to Market

Awardees:

Johns Hopkins Carey Business School
Toby Gordon
Nayoung Louie
Supriya Munshaw

Low-Cost Meningitis Vaccine for Sub-Saharan Africa

This 2014 Deals of Distinction™ Award from the LES Industry-University-Government Interface Sector (IUGI) went to the U.S. Food and Drug Administration (FDA), along with the National Institutes of Health (NIH), PATH, and the Serum Institute of India (SII) for MenAfriVac, a low-cost meningitis vaccine designed for use in sub-Saharan Africa. The pioneering vaccine, and the first one for developing countries that does not require constant refrigeration, is based upon a patent license from the NIH and FDA to PATH, and was subsequently sublicensed by PATH to SII under the Meningitis Vaccine Project, a partnership of PATH and the World Health Organization.

Meningococcal meningitis, a deadly bacterial infection of the brain, can be prevented with vaccination, but the technology is complex and generally beyond the capacity of infrastructures in most developing countries. This patent license agreement involving scientists and and technology transfer officers of FDA and NIH has made a critical contribution to developing and transferring the technology needed to manufacture a vaccine against the disease, and at an affordable cost for 26 African countries where group A meningitis is most common.

Under a novel partnership mechanism organized by PATH, NIH licensed a conjugate vaccine technology developed by Dr. Che-Hung Robert Lee and Dr. Carl Frasch of FDA's Center for Biologics Evaluation and Research to PATH. PATH worked with the Serum Institute of India, which agreed to scale up the technology and produce the vaccine at a cost that Africian countries could afford in exchange for technical know-how. The collaboration has been described in SciDev.Net as an "intriguing model" of vaccine development for developing countries, in which a vaccine with specific characteristics tailored to a particular population is developed at a modest cost and provisions to ensure sustainable access are built in from the start.

This license agreement includes financial incentives to the licensee for achievement of certain distribution milestones. The true "return on investment" goal for the NIH and FDA is not financial, but rather maximuming the public health impact of the license agreement. Introduced at large scale in the Burkina Faso in December 2010, the vaccine has now reached more than 150 million people in 12 African countries, with no case of group A meningitis reported so far in vaccinated populations.

"This deal stood out because it shows the true collaboration and teamwork of all parties involved," said IUGI Deals of Distinction Chair Thierry Musy-Verdel. "It also demonstrates that it is possible for research organizations such as federal laboratories and universities to license their technologies to organizations other than traditional pharmaceutical and biotech companies and to successfully achieve product commercialization and thus public utilization of their research."

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NCATS — NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

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Noel Southall
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Leorey Saligan

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John Schiller
Jeffrey Schlom
Thomas Schneider
Steven Seaman
Alla Shapiro
Suneet Shukla
Brad St. Croix
Kentaro Takada
Chris Takimoto
Anita Tandle
Michael Tangrea
Giovanna Tosato
Yien-Che Tsai
Kwong-Yok Tsang
Aykut Uren
Mathias Viard
Thomas Waldmann
Qiong Wang
Xin Wei Wang
Jun Wei
Allan Weissman
John Wunderlich
Chang-yun Xiong
Heng Xu
Yuji Yamaguchi
Taro Yamashita
Nozomu Yanaihara
James Yang
Yongwei Zhang

NEI — NATIONAL EYE INSTITUTE

Sheldon Miller
Fei Wang

NHGRI – NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Randy Chandler
Francis Collins
Maria Eriksson
William Gahl
Marjan Huizing
Riko Klootwijk
Eirini Manoli
Charles Venditti

NHLBI – NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Douglas Christini
Randall Clevenger
Robert Hoyt
Ozgu Kocaturk
Robert Kotin
Brian Safer
Stephen Wiener

NIA – NATIONAL INSTITUTE ON AGING

Bira Arya
Maire Doyle
Josephine Egan
Kenneth Fishbein
Nigel Greig
Harold Holloway
Edward Lakatta
Li Lin
John Pang
Wen Wei
Rui-ping Xiao
Xiaokun Zeng

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NIAAA – NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

