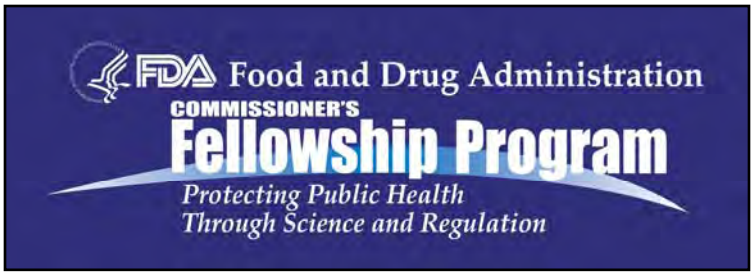
FDA Commissioner's Fellowship Program
Class of 2008



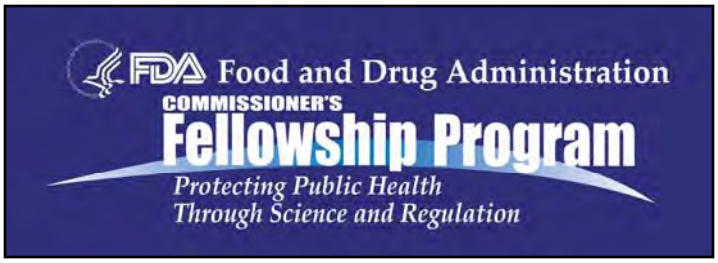
Program Synopsis

The FDA offers a two-year Fellowship Program, which provides an opportunity for health professionals and scientists to receive training and experience at the FDA. Fellows will train at FDA's new state-of-the-art White Oak campus in Silver Spring, Maryland or at other FDA facilities. Salaries are extremely competitive, and travel funds are available to attend scientific meetings.

Coursework
The Fellowship Program combines rigorous, graduate level, didactic coursework with the development of a hypothesis-driven, regulatory science research project. The coursework is designed to provide an in-depth understanding of the science behind regulatory review, encompassing the activities of the FDA across foods, drugs, devices, biologics, and cosmetics. Coursework during the two years includes graduate level public policy, FDA law, epidemiology, clinical trial design, and statistics.

Preceptors
Under the guidance of a FDA senior scientist Preceptor committed to mentoring, Fellows will explore a specific area of FDA regulatory science within any Center or Office. This experience can be in biology, physics, engineering, clinical reviews, biostatistics, informatics, epidemiology, risk analysis, or another aspect of FDA science.

If you have questions about the Program, please email us at:
fdacommissionersfellows@fda.hhs.gov



FDA Commissioner's Fellowship Program

Fellows

FDA Commissioner's Fellows
by Center

Center for Biologics Evaluation and Research (CBER)

Center for Devices and Radiological Health (CDRH)

Center for Drug Evaluation and Research (CDER)

Center for Food Safety and Nutrition (CFSAN)

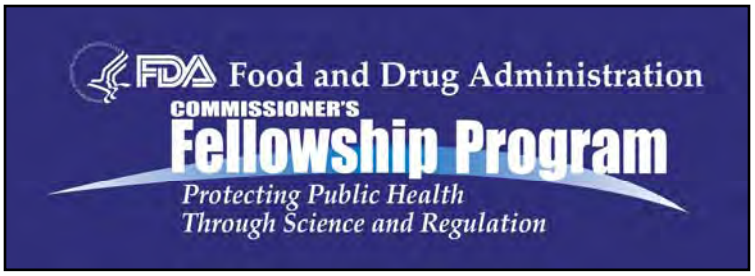
FDA Commissioner's Fellows
by Center, continued

Center for Veterinary Medicine (CVM)

National Center for Toxicological Research (NCTR)

Office of the Commissioner (OC)

Regenerative Medicine Fellowship (CDRH & CBER)



FDA Commissioner's Fellowship Program

Preceptors

FDA Commissioner's Fellowship Preceptors
by Center

Center for Biologics Evaluation and Research (CBER)

Center for Devices and Radiological Health (CDRH)

Center for Drug Evaluation and Research (CDER)

Center for Food Safety and Nutrition (CFSAN)

FDA Commissioner's Fellowship Preceptors
by Center, continued

Center for Veterinary Medicine (CVM)

National Center for Toxicological Research (NCTR)

Office of the Commissioner (OC)

Regenerative Medicine Fellowship (CDRH & CBER)

FDA Commissioner's Fellowship Program
Fellows

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Preceptors: Kathleen Clouse, Ph.D. & Keith Hull M.D.

Scientific & Professional Background

2005-2008 Research Associate, NIAID, NIH
Advisor: Professor Ellie Ehrenfeld

2002-2005 Postdoctoral Research Associate, Yale University, New Haven
Advisor: Professor Scott Strobel

2000-2002 Postdoctoral Research Associate, Yale University, New Haven
Advisor: Professor Jennifer Doudna

1994-1999 Graduate Student, University of Oxford, United Kingdom
Mentor: Professor David Stuart

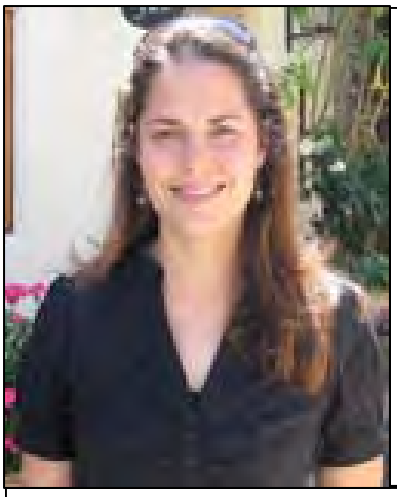
Research Interests

Structural biology of protein and RNA as it relates to understanding of the molecular mechanisms involved in viral replication.

FDA Commissioner's Fellowship Project Overview

An Assessment of the Mode of Action & Therapeutic Benefit of TNF Antagonists

Biological therapeutic proteins are now used successfully for the treatment of conditions that previously lacked effective treatments. However, these products can be ineffective for many patients and individuals that are responsive may experience serious adverse events. The project will involve a comprehensive analysis of the available experimental and clinical data for therapeutics targeting a specific protein known to have a role in inflammation. This information, combined with laboratory studies, will be used to establish structure/function relationships and ultimately gain insights into differences in efficacy and safety profiles between the individual therapeutics.



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Preceptor: Wendy Weinberg, Ph.D

Scientific & Professional Background
B.S. in Chemical Engineering, University of Texas at Austin, 2001
Ph.D. in Biomedical Sciences, University of California, San Diego, 2006
Post Doctoral Scholar, Bioengineering, Stanford University, 2008

Research Interests
I am interested in protein therapeutics for disease treatment and tissue engineering. My doctoral work focused on the role of the transforming growth factor beta superfamily and interacting pathways in colon cancer initiation and progression. My postdoctoral work involved engineering and investigating epidermal growth factor mimics for use as therapeutic agents for wound healing in diabetic patients. Additionally, I worked as part of a team to engineer a double network interpenetrating hydrogel for use as an artificial cornea by incorporating protein growth factors to mimic the natural corneal environment.

FDA Commissioner's Fellowship Project Overview
Mechanisms of Oncogenesis - Investigation of p63 and Interacting Pathways For Targeted Therepy and Biomarker Potential

Billions of dollars are poured into research and development of new drugs; however, this often does not translate into clinical progress. Physicians, industry, and regulators are hoping this will change with the advent of personalized medicine, in which genetic screening gives doctors evidence for tailoring treatments to patients, potentially improving care and saving money. We are working to understand the genetic determinants of the chemotherapeutic response and implicate novel pathways for cancer treatment in subsets of patients. Further, this work will be used to develop predictive preclinical *in vitro* and *in vivo* model. These will help identify which patients are likely to respond to certain therapeutics to help better specify a patient population for clinical trials, and facilitate implementation of personalized medicine with targeted therapies.

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Preceptor: Hana Golding, Ph.D.

Scientific & Professional Background
Moscow State University, Department of Physics (M.D., 1997, Ph.D. 2001)
National Heart, Lung, and Blood Institute, NIH (postdoctoral training 2002-2008)

Research Interests
- Developing and applying optical assays in biomedical research
- Fluorescence Spectroscopy and Microscopy
- Time-resolved fluorescence, FRET
- Biochemistry and Immunology

FDA Commissioner's Fellowship Project Overview
Search for Biomarkers of Adjuvant Toxicity - Development of in vitro Assays for PGE2 and Ca+2 Elevation as a Read-out for Potential Neurotoxicity of Adjuvants in vivo

Large numbers of new adjuvants for vaccines against infectious agents are under development. Adjuvants are designed to improve the immunogenicity of vaccines and to enhance responses in the elderly or infants. In many cases, new adjuvants represent substances selected using high throughput screening of compounds derived from microbial or eukaryotic cell extracts. In addition, the final composition of adjuvant products may contain micro- and nanoparticles, mineral salts, and oil-in-water emulsions. The goals of this project are to develop quantitative *in vitro* assays to measure the levels of molecules that trigger fever (such as PGE2) and mediators of neurotoxicity in human cell lines. These assays will be used for testing of novel adjuvants and viral vectors currently under development in pre-clinical and clinical studies.

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Preceptor: Larisa Rudenko, Ph.D

Scientific & Professional Background

Madras Christian College, Madras India	B.S. Zoology 1993
University of Poona, Pune India	M.S. Zoology 1995
Texas Tech University HSC, Lubbock TX	Ph.D. Cell Biology 2001
American Association for Lab Animal Science	ALAT Cert. 2007
Texas Tech University HSC, Lubbock TX	Clinical Research Mgmt. Cert. 2008
Baylor College of Medicine, Houston TX	Postdoctoral Fellow 2001-02
Texas Tech University HSC, Lubbock TX	Postdoctoral Fellow 2002-05
Texas Tech University HSC, Lubbock TX	Research Asst. Prof. 2005-08
Children's Hospital Los Angeles, Los Angeles CA	Oncology Trainee 2008

Research Interests

Initial research interests were related to control of gene expression, specifically transcript polyadenylation in mammalian male germ cells. This project subsequently morphed into a wider interest in spermatogenesis and gene expression and the use of transgenic and knockout technology to determine genes essential for the process. In support of these interests, I obtained certification in animal handling and colony management broadening my focus to animal models of disease. This led to an eye-opening training experience at Children's Hospital in Los Angeles where I worked on high-throughput drug testing for childhood cancers especially Ewing's Sarcoma using murine models created from patient samples. This training was accompanied by a need to understand the basis of human clinical trials and resulted in my completing a certification course in clinical research management. In short, my training has helped me evolve from a basic animal biologist to a molecular biologist and brought me full circle to the whole-animal model.

FDA Commissioner's Fellowship Project Overview

Genome Stability and its Role in Formulating a Durability Plan for Genetically Engineered Animals

The project I am working on as an FDA Commissioner's Fellow is a continuation of my evolution as a scientist and will allow me to lean heavily on my existing training as a zoologist, molecular biologist and transgenic disease model specialist while expanding my knowledge of FDA regulatory policy and practice. I will be compiling the state of knowledge regarding transgene stability in the genome of genetically engineered animals to determine the known risks involved in heritable rDNA use. These data will be used to prepare a manuscript and a durability assessment tool to provide guidance to industry on the use of GE animals and their post-market surveillance.

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Preceptor: Elliot P. Cowan, Ph.D.

Scientific & Professional Background

Post Doctoral Fellow-Physiology and Neurobiology	
University of Alabama at Birmingham	2007-2008
University of Alabama, Birmingham, AL Ph.D.-Molecular Virology	2002-2007
University of Maryland, College Park, MD B.Sc.-Physiology and Neuroscience	1999-2001
Belgrade University Medical School, Belgrade, Serbia	1995-1999

Research Interests

My doctoral research focused on a specific aspect of the HIV lifecycle. After completing my doctorate, I though it would be very useful to gain a better understanding of disease pathogenesis from the perspective of the host. To that end, I took on a postdoctoral fellowship which investigated the underlying principles of inflammation with a neutrophilic component. These types of inflammatory processes occur in a variety of conditions and infections of the lung. *Pneumocystis carinii* is a pathogen that causes pneumonia (PCP) in some HIV infected individuals. Hence, I decided to investigate whether a proposed theory about the interconnectedness of neutrophil influx into the lung caused by collagen breakdown holds true in the case of PCP. Additionally, I gained a much better comprehension of immunology. My research interest at the FDA is based on the same principle of gaining a better understanding of problems and issues depending upon the vantage point. Building upon the science and regulatory experience gained at PhRMA, my research project at the FDA combines regulation with scientific expertise, in order to evaluate safety and efficacy of products that are designed to protect public health.

FDA Commissioner's Fellowship Project Overview

Integrating Regulatory Review of Blood Donor Screening Tests and HIV Diagnostics with Public Need

Review of novel Human Immunodeficiency Virus (HIV) diagnostics and other blood screening tests by the Division of Emerging and Transfusion Transmitted Diseases (DETTD) have a profound impact on the blood supply of the United States and, as such, the public health of the country. One of the main problems encountered is to reconcile the advancing nature of science within the framework of existing regulations and guidances. Additional issues of concern involve the risk/benefit assessment of the novel products. Therefore, regulations and guidance documents need to be updated in order to accommodate advancements of science for the benefit of public health. Initially, the objectives of my project are to: 1. Gain an understanding of the review process for approval of blood donor screening tests and HIV diagnostics; 2. Develop expertise as a reviewer; 3. Achieve an understanding of interconnectivity of science policy and public health in order to bring critical products to market. HIV, among other transfusion transmitted pathogens, is a global pandemic. Therefore, not only does it pose a public health problem in the U.S., but also in the world. This project is directly in line with FDA's Mission in that it attempts to not only protect but also advance the public health by bringing crucial products to market. Moreover, lessons learned in the U.S. might also be applicable worldwide. Reminder

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Preceptor: Ashley Boam, MSBE & Hina M. Pinto, M.S.E.

Scientific & Professional Background
Francesca received a B.A. in Biology from Bucknell University in 2001 and M.D. from SUNY Stony Brook School of Medicine in 2005. She went on to do her internship and residency training in pediatrics at Children's National Medical Center, where she also completed some global health and health policy coursework through The George Washington University. Upon graduation from residency in June 2008 she worked as a pediatrician in the Emergency Department of Children's National Medical Center.

Research Interests
Having spent some months in the Cardiac Intensive Care Unit and Cardiology ward during residency, Francesca has first-hand experience in the diagnosis and management of children with congenital heart disease. This experience lends itself to her recognition of the need for further innovations in therapeutic options for these children. Inspired to participate, Francesca takes on FDA fellowship through the Center for Devices and Radiological Health where she will lend her clinical expertise to the Division of Cardiovascular Devices to help advance the development of pediatric cardiovascular devices.

FDA Commissioner's Fellowship Project Overview
Advancing Pediatric Cardiovascular Device Development

Despite an initial effort by FDA to spur the development of pediatric cardiovascular devices, there remains a significant unmet need for new devices designed for pediatric patients and for devices currently used off-label to be studied and appropriately labeled for use in children. As such, the primary focus of the project is to expand this effort. Methods include targeted outreach initiatives to the clinical community, guidance toward the development of efficient and pragmatic clinical trial designs, and assistance in the creation of national registries and other strategies to obtain critical post-market information. Clinical review support for applications related to pediatric devices, or use of adult devices in pediatric patients, is an additional key responsibility. The project spans multiple branches in the Division including the Interventional Cardiology Devices Branch and Circulatory Support and Prosthetics Branch.

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Preceptors: Theresa Mullin, Ph.D. & Janet Woodcock, M.D

Scientific & Professional Background
Ph.D. in Pharmacoeconomics, University of Maryland at Baltimore, 2009
M.S. in Immunology, Changchun Institute of Biological Products, Chinese Ministry of Public Health, China, 1997
M.D. in Preventive Medicine, Norman Bethune University of Medical Sciences, China, 1994

Research Interests
My research interests focus on drug postmarketing studies, including policy, drug safety and effectiveness, patient outcomes research, pharmacoeconomics and pharmacoepidemiology.

FDA Commissioner's Fellowship Project Overview
Impact of the FDA's Print Ads Requirement on Adverse Event Report

The requirements of section 906 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) went into effect on March 25, 2008. Section 906 of FDAAA mandates that published direct-to-consumer (DTC) advertisements for prescription drugs include the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. For DTC TV ads, DDMAC also is required to study whether it is appropriate to include this statement. The primary objective of my project is to examine the impact of the FDA's Print Ads Requirement on adverse event report. Furthermore, I hypothesize that adverse event reports have been increased after the FDA's requirement for adding Medwatch contact information in DTCA. I will be using the interrupted time-series analysis and the generalized linear model method, with DTCA spending data and AERS data as my data sources.

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Preceptor: Thomas Flynn, Ph.D.

Scientific & Professional Background

Ph.D. Universitas. Biochemistry (1987) Joszef Attila University. Szeged, Hungary
B.S. Biology (1979) Ricardo Palma University. Lima, Peru

1993-1997 Visiting Associate at the National Institute of Alcoholism and Alcohol Abuse of the NIH. Laboratory of Membrane Biochemistry and Biophysics.
1992-1993 Postdoctoral Fellow at the Osaka Bioscience Institute in Osaka, Japan. Dept. Cell Biology.
1988-1991 Postdoctoral fellow at the Eastern Virginia Medical School, Norfolk, VA. Dept of Biochemistry.

Research Interests

My research interests are on the Preclinical assessment of drug candidates, particularly in the areas of Drug Metabolism and in vitro toxicology. I have worked with several cell-based assays *in vitro* models to screen new chemical entities for Drug Discovery.

FDA Commissioner's Fellowship Project Overview

Evaluation of Hepatotoxicity Using an in vitro Fatty Liver Cell Model

Nonalcoholic fatty liver disease (NAFLD) has been referred to as the hepatic manifestation of the metabolic syndrome, and there is increasing recognition that drug-induced liver injury and hepatocarcinoma risk are associated with NAFLD. I propose to study drug-induced hepatotoxicity using an in vitro model of human liver cells for fatty liver disease. The evaluation of toxicity using several endpoints, might help to assess how liver disease could make liver cells more sensitive to drug-induced toxicity.

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Preceptor: Sanjai Kumar, Ph.D

Scientific & Professional Background
2000 Ph.D. Cell Biology, Duke University
1993 B.A. Biology, Brown University
2007-2008 Research Fellow, DETTD, CBER, FDA
2001-2007 Research Fellow, Laboratory of Parasitic Diseases, NIAID, NIH
2000-2001 Research Fellow, Department of Biology, Duke University
1993-1995 Publications Coordination Associate, Merck & Co., Inc. / Yoh

Research Interests
My current research interest is in the host response to parasitic infection and in the safety and effectiveness of vaccines against parasitic disease. During my post-doc at NIAID, I gained exposure to research in a wide variety of parasitic organisms and vector species that affect human health. My particular research focused on the growth and development of single-celled parasites that cause human disease, specifically malaria and leishmaniasis. I have a strong background in cell biology and expertise in molecular biology, biochemistry, and high resolution light microscopy.

FDA Commissioner's Fellowship Project Overview
Evaluation of a Radiation-Attenuated, Blood Stage Vaccine Against Malaria in the Murine Plasmodium berghei model

Malaria causes significant morbidity and mortality worldwide, and it negatively impacts the donor pool of the U.S. blood supply, yet there are currently no licensed vaccines against the disease. My project evaluates the safety and effectiveness of vaccine candidates against malaria in a mouse model of the disease. This project entails generating new vaccine candidates, evaluating their adverse effects on mice, determining the optimal immunization dose and schedule, and testing for protection against disease. The project explores the regulatory issue of safety in the development of biologics and blood products, and tests the correlation of immune response with vaccine effectiveness.

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Preceptor: Shaohua Zhao, Ph.D.

Scientific & Professional Background
University of Maryland at Baltimore County 1995-1999; BS in Biochemistry and Molecular Biology
New York University 1999-2004; PhD in Biomedical Science
Harvard School of Public Health 2004-2005; M.S. in Epidemiology
University of Maryland School of Medicine 2005-2006; post-doc in the Dept. of Epidemiology and Preventive Medicine
Association of Public Health Laboratories 2006-2008; Senior Manager for Food Safety

Research Interests
I am interested in applications of molecular strain typing methods to the epidemiology of foodborne pathogens, and the policies/regulations that result from the use of these technologies.

FDA Commissioner's Fellowship Project Overview
Source attribution of Salmonella to human diseases based on DNA Fingerprinting profiles

Using an interagency laboratory network called PulseNet, I will be looking at frequency distributions of various *Salmonella* PFGE patterns across retail meat, human, food animal, and imported food isolates. I will determine if any differences in frequency distributions are significant. I will also look at the association of patterns with food sources and determine if geography is a factor. Overall, these results should show that the *Salmonella* patterns associated with humans and foods have different but overlapping populations. The findings should support the existence of virulence and transmissibility differences between *Salmonella* strains. An understanding of the variability of strains in humans, foods, and animals will contribute to improved assessment of the public health risk posed by *Salmonella*.

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Preceptor: Li-Rong Yu, Ph.D.

Scientific & Professional Background

I studied biology and biophysics at University of Giessen in Germany, and received my Ph.D. training in neuroscience/neuropharmacology at Max Planck Institute for Brain Research in Frankfurt, Germany. My postdoctoral training was conducted at University of British Columbia in Vancouver, Canada. I then became an assistant professor in Department of Ophthalmology at University of British Columbia, and later in Department of Neurobiology and Anatomy at Wake Forest University School of Medicine, before joining the Commissioner's Fellowship Program. I have published 37 journal articles and 5 book chapters. My published papers have been cited over 1,150 times in the scientific literature (source: Science Citation Index, Dec. 2008).

Research Interests

My research interests include neurological disorders, brain development, proteomics techniques, and assay development. I have utilized the following techniques in my research: cDNA- and antibody-microarrays, electrophysiological recording *in vivo* (single unit) and *in vitro* (intracellular and field potential), immunocytochemistry, Western-blot, histochemistry, confocal imaging, electron microscopy, and animal surgeries (tracer injection, lesion, and minipump implantation for chronic drug infusion), among others.

FDA Commissioner's Fellowship Project Overview

Ahead of the Challenge - Setting up a Regulatory Standard for Proteomics Data Submission and Evaluation

Proteomics has emerged as a new and rapidly expanding field dealing with large-scale protein analyses. It is anticipated that in the near future proteomics data will be submitted to FDA to support, at the molecular level, drug actions and disease modifications. To date, however, no guideline is available concerning how to assess the quality of proteomics data. My project will therefore attempt to develop a framework which will guide future providers who submit proteomics data as well as future FDA committees who evaluate proteomics data. To this end, quality control experiments have been designed that will examine, at the pre-analytical, analytical, and post-analytical stages, respectively, critical parameters that can influence the accuracy of proteomics data. This project will help to establish quality control standards for proteomics data generation and evaluation, and to prepare FDA to meet future obligations to utilize proteomics data in conjunction with regulatory processes.

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Preceptors: Emily Shacter, Ph.D. & Jee Chung, Ph.D.

Scientific & Professional Background

2004–2008	Research Fellow. Laboratory of Bioorganic Chemistry. NIDDK/NIH.
2003–2004	Postdoctoral Research Associate. Southwest Center for Natural Products Research and Commercialization. The University of Arizona (UA).
2001–2003	Postdoctoral Research Associate. Center for Phytomedicine Research, UA.
1996-2001	Ph.D. Chemical Sciences (Pharmacy). National Autonomous University of Mexico (UNAM).
1989-1994	B.Sc. Biological Pharmaceutical Chemistry. UNAM.

Research Interests

My research interests are in the areas of natural products and protein chemistry, analytical chemistry, and structural biology. My areas of expertise include the development of analytical methods for the isolation, purification and quantification of small molecules and proteins, the structural characterization of molecules using 1D, 2D nuclear magnetic resonance, mass spectrometry, UV/VIS, FT-IR, circular dichroism, and optical rotation, the development of high throughput screening assays, the production of bioactive molecules by microbial fermentation, cloning, expression and purification of recombinant proteins, the characterization of protein-ligand interactions by NMR and calorimetry, enzyme kinetics, protein modeling and docking.

FDA Commissioner's Fellowship Project Overview

Expression and characterization of cyanovirin, a potenHIV-inactivating protein produced by two different expression systems

My fellowship project will focus on the analysis of Cyanovirin (CV-N) heterogeneity resulting from the use of different production procedures and on the investigation of the impact of different experimental conditions, such as sample preparation and protein concentration in the quantitative characterization of protein heterogeneity using liquid chromatography coupled to mass spectrometry. CV-N is a novel protein that is currently under preclinical development for the prevention of HIV infection. CV-N binds specifically to N-linked high mannose

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Preceptors: Keith Wonnacott, Ph.D., Bruce Schneider, M.D., Charles Durfor, Ph.D. & Elias Mallis, B.S.

Scientific & Professional Background
Post Doctoral Research at University of California at San Francisco Diabetes Center
Principle Investigator: Matthias Hebrok, Ph.D.
Project Hypothesis: Mesenchymal and vascular endothelial cell signals are required to drive the final stage of maturation of pancreatic beta cells from induced pluripotent and human embryonic stem cells.

Ph.D. in Neuroscience at Northwestern University Institute for Neuroscience
Principle Investigator: John A. Kessler, M.D.
Project: Homeodomain transcription factor Iroquois-1 regulates neuronal differentiation of neural stem cells.

B.S. in Biochemistry, University of Illinois at Chicago

Research Interests
Drawing from my thesis and post doctoral experience, I am interested in the clinical use of human pluripotent stem cell-derived products, neural stem cell biology and islet transplantation.

FDA Commissioner's Fellowship Project Overview
Regenerative Medicine Combination Device Review

The primary goal of my project is to improve the review process for combination products, which incorporate two regulated entities. For example, a cell product (biologic) that is transplanted in an extra cellular matrix (device) is a combination product. Many regenerative medicine therapies fall in this category. The field of regenerative medicine has grown significantly in the last 10 years, leading to an influx of submissions to the FDA that require coordination between multiple Centers. The goal of my project is to facilitate and promote collaborative efforts between the Centers.

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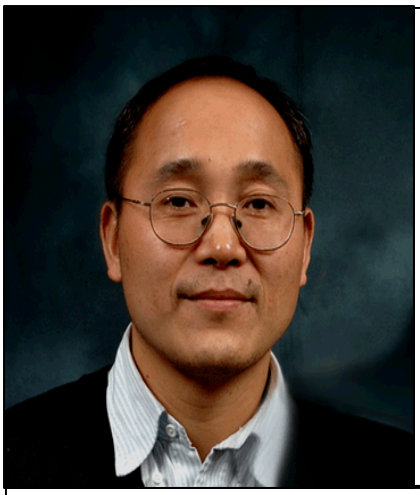
Preceptor: Ben D. Tall, Ph.D.

Scientific & Professional Background
I have over 10 years of experience in microbiology, cell biology, molecular biology, and immunology, and hold M.D. and Ph.D degrees. My previous research works are focused on "the signal transduction pathways involved in invasion, translocation and intracellular survival of *Campylobacter* and *Salmonella* in the human intestine," and "the immune response to *C. jejuni* and *S.* Typhi infection in monocytes and dendritic cells."

Research Interests
I am particularly interested in molecular pathogenesis, gene expression and control mechanisms, host-pathogen interactions, signal transduction, vaccine construction and testing, drug discovery, immunology and rapid diagnostic techniques, and animal models.

FDA Commissioner's Fellowship Project Overview
Analysis of the Role of Curli fimbriae, Extracellular Cellulose, and Related Regulatory Gene Expression in Cronobacter spp. that are Involved in Multicellular Behavior, Biofilm Formation, Host Colonization, and Bacterial Survival

Cronobacter species (Cs), formerly *Enterobacter sakazakii*, are emerging food-borne pathogens that cause severe sepsis, meningitis, and necrotizing enterocolitis in neonates and infants. In current study, the role of curli and cellulose expression in Cs will be investigated by using a site-specific mutagenesis procedure called Red Swab to create curli- and cellulose-deficient mutants as well as mutants deficient in several related regulatory genes. These mutants will be compared with wild type strains and the complemented strains in expression assays, in biofilm formation, and in cell adherence, invasion and survival assays. This work will determine the roles of these virulence factors, augment our understanding the pathogenesis of Cs, and contribute to the Agency's food safety efforts.



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Preceptor: Amit Mukherjee, Ph.D

Scientific & Professional Background
Oct. 2008 – present: FDA Commissioner's Fellow
June 2008 – Oct. 2008: Senior Research Fellow, NCI, NIH
Sept. 2004 – June 2008: IRTA Fellow, NIAID, NIH
Jan. 2003 – Aug. 2004: Spectrum Labs, Inc. Tempe, Arizona
June 2000 – Dec. 2002: Postdoc Fellow, University of Kansas Medical Center
June 1995 – May 2000, Ph.D. Student, University of Kansas Medical Center

Research Interests
I did my Ph.D. in microbiology at University of Kansas Medical Center, studying *Escherichia coli* cell division. Later I joined the NIH, studying small RNA identification in Bacillus anthracis and clp proteases in *E. coli*. I also have experience working in industry for testing veterinary hypersensitive responses to various immunogens. I developed an antibody-based microarray method to identify small RNAs and I have real time PCR research experience and was trained with BSL-3 settings.

FDA Commissioner's Fellowship Project Overview
Utilization of N-Acetyl-D-Galactosamine by Escherichia coli O157:H7

Escherichia coli O157:H7 can metabolize the amino sugar, N-acetyl-D-galactosamine (Aga). The transport of Aga into the cell is mediated in Aga operon by the phosphoenolpyruvate (PEP): carbohydrate phosphotransferase systems (PTS). However, E. *coli* O157:H7 isolates from the 2006 spinach outbreak were unable to utilize Aga due to a point mutation (Gly91Ser) in the *agaF* gene. One of my goals is to investigate if the mutation in AgaF affects its dimerization. A point mutation in the middle of *the agaI gene* (deaminase/isomerase) results in a premature stop codon and yet *E. coli* O157:H7 can still metabolize Aga. The hypothesis is that the mutation splits the gene into two open reading frames (ORFs) and either one of them or both together possess the enzymatic activity. I will test this hypothesis. The function of the AgaS protein in the Aga operon is not known but it has been reported that the sequence of *agaS* has limited homology to tagatose-6-phosphate ketose/aldose isomerase. *In vivo* and *in vitro* experiments will be performed to test this hypothesis. These genes can be used as biomarkers.

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Preceptor: Pak-Sin Chu, Ph.D.

Scientific & Professional Background
Work Experience:
2008 October – present Commissioners fellow - Food and Drug Administration - Maryland
1992 June – 2008 September Senior Research Fellow, Merck & Company- Rahway, New Jersey
Post – Doctoral experience:
1989 Dec.-1992 June - Purdue University-Indiana
1988 October-1989 Dec. Griffith University, Brisbane, Australia
Ph.D. in Natural Products Chemistry, University of Mississippi, 1988

Research Interests
Isolation, structure elucidation and synthesis of bioactive compounds from natural products in a variety of therapeutic areas including anticancer, antiviral, animal health, obesity, and infectious disease areas. This effort culminated in 27 papers, 12 of which are first author papers, in peer reviewed journals including Nature. I have extensive experience in both analytical and preparative HPLC method development. Development of varied chromatographic separation methods for purification of complex mixtures such as resin and silica based medium pressure and flash chromatography, size exclusion and ion exchange chromatography. Expertise in HILIC chromatography and solid phase extraction. Extensive use of NMR and MS for structure elucidation. Synthesis of Bioactive compounds.

FDA Commissioner's Fellowship Project Overview
A Sensitive Method for the Analysis of Methyltestosterone 17-alpha-glucuronide in Muscle Tissue of Fish by LC/MS/MS and Metabolic Profiling

I hypothesize that significant portion of methyltestosterone (MT) residues may exist as the glucuronide form in the fish tissue and that the glucuronide may be a better marker for monitoring purposes. In this investigation rapid and sensitive methods will be developed for profiling MT as well as MT glucuronide within extracts of fish muscle tissue. This would enable more efficient and extensive sampling to ensure safe consumption of fish.