George Kunos

NIAID – NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Robert Alexander
Yasmine Belkaid
Richard Bennett
Edward Berger
Joseph Blaney
Bimal Chakrabarti
Zhaochun Chen
Peter Collins
John Deleonardis
Suzanne Emerson
Ivo Francischetti
Ana Goncalvez
Dana Hsu
Yue Huang
John Jenkins
Shaden Kamhawi
Franklin Koh
Wing-pui Kong
Ching-juh Lai
Stephen Leppla
Shi-hui Liu
Victor Lobanenkov
Dmitiri Loukinov
Louis Miller
Bernard Moss
Brian Murphy
Gary Nabel
Daniel O'Brien
Tracy Perry
Elena Pugacheva
Robert Purcell
Judit Quasney
Jose Ribeiro
David Sacks
Jonathan Silver
Mario Skiadopoulos
Kanta Subbarao
Jesus Valenzuela
Stephen Whitehead
Yimin Wu
Zhi-yong Yang

NIAMS – NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Rebecca Baum
Paul Plotz
Nina Raben
Cynthia Schreiner
Shoichi Takikita
Tao Xie

NIBIB – NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Dale Kiesewetter
Robert Lutz

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

Peter Basser
Diana Blithe
Robert Bonner
Lily Zhongdong Dai
Amir Gandjbakhche
Israel Gannot
Jerry Keith
Joanna Kubler-Kielb
Darrell Liu
Fathy Majadly
Christopher Mocca
Lynnette Nieman
John Robbins
Rachel Schneerson

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NIDA — NATIONAL INSTITUTE ON DRUG ABUSE

Jonathan Katz
Amy Newman
Mu-fa Zou

NIDCD — NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Dennis Drayna
Changsoo Kang
Un-kyung Kim

NIDCR – NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Thomas Bugge
John Chiorini
John Cisar
Teresa Greenwell-Wild
Mark Hoon
Michael Iadarola
Laszlo Karal
Zoltan Olah
M Rosovitz
Nicholas Ryba
Michael Schmidt
Nancy Vazquez-Maldonado
Sharon Wahl

NIDDK – NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Carole Bewley Clore
Zhan-Guo Gao
Kenneth Jacobson
Jessica Kefer
Eduardo Padlan
Alberto Plaza
Joseph Shiloach
Dilip Tosh

NIEHS – NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Perry Blackshear

NIMH – NATIONAL INSTITUTE OF MENTAL HEALTH

George Dold
Newlin Morgan

NINDS – NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Bibiana Bielekova
Soren Lowell
Christy Ludlow
Henry McFarland
Roland Martin

Diffusion Tensor Magnetic Resonance imaging

Diffusion tensor imaging (DTI) is an MRI method that produces in vivo magnetic resonance images of biological tissues sensitized with the localized and contrasting characteristics of water diffusion, producing microscopic images of tissues. Water molecules become excited when exposed to a strong magnetic field, which causes the protons in water molecules to move in a coordinated and precise way. The intensity of each image element (voxel) reflects the best estimate of the rate of water diffusion at that location. Because the mobility of water is driven by thermal agitation and highly dependent on its cellular environment, the hypothesis behind DTI is that findings may indicate (early) pathologic change. The main clinical application of DTI has been neurological disorders, especially for the management of acute stroke patients. The NIH Office of Technology Transfer (OTT) licensed the patent estate (mainly U.S. Patent 5,539,310) claiming this technology to the "big-three" MRI instrumentation manufacturers: General Electric, Philips, and Siemens. The three companies have a DTI feature built into their existing MRI devices, which have been helpful in the imaging, diagnosis, and prevention for stroke patients.

NIH OTT also granted a license to Bruker BioSpin for use of the technique in MRI devices directed toward laboratory animals. Drs. Peter Basser, Denis LeBihan, and Carlo Pierpaoli, the inventors of the technique, were instrumental in actively identifying collaborators, potential licensees, and infringers of the technique.

Awardees:

NIH - *Eunice Kennedy Shriver* National Institute of Child Health and Development
Dr. Peter J. Basser
Dr. Denis LeBihan
Dr. Carlo Pierpaoli

NIH - Office of Technology Transfer
Michael Shmilovich

Drugs to Treat Malaria Targeting the Plasmodial Surface Anion Channel

Malaria is a life-threatening disease transmitted through the bite of mosquitoes infected with malaria parasites. In 2012, there were an estimated 219 million cases of malaria and an estimated 660,000 deaths, mostly among young children in sub-Saharan Africa. With the effectiveness of current drugs diminishing as resistant strains of malaria have emerged, new drugs are urgently needed. The plasmodial surface anion channel (PSAC) found on the surface of red blood cells infected with malaria parasites offers an opportunity to develop new drugs to treat and prevent malaria. The channel allows malaria parasites to live and grow inside the red cells of infected hosts. PSAC was first discovered at the National Institute of Allergy and Infectious Diseases (NIAID).