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Preceptor: Chandra S. Chaurasia, Ph.D., R. Ph.

Scientific & Professional Background
Bachelor in Pharmacy, Banaras Hindu University—India, May 1999
Ph.D., Industrial Pharmacy, St. John's University— New York, July 2008

Research Interests
My doctoral area of research has focused on the formulation development for intranasal drug delivery, preformulation studies, and in vitro permeation studies. I have worked with rat and rabbit animal models to investigate the plasma pharmacokinetics and brain distribution profiles after intravenous and intranasal delivery to assess whether there is the direct nose-to-brain transport pathway for a lipophilic anticonvulsant benzodiazepine. I also have experience in the method development and validation in bioanalytical sample analysis using LC/MS. My current research interests involve the application of my knowledge and experience in the review of clinical pharmacokinetic studies.

FDA Commissioner's Fellowship Project Overview
Project I: To review clinical pharmacokinetic studies conducted in support of ANDAs for new generic drug products
Project II: To assist in developing policy for in vivo bioequivalence studies of locally acting gastrointestinal new generic drug products

Currently, the Division of Bioequivalence is facing many controversial scientific issues associated with the assessment of bioequivalence studies of locally acting gastrointestinal generic and brand-name drug products. During my fellowship, I will be reviewing the clinical pharmacokinetic studies conducted in support of ANDAs for new generic drug products and assisting the Division of Bioequivalence in developing Individual Product Bioequivalence Recommendations for locally acting gastrointestinal new generic drug products. Posting of these recommendations on FDA's website will provide guidance to industry and other interested parties, which would result in decreased number of control correspondences received by Division of Bioequivalence pertaining to bioequivalence study recommendations.

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Preceptor: J. Eugene LeClerc, Ph.D.

Scientific & Professional Background
Harvard Medical School - Department of Microbiology and Molecular Genetics
Postdoc, 2005-2008

Cornell University - Attended 2000-2005
Ph.D., 2005, Microbiology

Michigan State University - Attended 1996-2000
B.S., 2000, Microbiology

Research Interests
My research training has primarily been in molecular biology of bacterial genetics, focusing at the bacterial-host interface. I also have experience in the cell biology side of mammalian cellular interactions with bacteria. I have worked with the foodborne pathogen *Listeria monocytogenes* and the intestinal commensal *Bacteroides fragilis*, among others. My current research interests involve application of my experiences to food safety and public health microbiology. Working in the FDA, I hope to help reduce the burden of foodborne disease.

FDA Commissioner's Fellowship Project Overview
Development of a Rapid Approach for Identification of Foodborne Bacterial Pathogens

Current methodologies for identification of outbreak-associated, foodborne bacteria are both labor intensive and time consuming. Advances in molecular technologies present the opportunity to amend current practices such that outbreak investigations are more rapid, constructive, and cost effective. During my fellowship, I will assess current strain typing approaches and technologies on the bases of discrimination (at the subspecies level), sensitivity, timeliness, throughput, portability, ease of use, and cost. I will investigate procedures for typing of the three major species of foodborne disease outbreak-causing bacteria (*E. coli*, *Salmonella* and *Shigella*). The final product will be a comprehensive, rapid microbial analysis of foodborne bacteria to be recommended for validation and subsequent use during outbreak investigations.

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Preceptor: Dianne Murphy, M.D.

Scientific&Professional Background

Johns Hopkins School of Public Health	Associate Faculty	2005-present
	Nutrition Fellowship	2000
	Preventive Medicine Residency	1996
	M.P.H., Epidemiology	1994
Johns Hopkins University School of Medicine	M.D.	1993
Centers for Disease Control and Prevention	EIS Officer	1996-1997

Sabbatical for textbook development, editing:

Food and Nutrients in Disease Management	CRC Press, 2009
Scientific Evidence for Musculoskeletal, Bariatric and Sports Nutrition	CRC Press, 2006

Research Interests

I am interested in physician education and primary care medicine, particularly in nutrition, which is powerful and often underutilized in the prevention and treatment of diseases.

FDA Commissioner's Fellowship Project Overview

Continuing Education for Pediatricians as a Qualitative Research Tool for the FDA

The risk-benefit profile of various medications can be different in adolescents and children than in adult populations where the medications were initially tested. The Office of Pediatric Therapeutics considers how drug labels guide practitioners in making risk-benefit analyses for individual patients. For example, does physician knowledge accurately reflect the drug label? What barriers to implementing the drug label information might practitioners caring for children be encountering?

The fellowship project hypothesizes that continuing medical education activities (CMEs) can provide qualitative data, which may be useful in identifying areas where physician knowledge and practice may be discordant with drug label recommendations. The project will develop CME activities across 2-3 topics, compare different CME formats such as conference lectures, computer-interactive sessions, audio-recordings, and expert panel discussions, and invite participation from practitioners who provide medical care to children and adolescents.

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Preceptor: Michael Marcarelli, PharmD

Scientific & Professional Background
Lester "Jao" Lacorte is a clinical research physician who comes to the FDA with Project Management experience in Clinical Operations and Safety at Cangen Biotechnologies, a start-up Biotech IVD company associated with Johns Hopkins. He served as Project Manager at Walter Reed Army Medical Center's Neurosurgery Department for a Tele-Medicine Initiative investigating Traumatic Brain Injury in support of the soldiers returning from the Gulf War. This involved initiating, developing and managing a Tele-Neurosurgery clinic while concurrently developing a portfolio of related clinical research. This aided in quantifying the need for greater war-time healthcare funding and support for the military wounded. Dr. Lacorte also has experience at the University of Pennsylvania's Nuclear Medicine Department coordinating clinical Oncology trials that combined PET scan technology with Radio-immunotherapy techniques.

Dr. Lacorte received his medical degree from the University of the East in the Philippines and his undergraduate degree in Biology at Rutgers State University in New Jersey. He holds various clinical research certifications including those from NIH. Dr. Lacorte is published in respected peer-reviewed journals including Clin Nucl Med, J Nucl Med and Eur J Nucl Med Mol Imaging.

Research Interests
Dr. Lacorte is interested in patient advocacy, to ensure that safe and efficacious products are developed and brought to market via well-designed and implemented clinical trials.

FDA Commissioner's Fellowship Project Overview
International Clinical Trials Harmonization in Medical Device Regulations for Human Participant Protections, GCP compliance and Data Integrity to Improve the FDA Review and Acceptability of OUS Pre-market Submissions

Dr. Lacorte is working in the Division of Bioresearch Monitoring (DBM) to identify and address challenges in the clinical review and acceptability of pre-market applications for clinical trials performed outside the United States (OUS). The challenges include identifying and addressing differences in overseas and country-specific regulatory authority and guidance practices. Another challenge is ensuring uniform compliance to GCP standards and human participant protections in medical device OUS clinical trials. Dr. Lacorte is also interested in the review and analysis of data integrity issues for FDA pre-market applications.

This project involves international inspections and educational outreach to FDA's overseas regulatory counterparts as well as in-country training for foreign clinical investigators, sponsors and start-up medical device companies. Dr. Lacorte also seeks to identify and address discrepancies discovered in the medical device review of OUS clinical trials for which foreign regulatory infrastructure may be lacking compared with those for drugs and biologics.

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Preceptor: Atin Datta, Ph.D.

Scientific & Professional Background

2003 – 2008	**Research Associate**	**University of Maryland Biotechnology Institute**	**Center of Marine Biotechnology**
2003	**Ph.D.**	**University of Maryland, College Park**	**Marine Estuarine and Environmental Science**
1998	**M.Sc.**	**Western Illinois University**	**Biology**
1995	**B.Sc.**	**Chulalongkorn University, Bangkok Thailand**	**Microbiology**

Research Interests

My research before joining the FDA centered on the microbiology and molecular biology of microorganisms that grow optimally in extreme conditions. For the past 10 years, I had been studying protein folding from archaea that thrive in extreme temperatures by characterizing a small heat shock protein (sHsp) from *Methanococcoides burtonii* (a psychrophilic archaeon) and *Pyrococcus furiosus* (a hyperthermophilic archaeon). I was also studying other molecular chaperones such as Hsp60 or nascent associated complex (NAC) to understand how they can cooperatively function with the sHsps.

FDA Commissioner's Fellowship Project Overview

Comparative Genomic and Transcriptome Analysis of Listeria Monocytogenes Strains Involved in Invasive and Gastroenteritis Listeriosis Outbreaks

Listeriosis has been known to be a serious invasive bacterial infection disease caused by foodborne pathogen, *Listeria monocytogenes*. The susceptible groups include pregnant women, neonates and immuno-compromised adults. However, growing numbers of evidence have revealed that *L. monocytogenes* can cause self-limited febrile gastroenteritis in healthy population. My project aims at the discrimination between the strains that are involved in invasive listeriosis and febrile gastroenteritis by the identification of the global gene expression and DNA sequences of *L. monocytogenes* isolated from different outbreaks using transcriptome analysis.

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Preceptor: Mitchell Cheeseman, Ph.D.

Scientific & Professional Background
Bachelor's degree in Medicine, Hengyang Medical College, China
Master's degree in Biochemistry, Dalian Medical University, China
Ph.D. in Biochemistry, University of Kuopio, Finland
M.Sc. in Computer Science, Rutgers University, New Jersey.
Postdoctoral Fellow at W. Alton Jones Cell Science Center, New York, NY
Postdoctoral fellow at Yale University School of Medicine, New Haven, CT
Research Scientist at Wyeth Pharmaceutical Corporation, Princeton, NJ
Research Assistant Professor at Vanderbilt University Medical Center, Nashville, TN
Bioinformatics Engineer as a SAIC contractor at National Cancer Institute Center for Bioinformatics
Senior Software Engineer as a Knowcean contractor at Department of Commerce
Commissioner's fellow at FDA

Research Interests
My interests are to apply computer skills to analyze the large number of datasets generated by modern biological and toxicological technologies, including high throughput screening, and to develop programs to facilitate the more effective applications of the existing knowledge and resources in FDA regulatory workflow.

FDA Commissioner's Fellowship Project Overview
Computational Implementation of CFSAN Food Additive Knowledge-Base within the review work-flow

We propose to develop and disseminate computational risk assessment methods and tools for use in regulatory decision making and to foster industrial product safety. The first specific aim is to develop a chemical-biological knowledge-base and to electronically capture risk assessment schema practiced within the workflow of the Office of Food Additive Safety (OFAS) at FDA's Center for Food Safety and Applied Nutrition (CFSAN). The knowledge base will include structural classification, threshold of toxicological concern (TTC) categories, and alerts with probabilistic treatments as well as prediction methods, more specifically, mode-of-action driven quantitative structural activity relationship (QSAR) models. Further, a wide range of biological assay results and omics data will be incorporated into the QSAR modeling methodology to more systematically bring molecular mechanisms into risk assessment and risk management paradigms. The second specific aim is to deliver easy-to-use modularized on-demand tools to reviewers within their risk assessment/risk management workflow. The knowledge-base and tools will be shared for public use through collaboration with international and other regulatory bodies.

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Preceptor: Stanley Stern, Ph.D.

Scientific & Professional Background
Swarthmore College, B.A. in Chemistry and Physics, May 2000
Cornell University, Ph.D. in Physics, Aug. 2007
Carnegie Mellon University, Postdoctoral Researcher, Jan. 2007-Oct. 2008

Research Interests
During my graduate and postdoctoral research, I applied physical techniques, such as x-ray and neutron scattering, to study the structure and function of biological systems (lipid bilayers, nucleic acids). I hope to apply my interdisciplinary training in biophysics to complex problems in regulatory science.

FDA Commissioner's Fellowship Project Overview
Development of a Handbook of Radiation Doses in Organs of Patients Undergoing X-ray Computed Tomography

The CT handbook will be a volume in a series, which promotes public health and radiation safety by contributing authoritative, publicly accessible dose information, used by medical staff to communicate risk to patients and optimize protocols to reduce dose. Major tasks in handbook development include: 1) identifying and parameterizing the most common CT exams; 2) calculating organ doses derived from Monte Carlo simulations in mathematical, anthropomorphic phantoms for specific CT scanners and exam protocols; and 3) developing averaging and normalizing approaches to obtain universal (scanner-independent) reference doses.

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Preceptor: William H. Tolleson, Ph.D.

Scientific & Professional Background
Postdoctoral Fellow, 2005-2008, Wadsworth Center, Albany, NY
The Ohio State University, Ph.D., 2005, Columbus, OH
Wittenberg University, BA, 1997, Springfield, OH

Research Interests
I am trained as a biochemist in enzyme mechanism. Understanding how an enzyme work would allow one to design mechanism-based inhibitors. I have developed assay methods and designed inhibitors for peptide deformylase. In addition, I am also interested in horizontal gene transfer that mediates the acquisition of antibiotic resistance genes from one bacterial strain to another. My focus has been on understanding the mechanism of conjugation in *Mycobacterium smegmatis.*

FDA Commissioner's Fellowship Project Overview
Alternative Substrates for Detection of Ribosome-inactivating Protein Toxins (RIPs) in Foods with High RNase Activity

I will be involved in developing a rapid PCR-based assay method to detect and verify the potency of the HHS Select Agents ricin, abrin, Shiga toxin, Shiga-like toxin-1, and Shiga-like toxin-2 present in foods with high endogenous levels of RNase activity. These deadly toxins pose an alarming threat due to their simple isolation from natural sources. Their mode of toxic action is through an RNA *N*-glycosidase enzyme activity that catalyzes the depuration of the conserved GAGA stem-tetraloop from the mammalian 28S ribosomal RNA. This action renders the 28S rRNA ineffective for cellular protein translation.

Ricin, abrin, and SEB are classified as potential bioterrorism Select Agents by DHHS and USDA. Their toxicity in humans is well documented. Category B Bioterrorism Agents are not believed to represent as high a risk for mortality as the more potent Category A Agents. However, the relative ease by which they can be produced renders them easily obtainable poisons. The use of Category B Agents for bioterrorism purposes would likely generate consumer panic regarding the safety of the food supply, complicating a public health crisis with additional adverse economic effects.

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Preceptor: Ira Berkower M.D., Ph.D.

Scientific & Professional Background
I received my BS degree in organic chemistry at SUNY-ESF (Syracuse, NY). My education continued at the University of North Carolina-Chapel Hill where I received my PhD in Biochemistry under Dr. Sharon Campbell. My doctoral dissertation was focused on protein structure/function using Nuclear Magnetic Resonance. I remained at UNC-Chapel Hill for my post-doctoral work but I changed fields into virology. I worked in Dr. Ralph Baric's lab where I studied the SARS-Coronavirus and worked at generating a vaccine for SARS using a novel methodology.

Research Interests
My research interests as a Commissioner's Fellow at the FDA under Dr. Ira Berkower are focused on the daunting task of generating a vaccine for Human Immunodeficiency Virus (HIV). I became interested in this project for multiple reasons. Scientifically the challenge of understanding and ultimately beating HIV is exciting and is a great way for me to apply my previous research in SARS vaccine design. I also chose this project because it has great public health aspects. A viable vaccine for HIV will relieve suffering and pain all over the world. Finally, I am interested in vaccine policy and gaining regulatory experience. Working with Dr. Berkower in the FDA Commissioner's Fellowship program is providing me with all of these opportunities.

FDA Commissioner's Fellowship Project Overview
Engineering HIV Protein gp120 for the Rational Design of an HIV Vaccine

The overall goal of my project is to generate an "open" form of the HIV protein, gp120 that will be a candidate for a future HIV vaccine. gp120 protrudes from the mature HIV virion and is responsible for binding the CD4-receptor resulting in virus entry and infection. Successful vaccines have been elusive in part because gp120 remains in a "closed" form where the CD4 binding site is occluded. The solvent exposed residues in the closed form are highly glycolyslated and also highly variable. Essentially, the closed form of gp120 does not generate a significant humoral immune response. Even if antibodies are generated, HIV can escape the immune response by mutating. The approach in my project is aimed at engineering a gp120 variant that populates an open form exposing the CD4 binging site for an immune response. The CD4 binding site is a desirable target because it is conserved and it is not glycosylated. Antibodies that bind the CD4 binding site on gp120 are protective. Success of this project may result in viable vaccine candidates as well as valuable tools for the continued study of HIV.

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Preceptor: Robert M. "Skip" Nelson, M.D., Ph.D.

Scientific & Professional Background
Education:
A.B., Biology and English Literature, Washington University in St. Louis, 2000.
V.M.D., University of Pennsylvania, 2005.
M.Be. (Master of Bioethics), University of Pennsylvania, 2008.

Professional Experience:
Private practice, companion-animal general medicine and surgery, 2005-2008.

Research Interests
My research interests span a broad range of topics in moral theory, the philosophy of science and medicine, medical ethics, and animal ethics.

FDA Commissioner's Fellowship Project Overview
Risk in Pediatric Research Ethics: Limits and Justifications

During my tenure at the FDA, my principal project will involve various issues in pediatric research ethics, including the philosophy of risk, risk/benefit (in)commensurability, and the normative justification of risk in nonbeneficial pediatric research. In addition to these foci, I continue to maintain a particular interest in animal ethics, and will likely pursue additional work in this area.

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Preceptor: Hediye Nese Cinar, M.D.

Scientific & Professional Background
Postdoc at University of Maryland, Baltimore
Ph.D. at University of Kalyani, Kolkata, India
M.Sc. in Biochemistry at University of Calcutta, India
B.Sc. in Chemistry at University of Calcutta, India

Research Interests
My research expertise are in the far reaching areas of science that span stem cell mediated gene therapy and study of mechanistic pathways of Osteoporosis onset. The cornerstone of my research training is primarily in Microbiology focusing on the bacterial pathogenesis and signal transduction. I have worked with the food borne pathogens *E. coli* and *S. typhimurium* on host-pathogen interaction. My current research interests find a synergistic culmination of my skills and aptitude on my present work on bacterial pathogens in *Caenorhabditis elegans.*

FDA Commissioner's Fellowship Project Overview
Determination and Functional Analysis of Differentially Expressed Genes in Caenorhabditis Elegans Upon Vibrio Cholerae Exposure

During my fellowship program, I will try to establish *Caenorhabditis elegans* as a host model for food borne pathogens. *C. elegans* became established as a powerful genetic model organism for the study of many different processes including development, neurobiology, apoptosis and more recently it has been used to study virulence mechanism of the bacteria, innate immunity and host pathogen interaction. Our present interest is identification and characterization of differentially expressed genes in *C. elegans* upon *Vibrio cholerae* exposure using expression microarrays.

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Preceptor: Larry Schmued, Ph.D.

Scientific & Professional Background

Clinical Research Certification	2007, Indiana University, IN, USA
Ph.D. – Neuroscience	2001, Nagpur University, Nagpur, India
M.Sc. – Biology	1996, University of Calcutta, Kolkata, India

Previous Experience:

Children's Hospital, Harvard University, Boston, MA	Jan, 2008- Oct 2008
Clinical Research specialist– Clinical Oncology	Jan 2007- Dec 2007
Indiana University, Indianapolis, IN	
Research Instructor-Pharmacology and Toxicology	Mar 2004-Dec 2006
Indiana University, Indianapolis, IN	
Post Doctoral Fellow-Division of Endocrinology	Sep 2000-March 2004
Tufts-New England Medical Center	

Research Interests

In today's world when different fields are converging to give a new meaning to science, I view myself as a Neurobiologist standing on the crossroads of emerging opportunities. Due to my formal training in functional neuroanatomy and neuroendocrinology, I find myself in a unique position to contribute in biomedical research. The areas of neuroendocrinology especially neural regulation of hypothalamus-pituitary-gonad, hypothalamus-pituitary-thyroid (HPT), and hypothalamus-pituitary-adrenal axes (HPA) are of my major interest. The role of melanocortin and other neuropeptides in HPT and HPA axes is another very intriguing facet to me and is my long term interest. I also have an active interest in molecular chaperones, and its role in regulating diabetes, obesity and Alzheimer's disease therapy. I am interested in neurotoxicology induced by different classes of neurotoxicants and disease therapeutics which ameliorate the pathology of neurodegenerative disease (Alzheimer's disease).

FDA Commissioner's Fellowship Project Overview

Development of novel histochemical markers of brain vascular elements and their application for localizing neurotoxicant induced pathologies

We have developed histochemical tracers for the detection of brain cell specific pathologies viz., Fluoro-Jade dyes which have been used exclusively to stain degenerating neurons and Black-Gold stains which detect myelinopathies, however, few specific markers are available to detect brain vascular elements. One cell type which has received relatively little attention is the vascular pericytes. Relatively little is known about its function in health or disease and there is no specific histochemical stain for localizing these cells at present. Therefore, one goal is to develop and characterize novel markers for brain vascular elements and then investigate the effects of 3 different classes of neurotoxicants *viz*., kainic acid, an NMDA agonist, 3-nitropropionic acid, an inhibitor of metabolic respiration and methamphetamine, a dopamine agonist on each of the above mentioned vascular elements. Our second goal is to characterize the response other vascular elements such as perivascular sheath to neurotoxic insults. The third goal is to develop fluorescent and bright field labeling at the vascular lumen.

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Preceptor: Tucker Patterson, Ph.D.

Scientific & Professional Background
University of Kansas, B.S. (Cell Biology) 1989-1991
University of Kansas, Ph.D. (Cell Biology) 1992-1998
University of North Carolina, Post-doctoral Fellow, 1999-2003
University of Arkansas for Medical Sciences, Instructor, 2004-2008

Research Interests
I was trained as a cell biologist and have worked in a number of research areas. As such, I have a wide range of interests including cytoskeleton, cell cycle, cell signaling, wound healing, and now, neurotoxicology.

FDA Commissioner's Fellowship Project Overview
Neuroprotective Effects of Pramipexole Against Methamphetamine- and MPTP/MPP+-Induced Cytotoxicity In in vitro and in vivo Models

Parkinson's disease is a progressive neurodegenerative disease that results in the death of dopaminergic neurons within the substantia nigra, which is an area of the brain important for control of body movements. The development and identification of drugs that are capable of preventing or retarding progression of this disease and other neurodegenerative diseases is an important research area. One class of drugs that has been shown to have neuroprotective properties is the dopaminergic agonists. Pramipexole is a dopaminergic agonist that is currently on the market for the treatment of Parkinson's. My research project is designed to study the mechanisms involved in the neuroprotective action of this drug. My hypothesis is that pramipexole will protect against neurotoxicity through anti-apoptotic and antioxidant mechanisms. I will address this hypothesis using two toxicological models of neurodegeneration in both primary rat forebrain cultures and mouse models of Parkinson's. Using standard assays to measure viability, oxidative stress, apoptosis, dopamine metabolism, and gene expression alterations, I anticipated that I will identify genes and molecular pathways that are involved in pramipexole's neuroprotective activity. Not only will this provide mechanistic insight into this drug, but it may ultimately lead to the identification of other therapeutic applications for pramipexole and/or new therapeutic targets for the development of more effective treatments for Parkinson's.

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Preceptors: Tom Gross, M.D. & Danica Marinac-Dabic, Ph.D.

Scientific & Professional Background
I am trained in CT surgery and CV medicine (research degree), and since 1998 full time in research and administration. I did a 3.5 year postdoctoral training at Yale Medical School with advanced course work in Decision sciences, Clinical Epidemiology, and Biostatistics including RWJ Clinical Scholar Program. I also completed a Ph.D. in Health Policy and Management at Johns Hopkins School of Public Health concentrating on health services research and outcomes research. In addition to my current appointment at FDA, I am Senior Service Officer/Senior Adviser at the AHRQ Since 2005. I lead interventions (including surgery), implantable devices and cardiovascular content area. I initiated the revascularization network and supervised two centers for Education and Research in Therapeutics (CERTS): Cardiovascular CERT and Device CERT. I also have a research and teaching experience from Royal College of Surgeons (RCS) of England and London School of Hygiene, UK where I served as faculty, did health services research, and advised National Collaborating Center for Acute Care (part of NICE).

Research Interests
Comparative safety and effectiveness evidence evaluation for implantable medical devices and interventions/surgery. Cardiovascular and orthopedic devices, surgery and interventions are currently ranked highest on my priority list. There is also limited understanding of the methodology to conduct these studies for interventions/surgery and devices which complicates the infrastructure investments that need to be made. This can complicate the development of the FDA Sentinel Initiative particularly in the device signal detection and confirmation setting. My research interests are to advance comparative safety and effectiveness methodology and conduct case studies and pilots that will serve as models for sentinel development in the area of devices and interventions.

FDA Commissioner's Fellowship Project Overview
Evaluation of Potential Data Sources and Feasibility of Developing a National Orthopedic Device Registry

To advance post-market safety and effectiveness drugs and devices, FDA is developing the Sentinel Initiative. This initiative will support active surveillance of marketed medical products by linking multiple existing electronic data sources that can be queried and analyzed to learn about issues. My projects are related to supervision and contributions of projects that will lead to sentinel in orthopedic and cardiac intervention areas. The projects will describe and evaluate existing routinely available resources for suitability for inclusion in a research network. They will involve interviews of data owners, evaluations of data resources, analysis of data to identify the most promising sources, case studies and publications.

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Preceptors: Elizabeth Mansfield, Ph.D. & Tonya Wilbon, B.S.

Scientific & Professional Background

Academic Background:

2005 Bachelors of Biomedical Engineering; University of Minnesota – Twin Cities
2005 Bachelors of Arts, Spanish; University of Minnesota – Twin Cities

Professional Background:

2006 – 2008 Biomedical Engineer, National Institutes of Health
2005 – 2006 Regulatory Affairs, Boston Scientific Corporation
2004 – 2005 Katherine E. Sullivan Fellow, Proyecto Nacional de VIH-SIDA, Ministerio de Salud de Ecuador

Research Interests

Outstanding regulatory policy issues as they relate to in vitro diagnostics, particularly as they relate to Laboratory Developed Tests and Point-of-Care devices. The development of appropriate technologies for resource-limited settings

FDA Commissioner's Fellowship Project Overview

Development of a guidance document recommending the least burdensome approach for CLIA-certified laboratories to comply with the quality system regulation

My commissioner's project will focus on creating a detailed comparison of the Quality System Regulation (QS reg) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). This comparison will highlight the similarities and differences between the two regulations as well as develop recommendations on how lab's compliance with the existing CLIA requirements may form a basis by which they can fulfill the FDA QS reg requirements. The development of both the comparison and recommendations will be carried out as an FDA-CMS collaboration to assure that statutory and regulatory requirements of both the FDA and CLIA systems are adequately and properly interpreted. The resulting recommendations will serve as a guide for those laboratories who seek FDA clearance or approval of their laboratory developed tests (LDTs) with a least burdensome approach for bringing LDT development and manufacturing into compliance with FDA's QS reg requirements.

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Preceptor: Patrick F. McDermott, Ph.D.

Scientific & Professional Background

I received my Ph.D. degree from the Center for Biotechnology, Jawaharlal Nehru University (JNU), New Delhi, India. During my Ph.D., I worked on the mechanism of action of anthrax lethal toxin. I have worked as a post doctoral research fellow at Vanderbilt University, University of Maryland, and National Institute of Health (NIH). My research at these places involved the characterization of an embryonic stem cell library generated by a gene trap vector, investigation of the role of Bundle forming proteins (bfp) in Enteropathogenic *E. coli* (EPEC), and identification of *in vivo* induced *Helicobacter pylori* genes, respectively.

Research Interests

My research interests lie in the area of bacterial pathogenesis. The relationship between a host and a pathogen is dynamic, as each modifies the activities and functions of the other. The outcome of such a relationship depends on the virulence of the pathogen and the relative degree of resistance or susceptibility of the host. Because of the magnitude of the infectious-disease problem, research efforts are being directed to understand the molecular mechanisms of bacterial pathogen-host interactions that will help in developing new or improved strategies to control and prevent bacterial infections.

FDA Commissioner's Fellowship Project Overview

Genotypic and Phenotypic Analysis of Historical Food Borne Salmonella Isolates

At present, I am working on the molecular analysis of food borne *Salmonella* isolates from the CVM's historical collection spanning six decades. Genotypic and phenotypic analysis of these isolates may be helpful in understanding the development and spread of resistance to human and veterinary drugs. The data gathered may be used to help determine the public health impact of antimicrobial use in food-producing animals and to make important medical and regulatory decisions.

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Preceptor: Richard Beger, Ph.D.

Scientific and Professional Background
Ph.D. Human Nutrition; University of Cambridge, UK, 1992
M.Sc. Biochemistry; University of London, UK. 1984
B.Sc. Chemistry; University of Tripoli, Libya, 1982
FDA Commissioner's Fellow 2008 – Present
Executive Director of a non-profit organization, 2006 -2008
Assistant Professor, University of Colorado Health Sciences Center, 1995-2005.
Research Scientist, worked for the British Medical Research Council (MRC), 1991 – 1995.

Research Interests
Metabolomics , particularly as it relates to energy metabolism and toxicology in humans and animals. Obesity, especially in the areas of macronutrient and energy balance mechanisms. The use of stable isotopes and other non-invasive techniques to address critical physiological questions and identifying biomarkers in human and animal disease and non-disease states.

FDA Commissioner's Fellowship Project Overview
Evaluation of Glycolysis and TCA fluxes in MPTP treated C57BL mouse model of Parkinson's disease

Parkinson's disease (PD) is a neurodegenerative disease that affects nearly1.5 million Americans. This disease is not well understood, is poorly diagnosed and as yet, has no cure. Deranged neuronal energy metabolism is implicated as potential cause of the condition, although the exact molecular mechanisms involved are unresolved. Therefore, the objective of this project is to investigate at the molecular level the mechanisms involved in neurotoxin induced Parkinson's disease in cell lines and animal models. Such studies could provide useful information about potential biomarkers that may serve as diagnostic tools for this condition in clinical settings. New techniques involving gas chromatography-mass spectrometry (GC-MS) and stable isotope tracers will be employed in the study to decipher these important and interesting issues in the development and progression of Parkinson disease-like conditions in these models.

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Preceptor: Igor Pogribny, M.D., Ph.D.

Scientific & Professional Background

2008-Present	FDA Commissioner's Fellow, Division of Biochemical Toxicology, FDA-National Center for Toxicological Research, Jefferson, AR
2007-2008	Postdoctoral Research Fellow, Office of the Associate Director for Regulatory Activities, FDA-National Center for Toxicological Research, Jefferson, AR
2007	Ph.D., Biochemistry and Molecular Biology, University of Arkansas for Medical Sciences, Little Rock, AR
2002	M.S,, Biology (emphasis in Microbiology), University of Louisiana at Monroe, Monroe, Louisiana
2000	B.S., Biology, University of Louisiana at Monroe, Monroe, Louisiana

Research Interests

My research interests include elucidating the role of epigenetics, specifically DNA methylation, in the etiology of human diseases, especially cancer. Abnormal DNA methylation has significant effects on the initiation and metastasis of cancer. The use of aberrant methylation events as tumor biomarkers may lead to a better understanding of the molecular mechanisms underlying carcinogenesis.

FDA Commissioner's Fellowship Project Overview

Relationship Between Hepatic Epigenetic Phenotype and Susceptibility to Hepatic Steatosis in Mice

Evidence has accumulated indicating an increased significance of steatohepatitis, a progressive form of fatty liver disease, in the development of hepatocellular carcinoma, especially in the U.S. However, the role of epigenetic alterations, such as DNA methylation, in the genesis of steatohepatitis and cause of individual susceptibilities to steatohepatitis are largely unknown. The aims of my study are to define the role of epigenetic alterations in the genesis of steato-hepatitis and to determine whether or not strain-specific susceptibility of mice to steatohepatitis is associated with individual differences in epigenetic status. It is anticipated that the FDA will ultimately be able to incorporate the knowledge gained from these studies into guidelines that consider the impact of epigenetic changes in evaluating susceptibility to human diseases, including steatohepatitis.