NIH technology transfer offices used conventional and unconventional mechanisms to develop and transfer the technology. Through funding under a conditional gift from nonprofit organization Medicines for Malaria Venture, the NIAID laboratory conducted screens of chemical libraries to identify small molecule inhibitors of PSAC. In response to an NIH advertisement, an anti-infective company, Microbiotix, Inc., approached scientists at NIAID and eventually entered into a partnership under a Cooperative Research and Development Agreement to develop several chemical scaffolds. Further collaboration is ongoing under a Small Business Innovation Research Grant awarded to the company.

As a result of technology transfer efforts, key scientists in the public and private sectors are collaborating to address an urgent unmet public health need to develop new drugs to treat and prevent a disease that burdens large populations worldwide. These efforts are in fulfillment of NIH's mission and advance drug development in an area where there is no market incentive due to a lack of perceived profitability.

Awardees:

NIH - National Institute of Allergy and Infectious Diseases
- **Dr. Sanjay Desai**
- **Dr. Michael Mowatt**
- **S. Dana Hsu**
- **Charles Rainwater**
- **Dr. Mukul Ranjan**

NIH - Office of Technology Transfer
- **Dr. Kevin Chang**

New Low-cost Meningitis Vaccine for Sub-Saharan Africa

Meningococcal meningitis, a bacterial infection of the brain that sweeps across sub-Saharan Africa in an area called the "meningitis belt," is now losing its power to inflict illness and death. Scientists and technology transfer officers from the U.S. Food and Drug Administration (FDA), along with technology transfer officers from the National Institutes of Health (NIH) Office of Technology Transfer (OTT), made a critical contribution in developing and transferring the technology needed to manufacture a vaccine against this terrible disease, and at an affordable cost for African nations like Burkina Faso, Chad, Ethiopia, and Niger. Meningitis can be prevented with vaccination, but the technology is complex and generally beyond the capacity of scientists in most developing countries. This new vaccine, designed specifically for the serotype that affects Africa, is based on a conjugate structure formed by a chain of sugars connected to a protein that the immune system responds to very well.

Under a novel partnership mechanism organized by the Program for Appropriate Technology in Health (PATH), NIH OTT licensed to PATH a conjugate vaccine technology developed by Dr. Che-Hung Robert Lee and Dr. Carl Frasch of the FDA. The Serum Institute of India, which worked with PATH, agreed to produce the vaccine cheaply in exchange for technical know-how. The collaboration agreement has been described by SciDev.Net as an "intriguing model" of vaccine development in developing countries, in which a vaccine with specific characteristics tailored to a particular population is developed at a modest cost and provisions to ensure that sustainable access is built in from the start.

After preclinical animal studies and a series of clinical trials in people in India and Africa's meningitis belt to assess its safety and effectiveness, the new vaccine, MenAfriVac, was approved by India in December 2009 for export to Africa. In June 2010, the World Health Organization (WHO) had prequalified the vaccine for use in global immunization programs. By the end of 2011, an estimated 55 million people had been vaccinated with MenAfriVac at a cost of only 40 cents per dose. In 2012, a low-cost meningitis vaccine designed for use in sub-Sahara Africa without refrigeration or cold-chain custody was launched, with sales of 100 million doses.

Awardees:

FDA - Food and Drug Administration
- **Dr. Carl Frasch**
- **Dr. Che-Hung Robert Lee**
- **Beatrice Droke**
- **Dano Murphy**
- **Dr. Willie Vann**

NIH - Office of Technology Transfer
- **Steven Ferguson**
- **Dr. Uri Reichman**
- **Peter Soukas**

Glybera®: First Gene Therapy Recommended for Approval in the West

On July 20, 2012, a committee of the European Medicines Agency recommended for regulatory approval the first gene therapy using an adeno-associated virus vector to treat lipoprotein lipase deficiency (LPLD), a very rare genetic disease. With a normal diet, patients lacking sufficient levels of lipoprotein lipase have abnormally high serum triglycerides and high levels of very low-density lipoprotein (VLDL), resulting in acute severe pancreatitis and chronic conditions associated with high levels of VLDL, such as cardiovascular diseases.

A team from the National Heart, Lung, and Blood Institute (NHLBI) discovered a means for producing recombinant adeno-associated virus (rAAV) in cultured insect cells. Based on these findings, NHLBI developed a robust and scalable process for producing large quantities of rAAV. Dutch biotechnology company uniQure adapted these methods to produce the therapeutic vector Glybera® for the treatment of LPLD. Glybera® expresses lipoprotein lipase in the patient's own tissue, restoring the body's ability to break down fat particles in the blood, thereby substantially reducing the incidence of pancreatitis.