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Preceptor: Robert P. Wise, M.D., M.P.H.

Scientific and Professional Background

University of Michigan:	Master of Public Health (Epidemiology), 2007
Michigan State University:	Doctor of Veterinary Medicine, 2003
Michigan State University	Bachelor of Science (Animal Science), 1999

Research Interests

My research interests include epidemiology, safety, and risk management related to medical products. Prior to joining the FDA, I worked in the epidemiology department of a pharmaceutical company. Assessing the benefit-risk profile of a medical product, which evolves over the product's lifecycle, can be challenging. I am particularly interested in answering research questions related to the safety using large health care databases.

FDA Commissioner's Fellowship Project Overview

Exploring Data Mining Methods for Vaccine-Associated Adverse Event Signal Detection in the Vaccine Adverse Event Reporting System (VAERS) Database

I am working on post-marketing safety surveillance of vaccines using the Vaccine Adverse Event Reporting System (VAERS) database, which contains reports of adverse events associated with vaccines submitted by manufacturers, health care professionals, and consumers. Projects will include investigating data mining methods to detect potential signals of adverse reactions due to vaccines, ways to improve the efficiency of the database by developing additional methods of detecting duplicates, and using text mining to identify possible medication errors.

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Preceptor: Renate Reimschuessel, Ph.D.

Scientific & Professional Background
Ph.D., University of Maryland, College Park, MD 2008
M.S., University of Maryland, Baltimore, MD 2001
B.A., Wesleyan University, Middletown, CT 1997

Research Interests
My area of interest is fish health using various diagnostics procedures including pathology, microbiology, parasitology, and molecular techniques. My previous research included field studies on the health of wild fish stocks and focused on the epidemiology and detection methods of mycobacterial infections in Chesapeake Bay striped bass.

FDA Commissioner's Fellowship Project Overview
Triazine Detection in Fish Tissues by High Performance Liquid Chromatography

Melamine (MEL), an industrial compound used primarily in the manufacture of plastics and flame retardants, and other related s-triazines, specifically cyanuric acid (CYA), were intentionally added to food/feed products in order to artificially inflate protein content analysis. Most notably the ingestion of these compounds caused renal failure in American pets in 2007, and kidney stones in Chinese infants in 2008. MEL has also been found in food animal feed, and while it appears as though chicken and hog excrete MEL with no detectable residuals in edible portions of animals following the withdrawal times studied, fish excrete MEL less rapidly and residues remain in filets. My project will be to: 1) Determine MEL and CYA residue concentrations in fish kidney and serum following oral administration of compounds either singly or in combination; 2) Determine the half life of residues in serum and kidney following various dosage levels and sequences of administration; 3) Correlate presence of MEL-CYA crystals in kidney wet mount and/or histology with residues found in serum, muscle and kidney by high performance liquid chromatography. Further, residues from kidney and serum will be compared with residues detected in muscle (filets). The results from this study will be used to design starting dose regimes for future mammalian studies.

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Preceptor: William Rodriguez M.D., Ph.D.

Scientific & Professional Background

2003 – 2007 CRTA Post-doc fellow at NIH
2007 – 2008 Staff Researcher at NIH
1998 – 2003 Ph.D. in Cancer Biology (with minor in Pharmacology), The School of Medicine, Wayne State University, Detroit, MI

Research Interests

Combining the Ph.D. program at WSU and the research experience received at NCI/NIH, I have devoted 10 productive years in the field of cancer research, in particular, cancer drug development. I have gained expertise in the PET tracer development and applying other non-invasive imaging modalities to evaluate cancer drug efficacy both in the clinical and preclinical settings. I have also gained expertise in developing cancer type specific gene therapy to treat cancer and apply multi-imaging modalities to assess the transfection rate of therapeutic gene in the living animal models.

FDA Commissioner's Fellowship Project Overview

Analysis of the Failed Clinical Trials in Pediatric Population

The Pediatric Exclusivity Program has resulted in more than 130 labeling changes including new dosing recommendation, safety, and efficacy findings. Approximately half of the products studied have been found to have substantive differences in efficacy, dosing, or safety in children when compared with adult populations since the program's inception (Smith, 2008). As of October 31, 2008, 48 of 157 drugs examined have been found to be ineffective when studied in children. I hypothesize that physiologic and biochemical processes are undergoing significant maturation during pediatric development and thus may have a significant direct impact on pharmacokinetic (PK) and pharmacodynamic (PD) profiles, endpoints of the study and dosing regimen, etc. To examine this hypothesis, I will use patient level data from FDA database to analyze and compare the primary endpoint, dose response, demographics, and PK/PD profile to determine if any of these factors played a role in the outcome of the failed clinical trials.

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Preceptor: Ying-Xin Fan, Ph.D. & Gibbes Johnson, Ph.D.

Scientific & Professional Background
Postdoctoral Associate, 2004-2008, Fox Chase Cancer Center, Philadelphia, PA
Ph.D., 2004, North Dakota State University, Fargo, ND
M.S., 1995, Nankai University, China

Research Interests
My scientific expertise lies in the application of wide array of biophysical and biochemical techniques, including various spectroscopic, chromatographic and electrophoresis techniques for protein characterization and structure-function exploration. As one of nature's strategies to conscript protein scaffolds to deliver numerous functions, some oligomeric proteins execute their duties by dramatic changes in their quaternary structure assembly. The knowledge of how these proteins' function is regulated by the conformational change provides a new way to design conformation-specific therapeutics or diagnostic agents.

FDA Commissioner's Fellowship Project Overview
Signaling Selectivity and Dimerization Propensity of Oncogenic EGFR Variants

Some common mutations in the kinase domain of epidermal growth factor receptor (EGFR) found in cancer cells exhibit elevated enzymatic activities and are more sensitive to tyrosine kinase inhibitor based cancer therapeutics. However, the molecular mechanisms of the EGFR kinase variants' involvement in the cancer cell development are far from being fully understood. Mutations in the tyrosine kinase domain may result in an alternation of the downstream signaling specificity, which facilitates the growth of cancer cells. Also, little is known regarding the mechanism of the constitutive activity of EGFR kinase mutations. The ErbB kinase activation mechanism may involve the dimerization and higher order oligomer formation. In this project, an array of cell signaling studies and biophysical characterization techniques will be combined to evaluate the signaling pathways preference and oligomerization propensity of oncogenic EGFR kinase variants.

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Preceptor: Steven Bauer, Ph.D.

Scientific & Professional Background

Postdoctoral Fellow (04/2007 - 10/2008)
National Institute of Health, NIA, Clinical Research Branch & Laboratory of Cellular & Molecular Biology, Baltimore, Maryland
Ph.D. Immunology (03/2003 - 11/2006)
Ruprecht-Karl-University, Heidelberg, Germany
M.Sc. Biotechnology (09/2000 - 06/2002)
Mannheim University of Applied Sciences, Mannheim, Germany
B.Sc. Microbiology (06/1993 - 11/1997) University of Calabar, Calabar, Nigeria

Research Interests
My research interest is in the field of immunology and cell biology focusing in cell therapies. I am interested in investigating the potential in-vivo therapeutic use of adipose derived mesenchymal stem cells to treat or prevent obesity. I am also interested in enhancing my expertise in regulatory affairs and clinical research phases which involves all the stages of application for Investigational New Drugs and Biologics License Application. I have previously investigated the use of bispecific antibodies retargeting Cytokine induced killer (CIK) cells against B-cell neoplasms as an adoptive immunotherapy. I also have expertise in developing fermentation process in a lab-scale production of pyruvate, using recombinant *E. coli* focusing on Fed-batch and diafiltration mode.

FDA Commissioner's Fellowship Project Overview
Adipose Derived Mesenchymal Stem Cell Therapy for Obesity

Obesity is a widespread epidemic in the United States and globally leading to substantial health and economic cost. Using cell and gene therapy may help combat the obesity epidemic. I am investigating the potential in-vivo therapeutic use of adipose derived mesenchymal stem cells to treat or prevent obesity in a mouse model.

The significance of this study is to determine if mesenchymal stem cells could potentially be used clinically as a cellular therapy for prevention or treatment of obesity. This study will contribute to the overall mission of the FDA in that it will give a better understanding of evaluating safety and efficacy in the review of future IND applications for stem cells, tissue and gene therapies.

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Preceptor: Carl E. Cerniglia, Ph.D.

Scientific & Professional Background

Arkansas State Boards Veterinary Medical Exam 6/2008
Texas State Boards Veterinary Medical Exam 4/2007

Texas A&M University, College Station, TX	PhD		Veterinary Microbiology
Texas A&M University, College Station, TX	DVM	5/2007	Veterinary Medicine
Texas A&M University, College Station, TX	BS	5/2002	Biomedical Science

Research Interests

My main research interest involves studying the molecular pathogenesis of foodborne pathogens *in vivo*. My previous graduate research work focused on unraveling the regulatory mechanisms of *Salmonella enterica* serovar Typhi Vi capsular antigen expression and implementing the calf model of enterocolitis to study the expression of *S.* Typhi Vi capsular antigen and the regulators that modulate its expression at the host-pathogen interface.

FDA Commissioner's Fellowship Project Overview

The Molecular Mechanisms of Fluoroquinolone Resistance Among Pseudomonas spp. Isolated from Imported Shrimp

The emergence of multidrug resistant pathogens infecting humans poses a serious public health threat, as the numbers of clinically effective antibiotics are diminishing. The use of antibiotics in animals produced for human consumption may be responsible for generating these antibiotic resistant organisms. In order to develop a better understanding of the potentiated antibiotic resistance transfer from imported shrimp, it is important to study the genes involved in antibiotic resistance among bacteria isolates. Thus, my project involves studying the molecular mechanisms of fluoroquinolone resistance in *Pseudomonas* spp. isolated from imported shrimp.

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Preceptor: Brenton McCright, Ph.D.

Scientific & Professional Background

Postdoctoral Fellow (2007-2008); Northwestern University, Feinberg School of Medicine Department of Microbiology-Immunology, Chicago, IL

Ph.D. (2000-2007) Integrated Graduate Program in the Life Sciences, Northwestern University, Evanston, IL

B.S. (1996-2000) James Madison University, Harrisonburg, Virginia

Research Interests

I am interested in the field of cellular and gene therapies especially as it pertains to human disease and the immune system. My research background is in the field of immunology specializing in the area of T-cell tolerance. I previously investigated the effects and mechanism of an antigen-specific tolerance therapy in the animal disease model, experimental autoimmune encephalomyelitis, a $CD4^+$ T cell mediated model of multiple sclerosis.

FDA Commissioner's Fellowship Project Overview

Evaluation of Adult Murine Derived Mesenchymal Stem Cells for the Treatment of Cardiovascular and Ischemic Injury

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) strives to ensure the safety, purity, potency, and effectiveness of biological products. In order to help CBER achieve these goals, my project is trying to identify potential biomarkers that can be used to predict the quality, potency and safety of stem-cell based product reliability. In particular, I my research efforts will focus on characterizing bone-marrow derived mesenchymal stem cells (MSC) using a mouse model of hindimb ischemia to look at critical features of MSC function.

Lower limb ischemia is a major health problem manifested by pain at rest, nonhealing wounds, ulceration and gangrene. In advanced stages, amputation is often undertaken to alleviate symptoms as there is currently no approved effective treatment. Novel therapeutic approaches to induce angiogenesis include the use of autologous bone marrow cells which are promising but the benefits and mechanism of the treatments are poorly understood. These novel cellular and tissue based therapies are regulated by the FDA in the CBER and in the Office of Cellular, Tissue and Gene Therapies (OCTGT). To aid our understanding of this therapeutic area, this project will use murine models of cardiovascular and ischemic injury to determine if cellular products such as mesenchymal stem cells activate signaling pathways required for tissue repair. Our animal model systems will utilize transgenic mice to generate biomarker specific readouts in response to injection of therapeutic cells such as those used for cardiovascular and ischemic injury.

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Preceptors: Frank Torti, M.D., M.P.H. & Randy Lutter, Ph.D.

Scientific & Professional Background

Kevin received his B.A. in biochemistry from Occidental College in 1996. After completing his undergraduate studies, Kevin spent three years at the National Institute of Allergy and Infectious Diseases as a pre-doctoral fellow and a staff biologist studying allergic inflammation and molecular signal transduction. He then attended Northwestern University where he earned his Ph.D. in biological sciences in 2005. His dissertation research developed a biomaterials-based tissue engineering approach to nerve regeneration and spinal cord injury repair. After completing his doctorate, Kevin was awarded a Christine Mirzayan Science and Technology Policy Graduate Fellowship at the National Academy of Sciences to examine the effects of the Bayh-Dole Act and public-private partnerships on academic research. After completing his fellowship at the National Academies, Kevin conducted a postdoctoral fellowship at Aastrom Biosciences, developing bioreactor-expanded adult human bone marrow-derived stem cells to facilitate tissue repair. Kevin then worked as a Senior Consultant for Booz Allen Hamilton, providing technical expertise to government contracts in the areas of regenerative medicine and global health. Kevin was selected as the 2006-2007 MRS/OSA Congressional Fellow with the American Association for the Advancement of Science's Science and Technology Policy Fellowship Program. In that capacity, he spent a year as the science advisor for Congresswoman Doris O. Matsui (D-CA) during which he wrote legislation to promote science communications training that was signed into law with the *America COMPETES Act* (P.L. 110-69). Kevin then spent the year prior to joining the FDA as Legislative Assistant to Congresswoman Anna G. Eshoo (D-CA) handling science- and research-related policy issues.

Research Interests

Kevin's interests are in the area of technology transfer and improving the communication of science to facilitate the transition of basic research into new products and treatments. He has worked throughout his career to improve the public understanding of science, especially with respect to emerging cross-disciplinary biomedical technologies such as tissue engineering and stem cell research.

FDA Commissioner's Fellowship Project Overview

Science Policy and Outreach in Regenerative Medicine

Kevin's project at the FDA will work to improve the interaction between the FDA and the tissue engineering research community. He will examine the outreach efforts by the FDA to educate the tissue engineering community about research considerations that will enhance technology transfer into the clinic. Kevin will also be working to improve coordination efforts between the FDA and other government agencies to accelerate tissue engineering technology development.

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Preceptors: Keith Wonnacott, Ph.D., Bruce Schneider, M.D.,
Charles Durfor, Ph.D. & Elias Mallis, B.S.

Scientific & Professional Background

Washington University in St. Louis	D.Sc. in Biomedical Engineering	2006
Washington University in St. Louis	B.S. in Biomedical Engineering	2001

Research Interests

My previous research has focused on cell and tissue mechanics especially related to the cardiovascular system. In addition, I have done extensive research in cardiovascular tissue engineering not only from the standpoint of fabricating constructs for replacement of damaged and diseased tissues but also to develop model system to study cell and tissue mechanics.

FDA Commissioner's Fellowship Project Overview

Development of a Cross-Center (CDRH/CBER) Collaboration on Characterization of Biologic Products to Improve Safety, Efficacy, and Consistency

I am working on the multi-center fellowship in regenerative medicine. This project involves working in both CDRH and CBER to address issues related to regenerative medicine products that require expertise from both centers. With my background in tissue engineering, I will be able to offer both centers my expertise and help expand on their knowledge base in regenerative medicine. Another aspect of this project is to foster increased collaboration between the centers. My primary project is organizing a cross-center discussion group to address issues unique to mechanical characterization of cell/scaffold products. By working and reviewing applications in both centers, I will have a unique prospective to harmonize the way these products are reviewed in both centers and to suggest ways to improve the review of these combination products. This project will be supplemented with the organization of a regenerative medicine seminar series to bring in both internal and external experts in the field of regenerative medicine to provide the FDA with understanding of emerging issues and technologies related to regenerative medicine. Finally, I will compile and make available resources on regenerative medicine that will benefit both FDA reviews and stakeholders.

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Preceptor: Mansoor Khan, Ph.D.