The National Institutes of Health (NIH) Office of Technology Transfer executed a nonexclusive license to the rAAV baculoviral manufacturing technology with uniQure. The license provides uniQure with an added dimension to its manufacturing platform. Under a separate exclusive license executed in 2011, the company is also working on other gene therapy products using AAV5 vectors technology invented by Drs. Robert Kotin and John Chiorini of NHLBI.

The combined effort of NIH and uniQure has the potential to greatly increase the therapeutic reach of gene therapies to benefit large patient groups. It would also enable the treatment of diseases that require the systemic (as opposed to local) expression of therapeutic genes in patients' tissues.

Awardees:

NIH - National Heart, Lung and Blood Institute
- **Dr. Robert Kotin**
- **Dr. John Chiorini**
- **Dr. Vincent Kolesnitchenko**
- **Dr. Alan Deutch**

NIH - Office of Technology Transfer
- **Dr. Betty B. Tong**
- **Jeffrey Walenta**
- **Mojdeh Bahar**
- **Richard Rodriguez**
- **Dr. Mark Rohrbaugh**

Novel Therapeutic for Tuberculosis – SQ109

According to the World Health Organization, tuberculosis (TB) causes approximately 1.5 million deaths worldwide each year. More than one-third of the world's population has tested positive for *Mycobacterium tuberculosis* (*Mtb*), the bacterium that causes TB, but are not yet ill (latent infection). Of these, approximately ten percent are expected to progress to active TB infection. Treatment is lengthy, and the drugs often come with serious side effects. This has led to poor treatment compliance and allowed the rise of drug-resistant TB strains.

The National Institute of Allergy and Infectious Diseases (NIAID) and Sequella, Inc. began collaborating in 1999 to identify and develop new drugs against TB based on a current TB drug ethambutol (EMB), an ethylenediamine compound. Under a Cooperative Research and Development Agreement (CRADA), they synthesized and screened more than 100,000 second-generation ethambutol molecules, which led to the selection and early development of SQ109.

Sequella is conducting clinical trials with SQ109 as a drug for the treatment of TB, *Helicobacter pylori* (*H. pylori*) infections, and gastric carcinomas. The knowledge gained by NIAID during this collaboration contributes to the laboratory's understanding of the mechanism of action of EMB, and may lead to the discovery and development of future therapeutics.

Sequella continues to advance the development of SQ109 as a therapeutic, and has filed two Investigational New Drug applications for its use against TB and *H. pylori*-related duodenal ulcers. The FDA and the European Medicines Agencies granted the company Orphan Drug status for SQ109 for use against drug-susceptible and drug-resistant TB. Sequella also commenced Phase II trials using SQ109 to treat *H. pylori*-associated duodenal ulcers. In addition, NIAID and Sequella continue to collaborate to study the potential of SQ109 as a tracer to identify TB lesions. These technology transfer activities have resulted in the development of an exciting new drug that exceeds both parties' expectations at the start of the collaboration.

Awardees:

NIH - National Institute of Allergy and Infectious Diseases
Dr. Clifton Barry III
Meghan Van Horn
Tristan Mahyera
Dr. Mukul Ranjan

NIH - Office of Technology Transfer
Edward Fenn

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 by 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 since most noise travels from office to office through the space above the suspended interior ceiling, called a plenum, which is 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. As an Institute within the National Institutes of Health (NIH), NIAID 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 office and laboratory buildings is anticipated. The licensee is actively marketing the technology contemporaneously.

Awardees:

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

NIH - Office of Technology Transfer
Michael Shmilovich

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CC- CLINICAL CENTER

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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
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David Munroe
Makoto Nagashima
Sang-kon Oh
Barry O'Keefe
Joost Oppenheim
Pasquale Pagliaro
Claudia Palena
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Thierry Passeron
Ira Pastan
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Yossef Raviv
Nicholas Restifo
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Lawrence Samelson
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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

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Josephine Egan
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NIAID – NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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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
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Yasutaka Hoshino
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Peter Kwong
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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

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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
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Giovanni Di Pasquale
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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

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NIMH – NATIONAL INSTITUTE OF MENTAL HEALTH

Stephen Huffaker
Joel Kleinman
Edward Unsworth
Daniel Weinberger

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.

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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

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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.

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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.

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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