Scientific & Professional Background

Education:

2008: University of Michigan, Chemical Engineering, Ph.D.
2005: University of Michigan, Chemical Engineering, M.S.E.
1994: University of Michigan, Environmental Engineering, M.S.E.
1993: New Mexico State University, Chemical Engineering, B.S.

Professional Experience:

2000-2002: Intel Corporation, Senior Chemical Engineer
1995-2000: Intel Corporation, Facilities Engineer

Research Interests

Interests include nanotechnology and the driving force behind the properties that differ from bulk materials; technology transfer from bench- to pilot- to full-scale manufacturing, especially the relationship among the three; kinetic modeling of crystallization phenomena; technology innovation/commercialization. Areas of expertise include quantum dot synthesis and characterization, analytical methods, kinetics, semiconductors, process control, water/ wastewater treatment technologies.

FDA Commissioner's Fellowship Project Overview

The in situ Analysis, Characterization and Scale-up of the Coprecipitation of a Model Drug and Polymer

The co-precipitation of a drug substance has not been well-studied due to inadequate analysis of the particle dynamics. New *in situ* technologies should now enable us to characterize the kinetic and thermodynamic behavior that governs co-precipitation. I will, therefore, develop a consistent, scalable and robust manufacturing process for co-precipitation. My objectives are to: 1) Elucidate the effects of crystal nucleation and growth during co-precipitation; 2) Develop a scale-up strategy using dimensional analysis; 3) Define a design space by incorporating "Quality by Design" through the use of Process Analytical Tools (PAT). We can, through these efforts: 1) Accelerate time-to-market; 2) Reduce product quality variation; 3) Improve operating efficiency; and 4) Reduce post-marketing supplements.

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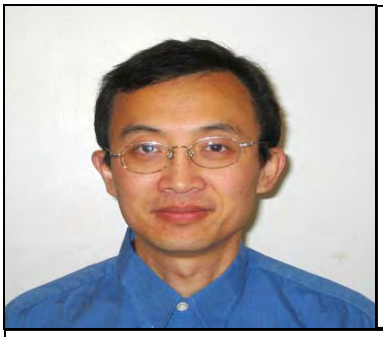
Preceptor: Indira Hewlett, Ph.D.

Scientific & Professional Background
Post-doc, Department of Chemistry, *University of Pennsylvania/University of Marburg*, 2008
Ph.D. & M.S., Chemical and Biomolecular Engineering, *University of Pennsylvania*, 2003-2008
B.E., Chemical Engineering, *Stevens Institute of Technology*, 1998-2003
B.S., Chemistry, *New York University*, 1998-2003
Summer Associate, Pharmaceutical Sciences Division of R&D, *Pfizer Inc.*, 2002

Research Interests
Microarray Development and Assay Miniaturization: we were the first to show that acoustic dispensing technology allows multi-component, nanoliter bio-arrays to be assembled entirely on a chip and features many advantages over pin spotting. Miniaturization enables thousands of data points to be generated and analyzed in parallel, reducing cost, time, and reagents consumed.
High-Throughput Screening and Biotechnology: screening large compound libraries with liquid-handling robotics and optimally designing an *in vitro* detection assay for a given target of interest are crucial first steps for successful drug discovery and development campaigns.
Development of Organometallic Kinase Inhibitors: combinatorial synthesis around a kinase-seeking ruthenium scaffold has allowed for the specific design of potent compounds that hit kinases (a major class of drug targets in Pharma) selectively with minimal off-targeting.

FDA Commissioner's Fellowship Project Overview
Design and Development of Rapid and Sensitive HIV Diagnostics Through Application of Nanotechnology, Biodetection Strategies, and Analytical Science

To ensure the safety of the world's blood supply and to promote better medical treatment, infectious blood-borne diseases must be quickly and effectively detected and identified. The need for simple, rapid, point-of-care diagnostics is urgent in resource-limited countries (such as those in Africa) where the availability of sophisticated equipment and trained personnel is scarce. It is one of FDA's missions to use science and research to make available to the public tools and innovations that will reliably protect and promote the health of people around the globe. One aim is to design and optimize HIV assays using nanotechnology. Gold, silver, and europium nanoparticle-based assays are more sensitive than fluorescence-based ELISA formats and are easier to manage than complex PCR methods. A second goal is to develop a lateral-flow device for HIV that is similar to a home pregnancy test. This kind of diagnostic tool would promote and improve point-of-care and field testing in resource-limited areas as it is low cost, visual, and simple to use. A third objective is the assembly of a genomic microarray against HIV. A chip targeting different strains of the virus can be used to determine the variants present in a blood sample. This is important for medical treatment and characterizing the diversification of the virus within a given geographic location or group. Expertise in these areas will help FDA develop review criteria and standards for effective regulation of future diagnostic devices which will undoubtedly utilize these emerging nanotechnologies and devices. Analytical techniques, other chip-based platforms, and research collaborations that contribute to these aims will also be actively pursued and explored



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Preceptor: Miles Braun, M.D., M.P.H.

Scientific & Professional Background

Graduate Certificate in *Clinical Trial Design and Project Management*, Northeastern University, Boston, MA. 2005. Ph.D. in *Pharmacology*, Kent State University in cooperation with Northeastern Ohio Universities College of Medicine, Kent, OH. 1999. Bachelor of Medicine (MD equivalent), Shanghai Second Medical University, Shanghai, China. 1990. Member, Institutional Review Board, Partners Human Research Protection Program, Partners Healthcare System, Inc., Boston, MA, 2005 – 2008. Instructor in Neurology and Assistant in Neuroscience, Massachusetts General Hospital and Harvard Medical School, Boston, MA, 2003 – 2008. Research Fellow in Neurology, Massachusetts General Hospital and Harvard Medical School, Boston, MA, 1999 – 2003. Graduate Instructor, Medical Physiology Laboratory, Northeastern Ohio Universities College of Medicine, Rootstown, OH, 1995 – 1999. Research Assistant, Department of Pharmacology, Northeastern Ohio Universities College of Medicine, Rootstown, OH, 1994 – 1999. Resident, Department of Cardiovascular & Thoracic Surgery, Renji Hospital, Shanghai Second Medical University, Shanghai, China, 1990 – 1993.

Research Interests

Prior to joining FDA, I had extensive experience in translational research on animal models of neurodegenerative diseases (e.g., Parkinson's disease) using both genetic and pharmacological approaches. Recently, I have been interested in the field of clinical research and drug development. As a result, I have obtained further training in clinical trial design and management, participated in an early phase II study and reviewed clinical studies as an IRB member. I hope that through this fellowship program, I will gain substantial knowledge and experience in the FDA regulation process, science and law regarding the products development.

FDA Commissioner's Fellowship Project Overview

Finding Promising Orphan Products

The goal of my project is to find designated orphan products that have potential for further development. The Office of Orphan Product Development (OOPD) at FDA, where I am located, has granted 1892 orphan designations since 1983 (as of August 29, 2008). Among these designations, however, more than 82% of products have not received market approval, even though 62% of these unapproved products were designated more than five years ago. As an essential mission of OOPD to facilitate orphan product development, we plan to use all available information within FDA (e.g., individual IND, NDA or BLA application files, etc) to study the reasons why these orphan products failed to reach market approval. Particularly, we are interested in finding orphan products that are stalled in development without inherent product problems; that is, promising orphan products. We will focus on the products that have completed at least one phase II study that has shown clinical efficacy with no serious safety issues. The results generated from this project will provide not only a clearer picture for the overall clinical development status of orphan designations but also useful insights for future successful orphan product development.

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Preceptor: Mike Myers, Ph.D.

Scientific & Professional Background
B.S. and M.S. in biology, Fudan University
Personal care product development, Unilever Co.
Application chemist, Rhone-poulenc Co.
Ph.D. in biology, NUS
Research Associate, Waksman Ins., Rutgers Univ.
Research fellow, NIH

Research Interests
Biomarkers for inflammation diseases and cancer, integrative genomics, systems biology, miRNA, developmental biology, bioinformatics

FDA Commissioner's Fellowship Project Overview
Application of Systems Biology to Characterize the Inflammatory and Immunological Responses in Swine

Inflammation is a natural biological response to exogenous pathogen or damage. Many human and animal diseases are associated with abnormal inflammation such as allergy, myopathies, immune system disorders, and cancer. Although non-steroidal anti-inflammatory drugs (NSAIDs) are approved for use in fever reduction in swine, there are no drugs approved to control inflammation in swine. This is largely due to lack of validated inflammation models to assess NSAID efficacy. Systems biology approach will be used to identify novel biomarkers for evaluation of the efficacy of non-steroidal anti-inflammatory drugs in pigs. Specifically, we are planning to identify key genes and lipids that play essential roles in a soft-tissue inflammatory model in porcine. The selected biomarkers will then be evaluated for their potential to predict NSAID efficacy. This research will develop and validate a soft-tissue inflammation model that can be used by the pharmaceutical industry to demonstrate the clinical efficacy of NSAIDs in swine.

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Preceptor: Badar Shaikh, Ph.D.

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Scientific & Professional Background

Research Assistant Professor, 2006-2008
The University of North Carolina at Chapel Hill

Post Doctoral Research Associate, 2004-2006
The University of North Carolina at Chapel Hill

Ph.D. in Pharmaceutical Sciences, 2004
The University of North Carolina at Chapel Hill

Research Interests

My research interest involves the understanding of depletion of anthelmintic drugs in fish using trillium labeled and non-labeled medicines, in vitro metabolism studies using liver microsomes, as well as HPLC and LCMS method development and validation. Prior interest included medicinal chemistry and natural products, anti-AIDS drug discovery and design.

FDA Commissioner's Fellowship Project Overview

Disposition of Selected Veterinary Drugs in Edible Aquatic Species

During the two years of fellowship at Center for Veterinary Medicine at FDA, I will conduct the research on the metabolism and residue depletion of two potent broad-spectrum anthelmintic agents, albendazole and ivermectin, to establish marker residue (MR) in one of the finfish species, yellow perch. Similarities of drug metabolizing enzyme activities of various species of fish may also be evaluated to ascertain their potential role in the establishment of the species grouping. The data from current and related studies will allow us to group and develop model species with similar metabolism and residue depletion profiles, resulting in reduced need to perform detailed studies in each species. The work on species or crop grouping will provide the CVM with science base to set guidelines for speedy drug approval in multiple aquatic species as well as stimulate the drug industry to sponsor new drugs for fish species used for human consumption. Therefore, findings from this study may speed up the drug approval process in multiple aquacultured fish species, as well as set up the MR for market surveillance to monitor potential unauthorized drug use.

FDA Commissioner's Fellowship Program

Preceptors

Steven R. Bauer, Ph.D.
Division of Cellular and Gene Therapies
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research

Fellow: Freddy Tita-Nwa, Ph.D.

Background
B.S., University of Maryland; College Park
Ph.D., University of Maryland; College Park
Previous Employment: Basel Institute for Immunology (1986-1991)

Research Interests
Human adult mesenchymal stem cells (hMSC) are currently used in clinical trials for many clinical indications including heart, bone, and spinal cord repair, improved bone marrow reconstitution, and treatment of inflammatory diseases. In addition, hMSCs have been proposed for treatment of gastrointestinal effects of acute radiation syndrome. MSCs will play an important role in the rapidly advancing fields of regenerative medicine and cell-based therapies that aim to repair, replace, restore, or regenerate cells, tissues and organs damaged by disease, injury, or aging. Manufacturing of large numbers of cells outside the natural environment of the human body may lead to ineffective or dangerous cells, so it is important to understand and carefully control the production process and to define measures that reliably predict safety and efficacy of the MSC-based products.
Current methods to characterize hMSCs rely on a few cell surface markers combined with qualitative, imprecise measures of cell activity.

Richard Beger, Ph.D.
Branch Chief, Center for Metabolomics
Division of Systems Toxicology
National Center for Toxicological Research

Fellow: Bakary J. Sonko, Ph.D.

Background
M.S., Marquette University
Ph.D., Purdue University
FDA Experience - 10 years

Research Interests
Metabolomics technologies offer noninvasive preclinical and clinical diagnostic potential without added risk of exposure to ionizing radiation. The research initiatives of the Center for Metabolomics focus on FDA Critical Path initiatives to develop translational biomarkers of disease, toxicity, and susceptibility. The Center also plays a crucial role in the FDA voluntary program to evaluate metabolics data submitted to the Agency with regulatory submission packages. The metabolomic facility uses state of the art NMR and MS equipment to analyze metabolites in biofluid and tissue samples from preclinical and clinical studies. The NMR lab is equipped with a Bruker 600 MHz NMR that has a cryoprobe and a magic angle spinning (MAS) probe. The Center fo Metabolomics recently added a Waters UPLC-Qtof Premier mass spectrometer system and an Agilent GC mass spectrometer system that will be used to evaluate lipids in biosamples from toxicity and personalized medicine studies. Initial studies were focused on the development of translational biomarkers of acute liver and kidney toxicity. Newer projects are evaluating non-invasive biomarkers of susceptibility to hepatotoxins.

Ira Berkower, M.D., Ph.D.
Division of Viral Products
Office of Vaccine Research and Review
Center for Biologics Evaluation and Research

Fellow: Kirk Prutzman, Ph.D.

Background
B.S. and M.S. in chemistry from Yale University
M.D. and Ph.D. from Albert Einstein College of Medicine
Ph.D. with Dr. Jerard Hurwitz in Molecular Biology

Research Interests
Dr. Berkower's regulatory responsibilities include evaluation of vaccines for HIV, pandemic influenza, seasonal influenza, in addition to evaluation of novel vaccine adjuvants. One important question in the evaluation of new vaccines, viral vaccines in particular, is whether neutralizing antibodies develop and play a role in protection. The focus of Dr. Berkower's research is to use different vaccine platforms to expose regions of the viral proteins known to elicit neutralizing antibodies and then evaluate them for whether the platforms allow for improved induction and binding of antibodies. In particular, we express viral antigens (HIV, hepatitis B virus, and VEE) by recombinant DNA methods and have developed a novel method to incorporate them into 22 nm virus-like particles. We are studying ways to expose the known neutralizing sites on the HIV envelope proteins gp120 and gp41 for improved antibody binding and antibody induction. In the case of gp120, we have recently found modifications of the protein that improve accessibility for antibody binding to an important neutralizing site. For gp41, we have expressed a cross reactive neutralizing epitope in close approximation to a lipid surface, similar to its location on the surface of HIV virions. These particulate antigens are being explored for the ability to induce antibodies to these shared determinants. In addition, we are working on the use of rubella vaccine virus as a live viral vector for many of the same antigens. This project has recently succeeded in the stable expression of a reporter gene, and we are now working to incorporate useful vaccine antigens into the vector. This has the potential to present vaccine antigens in the context of an ongoing infection.

Ashley B. Boam, M.S.B.E.
Chief, Interventional Cardiology Devices Branch
Division of Cardiovascular Devices
Center for Devices and Radiological Health

Fellow: Francesca Dolcimascolo, M.D.

Background
B.S.E. Biomedical Engineering, Tulane University
M.S.B.E. Biomedical Engineering, University of Alabama at Birmingham
FDA Expert scientific reviewer and Master reviewer, 1993-present

Regulatory Interests
As Chief of the Interventional Cardiology Devices Branch (ICDB), Ms. Boam has primary regulatory oversight for multiple pediatric cardiovascular devices, including cardiac occluders and stents for aortic coarctation and pulmonary artery stenosis. Despite the recent implementation of new legislation directed at pediatric device development (FDAAA), there remains a significant unmet need for new devices designed for pediatric patients and for devices currently used off-label to be studied and appropriately labeled for use in pediatric patients. Ms. Boam's regulatory interests include development of efficient and pragmatic clinical trial designs for pediatric cardiology devices, publication of device-specific guidance documents, development of national registries and other strategies to obtain critical postmarket information, and outreach efforts to the clinical community who treat and care for these patients. Ms. Boam's experience and expertise in the regulation of coronary drug-eluting stents (DES), which also fall within her regulatory purview, will be directly applicable to these challenges. Efforts in the DES arena have included publication of a comprehensive guidance document, multiple outreach efforts, and several publications, including articles on clinical trial design. To further her interests in the area of pediatric cardiology devices, Ms. Boam participates in the American Academy of Pediatrics Cardiovascular Devices Subcommittee and recently gave an invited presentation on FDA's perspective on the development of pediatric devices at the annual meeting of the American College of Cardiology.

M. Miles Braun, M.D., M.P.H.
Office of Orphan Products Development
Office of the Commissioner

Fellow: Kui Xu, M.D.

Background
B.A., Wesleyan University
M.D., State University of New York at Buffalo
M.P.H., Johns Hopkins University School of Public Health
FDA Experience – 14 years

Research Interests
Dr. Braun's research interests include: epidemiology, orphan products, biologics, vaccine and drug safety, how to get more and better products to patients, and data mining.

Carl E. Cerniglia, Ph.D.
Director of the Division of Microbiology
National Center for Toxicological Research

Fellow: Quynhtien Tran, D.V.M.

Background
Ph.D. Microbiology , North Carolina State University, 1976
M.S. Universidad Autonoma de Barcelona, Spain
NCI Fellow University of Texas at Austin from 1976-1980

Dr. Cerniglia is active in a variety of government and academic committees and national and international review panels. Dr. Cerniglia is currently serving on a panel at World Health Organization on Antimicrobial Residues in Foods, is a member of several editorial boards, a ASM Foundation of Microbiology lecturer, and his work has resulted in 300 technical publications, 30 book chapters, and numerous review articles.

Research Interests
Dr. Cerniglia's principle research at NCTR since 1980 involves: 1) food safety/biosecurity and methods development; 2) gastrointestinal microbiology; 3) microbial transformation of drugs as models of mammalian metabolism; and 4) biochemistry, genetics of polycyclic aromatic hydrocarbon metabolism and the biodegradation of priority pollutants in the environment.

Chandra S. Chaurasia, Ph.D., R. Ph.
Division of Bioequivalence II
Office of Pharmaceutical Sciences
Center for Drug Evaluation and Research

Fellow: Paramjeet Kaur, Ph.D.

Background
B. Pharm. Mysore University, India
M.S. Pharm. Chem. Philadelphia College of Pharmacy and Science, Philadelphia
Ph.D. Medicinal Chemistry, Virginia Commonwealth University, Virginia

Research Interests
Dr. Chandra Chaurasia volunteered to serve as a preceptor for one of the fellows. Dr. Chaurasia is currently a team leader in the Division of Bioequivalence 2 , in the Office of Generic Drugs. Dr. Chaurasia's responsibilities are to supervise the writing of scientific reviews of bioequivalence submissions to Abbreviated New Drug Applications (ANDAs), by 5 review scientists in his team. Dr. Chaurasia's team specializes in review of clinical pharmacokinetic studies of potential new generic drugs to treat several types of neurological disorders (such as depression and attention deficit disorder), drugs to treat addiction, antiplatelet/anticoagulent drugs, and a wide variety of antibiotics. Dr. Chaurasia joined the FDA as a clinical pharmacokinetic review scientist in 1998. He worked as a scientific reviewer in the Division of Bioequivalence from 1998-2002, and in the Office of Clinical Pharmacology and Biopharmaceutics from 2002-2006. In 2006, he was promoted to his current position as team leader in the Division of Bioequivalence 2.

Mitchell A. Cheeseman, Ph.D.
Deputy Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

Fellow: Zhongjun Luo, Ph.D.

Background
B.S., University of Memphis
Ph.D., University of Florida

Research Interests
My research is in the use of computational methods in safety assessment of chemicals in the food supply and in establishing risk-based exposure thresholds to ensure the safety of the food supply. The concept of thresholds of toxicity is one that underpins the entire field of toxicology. I have been a lead developer of and an expert in the application of FDA's Threshold of Regulation (TOR) approach to risk management of minor chemical exposures. I have also contributed significantly to the development the Threshold of Toxicological Concern (TTC) paradigm that is now in use and in development for a wide variety of regulatory processes and decisions. In 2000, I led the first formal integration of computational toxicology into a pre-market safety assessment program at FDA. This work contributed greatly to focusing Agency resources on issues of greatest public health concern. My current research is focused on the use and limitations of structure activity analysis in the safety assessments of food ingredients and packaging components. This work has already contributed to new approaches to regulation at FDA and internationally including the regulation of components of food packaging, food flavors, contaminants in food, cosmetic ingredients, and impurities in pharmaceuticals. The regulatory concept and approach known as the Toxicological Threshold of Concern (TTC) was developed under the auspices of the FAO/WHO Joint Expert Committee on Food Additives (JECFA) and the European International Life Sciences Institute (ILSI) between 1996 and 2004. It is currently being applied by JECFA to the safety assessment of flavors, by the European Medicines Agency (EMEA) to the regulation of impurities in pharmaceuticals, and in the form of FDA's TOR process to the regulation of food contact materials in the U.S. In addition, the TTC is proposed for application to diverse areas such as cosmetic ingredients, food contaminants, impurities in agricultural chemicals, and chemicals in personal care products.

Jee Chung, Ph.D. and Emily Shacter, Ph.D.
Division of Therapeutic Proteins
Office of Biotechnology Products
Office of Pharmaceutical Sciences
Center for Drug Evaluation and Research

Fellow: Maria-Teresa Guttierriez-Lugo, Ph.D.

Background

Emily Shacter, Ph.D.
Chief, Laboratory of Biochemistry
B.S. University of Maryland; Ph.D. Johns Hopkins University
Research Associate Professor in the Department of Pediatrics/Uniformed Services University of the Health Sciences. Senior Investigator in the Division of Therapeutic Proteins/Center for Biologics Evaluation and Research/FDA

Jee Chung, Ph.D.
Biologist
B.S. University of Chicago; Ph.D. Rutgers University
Post-doctoral Associate at Weill Medical College of Cornell University
Interagency Oncology Task Force Fellow at National Cancer Institute/FDA

Research Interest

The potential future development of bio-generic drugs, also known as Follow-On Protein Products, will rely heavily on analytical techniques to demonstrate similarity to the innovator product. Analytical tools that play a major role in protein structure characterizations are mass spectrometry, nuclear magnetic resonance, circular dichrometry, x-ray crystallography, capillary electrophoresis, and high performance liquid chromatography, just to name a few. Mass spectrometry is widely used by academic biochemists, but the use is limited in the biotechnology industry. Our laboratory is interested in pursuing a research project to determine the utility of mass spectrometry to assay complex commercial therapeutic proteins with emphasis on determining the powers and pitfalls of the various forms of mass spectrometry and the role of sample preparation on the accuracy and precision of the analysis. The goal of the research project will be to develop a thorough understanding of current technology on mass spectrometry to facilitate the review of biotechnology protein products.

Pak-Sin Chu, Ph.D.
Research Chemist
Division of Residue Chemistry
Center for Veterinary Medicine

Fellow: Hiranthi Jayasuriya, Ph.D.

Background
B.S., University of California, Davis
M.S., University of California, Davis
Ph.D., University of California, Davis
Joined the FDA in 1992

Research Interests
Dr. Chu's research focuses on analytical method development for drug residues in biological matrices and on their metabolism and disposition in animals. His current research efforts are aimed at developing analytical methodologies for hormones and for their metabolites. Conventional methods of determining hormone residues typically involve an initial hydrolysis of the phase II conjugates followed by derivatization and detection on gas chromatography–mass spectrometry. Information concerning the identity of the conjugates (glucuronides or sulfates), however, is lost after hydrolysis. For this reason, Dr. Chu is investigating new approaches of detecting and quantifying the intact phase II conjugates using liquid chromatography–tandem mass spectrometry.

Hediye Nese Cinar, M.D.
Division of Virulence Assessment
Center for Food Safety and Applied Nutrition

Fellow: Surasri Sahu, Ph.D.

Background
M.D., Dokuz Eylul University School of Medicine, Turkey
Previous Employment: Postdoctoral researcher, University of California Santa Cruz, USA

Research Interests
I study virulence mechanisms of foodborne bacteria and molecular mechanisms of innate immunity using genetic model organism *Ceanorhabditis elegans* as host model. Model pathogenesis systems employing this nematode as host system provide a venue to study the genetics of bacterial infection from both the pathogen and hosts perspectives. Our research projects include: Development of model pathogenesis systems using *C. elegans* as host organism for pathogens such as *Vibrio sp., Enterobacter sakazaki, Bacillus anthracis, Yersinia pestis, Francisella tularensis Listeria monocytogenes* and identification and characterization of the virulence and host response genes using genome level mutant and RNAi screens and expression microarrays. Research opportunities in our group include development of model pathogenesis systems using *C. elegans* as host model. Genome-wide mutant and RNAi screens in both bacteria and host genomes will be conducted to identify virulence and innate immunity genes.

Kathleen A. Clouse, Ph.D.
Director, Division of Monoclonal Antibodies
Office of Biotechnology Products
Office of Pharmaceutical Science
Center for Drug Evaluation & Research

Fellow: Peter Adams, D.Phil

Background
B.S., Science Education; Ohio State University, Columbus, OH
B.S., Medical Technology; City University of NY, Staten Island, NY
Ph.D., Pathobiology; University of Minnesota, Minneapolis, MN
Previous employment: Georgetown University (Res Asst. Prof; 1986-89)

Research Interests
The existence of multiple HIV subtypes and the ability of the virus to rapidly mutate and evade immune recognition have hindered the development of preventive vaccines or effective cures for HIV disease. Alternative immune-based therapies are currently under development, including monoclonal antibodies or related molecules designed to prevent virus entry or to target endogenous cytokines, whose aberrant production contributes to disease pathogenesis by inducing or potentiating HIV replication. Despite major advances in identifying relevant targets and promising pre-clinical results, many therapies have unexpected clinical outcomes due to multiple functions of the target molecule. Our laboratory investigates the effects of HIV and its associated genes and gene products on cytokine production in human monocytes, macrophages and T-cells, as well as the reciprocal effects of these cytokines on virus replication and cellular function. A parallel project assesses the role of cell membrane expressed oxido-reductases in facilitating HIV entry by enabling conformational changes in the HIV envelope via disulfide bond remodeling after engagement of the virus receptor. The goal of our research is to understand the mechanisms involved in HIV entry and the cellular factors that modulate or are modulated by HIV replication, which have the potential to impact therapeutic efficacy and/or adverse events. The knowledge gained from these studies will: (1) Facilitate review and development of cytokines and/or their antagonists for treatment of HIV and other viral diseases by clarifying their mechanism of action with regard to their potential to mediate both therapeutic and adverse effects, (2) Support the development of potential surrogate markers to monitor therapeutic and adverse events, and (3) Facilitate development and review of *in vitro* assays that can be used to measure biological activity (potency assays) of proposed new products.

Elliot P. Cowan, Ph.D.
Division of Emerging and Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Fellow: Uros Djekic, Ph.D.

Background
B.A., Williams College
Ph.D., Washington University, St. Louis
Previous Employment: National Institute of Neurological Diseases and Stroke, NIH, Special Expert (1986-1993)

Research Interests
The preceptors are senior regulatory scientists in the CBER division responsible for the review of tests used to screen blood donors for transfusion-transmissible agents including emerging infectious diseases (EIDs) and for the review of HIV diagnostics.

Atin R. Datta, Ph.D.
Office of Applied Research and Safety Assessment
Division of Virulence Assessment
Center for Food Safety and Applied Nutrition

Background
B.Sc. University of Calcutta
M.Sc. University of Calcutta
Ph.D., University of Bombay

Previous Employment:
Visiting Fellow. NIADDK, National Institutes of Health, Maryland, USA (1980-1983)
Research Associate: University of Maryland, College Park, Maryland, USA (1983-1986)

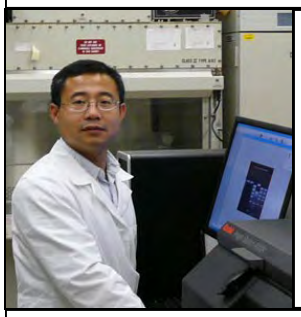
Research Interests
Foodborne listeriosis continues to pose a serious public health problem. The high mortality rate, expenses involved in medical care, and the loss of food products result in the total societal impact that is staggering. Although most outbreaks involve septicemia, meningitis, abortion and death, the first symptom in many outbreaks is gastroenteritis. Current knowledge related to listeric gastroenteritis is extremely limited. Our current research activities aims to characterize various gastroenteritis outbreak strains *of L.monocytogenes* by phenotypic and genetic means and to identify virulence factors that contribute to this disease manifestation. Further characterization of these genes and their functions would be carried out by site specific mutagenesis, cloning and appropriate in-vitro and in-vivo studies. Although food preservation at refrigerator temperatures worked well with many foodborne pathogenic bacteria, Listeria poses unique challenge because it can grow reasonably well at refrigeration temperature. At about 40C *L.monocytogenes* grows with a doubling time of 1.3-1.5 days. The organism can also withstand repeated freezing and thawing and long term storage at sub-zero temperature. *L.monocytogenes* also reported to exhibit high tolerance to salt, and pH making it one of the most tolerant organisms to environmental stress conditions. Our goal for this project is to apply current molecular biology, genomics and bioinformatics tools to identify the genes involved in growth of *Listeria* at refrigerator temperature and understand the biochemical mechanism underlying this phenomenon. Additional goals will include the study of the interaction of cold tolerance and other stress tolerance and virulence potential. Finally we hope that a clearer understanding of the cold tolerance will help to identify means that would drastically if not completely eliminate Listerial ability to grow at refrigeration temperature. Development of such treatment/s would help to reduce the growth potential of *Listeria* in foods stored for long time at refrigeration temperature thereby reducing the incidence of foodborne listeriosis.

Charles N. Durfor, Ph.D.
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Fellows: Jeremiah Wille, D.Sc. & Caitilin Hamill, Ph.D.

Background
B.S., College of William Mary
Ph.D., University of Virginia

Research Interests
Since 1994, Dr. Durfor has served within the Center for Devices and Radiological Health's Office of Device Evaluation as Scientific Reviewer and IDE/PMA Team Leader in the Plastic and Reconstructive Surgery Branch. In this role he performed and supervised the review of the first cellular medical devices to receive FDA approval as well as other products composed of protein, polysaccharide and biomimetic components that are used to treat a diverse array of indications (e.g., wound repair, surgical adhesion prophylaxis, and cosmetic correction of soft tissue defects). From 1988-1993 Dr. Durfor was a scientific reviewer in the Center for Biologics Evaluation and Research (CBER), which is the other component of the FDA involved in the regulation of cellular-derived products. During this time he reviewed manufacturing, preclinical and clinical data for a variety of biotechnology products. He also participated in the preparation of two CBER "Points to Consider" documents on Transgenic Animals and Monoclonal Antibodies. Prior to government service, Dr. Durfor performed research in the private sector resulting in five patents and 12 publications in the fields of biochemical modification of electrode surfaces, metalloprotein enzymology, and monoclonal antibody catalysis.



Ying-Xin Fan, Ph.D.
Staff Fellow
Division of Therapeutic Proteins

Fellow: Lei Tang, Ph.D.

Scientific & Professional Background
1987—B. S., Analytical Chemistry, Wuhan University; 1992—M. S., Analytical Chemistry, Tsinghua University; 1997—Ph. D., Molecular Biology and Biochemistry, Chinese Academy of Sciences; 1997-1999: Visiting Fellow, National Institutes of Health; 1999-2001: Research Fellow, Holland Laboratory, American Red Cross.

Research Interests
Dysregulation of ErbB receptor activity, especially EGFR and ErbB2, has been implicated in various human cancers. Accordingly, these receptors have been intensely studied to understand their importance in cancer biology and as therapeutic targets. FDA currently regulates more that 13 ErbB receptors targeted cancer treatment drugs. However, relatively little is known regarding the molecular mechanisms by which the activity and specificity of the receptor kinases are regulated. We propose that the kinase activation results in an alteration of the kinase specificity, which in turn results in the pathway-selective stimulation of cell signaling. Our recent results have demonstrated that activation of EGFR or ErbB2 is accompanied by a change in the kinase specificity towards select downstream signaling proteins. We believe that our research project will provide new insight on the fundamental molecular mechanism for receptor kinase activation and regulation during signaling and in turn facilitate development of new ErbB receptor-targeted cancer treatments.

Thomas J. Flynn, Ph.D.
Division of Toxicology
Office of Applied Research and Safety Assessment
Center for Food Safety and Applied Nutrition

Fellow: Martha Garcia, Ph.D.

Background
B.S., University of Pennsylvania
Ph.D., Temple University Medical School
Postdoctoral Training: Temple University
Developmental Biology (1977-1980)

Research Interests
Liver toxicity is the leading cause of "black box" warnings and post market withdrawal of drugs, and several dietary supplements are suspected of causing acute liver toxicity in humans. As yet, there are no tests available that accurately predict the potential of chemicals to cause acute liver injury, nor are the biological mechanisms of action of many known liver toxicants clearly understood. Work in my laboratory has focused on the use of human liver cells in culture as a model for both predicting liver toxicity of unknown chemicals and for elucidating the mechanisms of action of known liver toxicants. One current project, which is funded by the FDA Office of Women's health, is addressing the question of why the incidence of chemical-induced liver injury is much higher in women than in men. These studies include evaluation of the effects of sex hormones and mediators of inflammation on the toxicity of model chemicals to cultured human liver cells. These studies may assist the FDA in establishing labeling for safe use of regulated products by women.

Hana Golding, Ph.D.
Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

Fellow: Ksenia Blinova, Ph.D.

Background
B.S. Hebrew University of Jerusalem Israel
Ph.D. Oregon Health Sciences University
Previous Employment:
Research assistant in a Cellular and Clinical Immunology Lab. at the South-African Institute for Medical Research (under Prof. Arthur Rabson), Johannesburg, South Africa.

Research Interests
The research portfolio of Dr. Golding includes several projects, all related to viral pathogens, potential agents of bioterrorism and emerging infectious diseases. Key projects include the following:
1) Novel vaccine adjuvants: Development of new *in vitro* assays and small animal models to identify new biomarkers predictive of vaccine safety. Both acute responses and long term perturbation of the immune system, including breakdown of self-tolerance will be evaluated. Knowledge will contribute to guidance documents. 2) Pandemic and seasonal Influenza vaccines: new leaps into the 21st century: Development of new molecular tools to evaluate the complete humoral immune responses following influenza infection and vaccination. Try to understand the qualitative changes in the immune responses to adjuvanted vaccines. Explore the requirements for elicitation of broadly neutralizing antibodies. Use the knowledge gained towards development of improved vaccines and new criteria for advancement of pre-pandemic vaccines. Knowledge may contribute to guidance documents. 3) Biodefense-smallpox preparedness: Validation of "whole body Bioimaging" using several pathogenic vaccinia viruses expressing "reporter genes". These important animal models are used for the evaluation of new smallpox vaccines and post-exposure prophylaxis with immune based therapies and new anti-viral drugs. These models could replace the need for lethality end-points and will facilitate bringing new safe and effective smallpox vaccines and therapies to licensure.

Thomas P. Gross, M.D., M.P.H.
Director, Division of Postmarket Surveillance
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

Fellow: Art Sedrakyan, Ph.D.

Background
M.D., University of Colorado Health Sciences Center
M.P.H., Johns Hopkins University School of Hygiene and Public Health
Board Certified: Pediatrics, General Preventive Medicine, Clinical Pharmacology

Research Interests
My interests have focused on building postmarket infrastructure and capabilities to provide general, and product-specific, surveillance and epidemiologic means to monitor and evaluate the performance of medical devices once approved for marketing. To that end, our Division has explored/implemented innovative surveillance methods, established a robust post-approval study program (largely based on observational studies), and is building a viable applied research program. We are leaders in medical device surveillance and epidemiology, and are the editors/authors of the first book on the subject (*Medical Device Epidemiology and Surveillance)*. In March 2008, the FDA announced its Sentinel Initiative. The initiative calls for establishing major public-private partnerships to provide the national infrastructure and capability to optimally monitor and evaluate the safety of FDA-regulated products, including medical devices. There is a need to develop a national infrastructure to effectively understand the postmarket performance of orthopedic implants (e.g., total hip or knee replacements). Complementary efforts have to be explored and developed to create a nationally-distributed network of implanting institutions to begin to provide both short- and long-term (through linked databases) national profiles of device-specific performance.

Indira Hewlett, Ph.D.
Division of Emerging and Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Fellow: Eric Wong, Ph.D.

Background
B.S. University of Madras, India
Ph.D. State University of New York, Albany, NY
Previous Employment: Imperial Cancer Research Fund, London, UK - 1980-1982
NCI/NIH, Bethesda, MD - 1982-1985
Senior Staff Fellow - Division of Virology, CBER, 1985-1987

Research Interests
DETTD in OBRR has responsibility for regulation of all donor screening and HIV diagnostic tests. To support this regulatory mission, the laboratory conducts research on 1) novel detection methodologies e.g. nanotechnology and their application to detection of HIV, blood borne biodefense agents and pandemic influenza viruses and 2) HIV diversity and its impact on diagnosis and pathogenesis in the context of blood and patient safety. We are evaluating the potential for nanoparticles to enhance sensitivity and simplify formats of assays to detect HIV, biodefense agents and pandemic influenza. In the HIV/AIDS project we are characterizing novel emerging strains of HIV in Cameroon where viral diversity is high and novel forms emerge at a fairly rapid rate. Several new recombinant forms have been identified, their impact on diagnostic test performance is being evaluated and reference reagents for assay standardization are being developed. Studies should provide insights into the significance of HIV diversity for diagnosis and the global spread of these new strains in the future.

No photo available	**Keith Hull M.D., Ph.D.** Center for Drug Evaluation and Research Office of Drug Evaluation II Division of Anesthesia, Analgesia, and Rheumatology Products Fellow: Peter Adams, D. Phil.

Scientific & Professional Background
07/1999-06/2002 Rheumatology Fellowship, National Institute of Arthritis, Musculoskeletal and Skin DiseasesNational Institutes of Health, Rockville, Maryland
06/1997-07/1999 Internal Medicine Residency, Department of Internal Medicine, Georgetown University, Washington, D.C.
08/1993-05/1997 MD, Boston University School of Medicine, Boston, Massachusetts
08/1988-08/1993 PhD, Pharmacology, Massachusetts College of Pharmacy, Boston, Massachusetts

Research Interests
My basic research interests include the study of the genetic and immunological mechanisms contributing to autoimmune and autoinflammatory diseases. Clinically, my research interests involve the study of autoimmune diseases and clinical trial designs for rare diseases.

No photo available	**Gibbes Johnson, Ph.D.** Chief, Lab of Chemistry Center for Drug Evaluation and Research Fellow: Lei Tang, Ph.D.

Background
B.S. Bloomsburg University;
Ph.D., Arizona State University.

Research Interests
Therapeutic enzymes are the most challenging proteins regulated by the FDA from a structural and bioactivity/potency perspective. Many of the enzymes are used for life saving enzyme replacement therapies for patients with lysosomal storage diseases. To function clinically the enzymes must bind to target cell surface mannose-6-phosphate receptors, be internalized and delivered to the lysosomal compartments. Carbohydrate moieties, in addition to catalytic competency, are thus critical product attributes for enzyme potency. The bis mannose-6- phosphate containing oligosaccharides are responsible for binding the enzymes to cellular receptors. Sugars moieties can also influence the protein's pharmacokinetic and pharmacodynamic parameters, as well as play roles in the molecules ability to initiate harmful immune responses. Our regulatory experience has revealed that relatively modest changes in fermentation can result in significant structural changes that impact critical potency attributes. In one well documented situation this has resulted in a drug shortage for patients who are desperately in need of an approved therapeutic enzyme. One goal of our research is to evaluate the applicability of using Process Analytical Technology (PAT) to on-line bioreactor potency measurements for therapeutic enzymes.

Mansoor A. Khan, R.Ph., Ph.D.
Director, Division of Product Quality Research
Senior Biomedical Research Scientist (SBRS)
Center for Drug Evaluation and Research

Fellow: Juandria Williams, Ph.D.

Background
Ph.D. in Industrial Pharmacy, May 1992, St. John's University, New York.
M.S. in Pharmaceutics, January 1988, Idaho State University, Idaho.
M.S. in Pharmaceutical Technology, Andhra University, Waltair, India
B.S. in Pharmacy, July 1982, Kakatiya University, India.

Research Interests
Drug delivery systems and formulation of "challenging" molecules including nanoparticles, manufacturing sciences and its impact on product safety, evaluation of product variability due to composition and processing changes, physical and chemical stability of drug products, therapeutic equivalence of brand and generic drugs, Quality by Design, and Process Analytical Technologies.

Sanjai Kumar, Ph.D.
Principal Investigator and Chief
Malaria Research Program
Division of Emerging and Transfusion Transmitted Diseases
Center for Biologics Evaluation and Research

Fellow: Noel Gerald, Ph.D.

Background
Previous Employment:
Adjunct Faculty (1996 – 2003), Department of Molecular Microbiology and Immunology, Johns Hopkins University
Senior Investigator (1996 – 2001), Malaria Program, Naval Medical Research Center
Senior Staff Fellow/Visiting Scientist/Visiting Associate and Visiting Fellow (1996 – 1987), Laboratory of Parasitic Disease, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Research Interests
More than 2.6 billion people live in areas where malaria is transmitted that results in 300 to 500 million new infections and more than one million deaths each year. The primary interests of the CBER Malaria Research Program are the following: 1) To develop methods to detect malaria parasites in blood donors to minimize the incidence of transfusion-transmitted malaria, 2) To understand the molecular basis of malaria pathogenesis and immunity and develop laboratory methods that predict the safety and efficacy of candidate recombinant and live, attenuated malaria vaccines. Dr. Kumar's laboratory is currently conducting malaria research projects for: 1) Development of methods to detect malaria parasites in blood donors; 2) Understanding the molecular basis underlying the pathogenesis of cerebral malaria;
3) Understanding the immunological correlates of naturally-induced and vaccine-induced immunity against malaria; 4) Identification of biomarkers that could be used to predict the safety and virulence of live attenuated malaria parasite vaccines.

Joseph E. LeClerc, Ph.D.
Director, Division of Molecular Biology
Center for Food Safety and Applied Nutrition

Fellow: Mark Kazmierczak, Ph.D.

Background
B.S., University of Vermont
Ph.D., Oak Ridge Graduate School of Biomedical Sciences, Univ. of Tennessee
Postdoctoral, Harvard Medical School
Previous Employment:
University of Rochester School of Medicine and Dentistry
DNX, Inc., Princeton, NJ

Research Interests
Joseph E. LeClerc, Ph.D., serves as Director, Division of Molecular Biology, in the Office of Applied Research and Safety Assessment of CFSAN. Dr. LeClerc's research at FDA involves the evolution and emergence of food-borne pathogens and methods for precise identification of enteric pathogens that contaminate the food supply or that might be used as bioterrorist agents. Dr. LeClerc participates with DHS and the FBI on the Inter-Agency Scientific Working Group on Microbial Genetics and Forensics, which sets policy for laboratories carrying out forensics analyses; the Microbe Project, an IWG that serves as a focal point in the government for initiatives involving microbial research; and the FDA Antibiotic Resistance Steering Committee, which coordinates AR activities among the Centers of the FDA. Among over sixty publications, Dr. LeClerc (publishing as J. Eugene LeClerc) has research reports in *Science*, *Proc. Natl. Acad. Sci. (USA)*, *Nature*, and *J. Mol. Biol.* He has also served on the Editorial Board of *Environmental and Molecular Mutagenesis*.

Randall Lutter, Ph.D.
Deputy Commissioner for Policy
Office of the Commissioner

Fellow: Kevin Whittlesey, Ph.D.

Randall Lutter, Deputy Commissioner for Policy of the Food and Drug Administration, leads the agency's activities in the areas of policy development and coordination, agency-wide planning, counter-terrorism and preparedness, as well as advisory committee oversight and management. He is the agency's key policy lead and spokesperson on a variety of issues, including nanotechnology, advisory committees, and the risks of unapproved imported and counterfeit drugs. Dr. Lutter has served as co-chair of the Counterfeit Drug Task Force and as co-chair of FDA's Nanotechnology Task Force. As chair of the FDA Regulatory Policy Council he coordinates the development of regulations and guidance across the agency. From 2005 to 2007 he served as Associate Commissioner for Policy and Planning at FDA.

Before joining FDA, in 2003, Dr. Lutter was resident scholar with the American Enterprise Institute and fellow with the AEI-Brookings Joint Center for Regulatory Studies. From 1991 to 1997 he served at the Office of Management and Budget in the Office of Information and Regulatory Affairs and from 1997 to 1998 he was senior economist for regulation and the environment at the President's Council of Economic Advisers. He taught at the State University of New York at Buffalo after earning his Ph.D. in economics at Cornell University in 1986. His research papers have appeared in *Science*, *Environmental Science & Technology*, the *Journal of Political Economy*, *Regulation*, and other journals.

Elias Mallis, B.S.
Acting Deputy Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Fellows: Jeremiah Wille, D.Sc. & Caitilin Hamill, Ph.D.

Background
B.S., Electrical Engineering, University of Maryland at College Park
FDA Experience - 15 years

Research Interests
As the Branch Chief of the Cardiac Electrophysiology and Monitoring Branch (CEMB) in the Division of Cardiovascular Devices, Mr. Mallis is responsible for oversight of device review of a variety of cardiac diagnostic and therapeutic devices in the fields of electrophysiology, heart failure, and cardiac surgery. This includes the class of device technologies designed for use with safe and effective delivery of gene therapy for treatment of cardiac disease.

No photo available

Elizabeth A. Mansfield, Ph.D.
Office of In Vitro Diagnostic Devices Evaluation and Safety
Center for Devices and Radiological Health

Fellow: Katherine Serrano, B.S.

Background
B.A., University of Pennsylvania
Ph.D., Johns Hopkins University
Previous Employment: Affymetrix, Inc., Director of Regulatory Affairs, 2004-2006; NIH Staff Fellow, NIAMS, 1998-2001

Research Interests
The Office of In Vitro Diagnostics (OIVD) regulates laboratory testing devices used in medical care of humans. It is estimated that 10 billion laboratory tests are performed in the U.S. per year and that these impact 70 to 80% of medical decision making. There are a number of outstanding policy issues regarding IVDs, many of which are the result of rapidly changing technologies used for testing, and others of which stem from a 30-year old policy of enforcement discretion (i.e., deliberate non-enforcement of applicable regulations) towards certain types of IVDs called laboratory-developed tests (LDTs). This use of non-enforcement has raised issues of science, policy and regulatory parity. In an attempt to protect and promote the public health, I am working to provide a more comprehensive, coherent risk-based framework for regulatory oversight of new molecular diagnostic tests and instruments with the clear objective of clarifying and shortening transfer of new tests from the research lab to the patient bedside. A critical initiative in this work is undertaking an analysis of FDA's Quality System regulations as they relate to laboratory developed tests and determining how they can be integrated with existing regulatory oversight provided by the Clinical Laboratory Improvement Amendments and its application to different facets of testing.

No photo available

Michael E. Marcarelli, PharmD, M.S.
Director, Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and Radiological Health

Fellow: Lester Lacorte, M.D.

Background
B.S., Northeastern University
PharmD, University of Arkansas
M.S., Johns Hopkins University
Previous Employment: U.S. Drug Enforcement Administration & Department of Veterans Affairs

Regulatory Interests
Clinical trials are the most costly and critical aspect of medical product development. These trials are generally multi-national and multi-centric in nature and involve a significant commitment of resources, which is oftentimes a scarce commodity in a business. Since the majority of medical device firms are considered small businesses it is critical for these companies to effectively allocate funds to control and manage aspects of the clinical trial that have the greatest impact on data quality and human subject protection. It is also incumbent upon FDA to assure effective oversight of this process in a way that makes sense and is not overly burdensome to the development of advanced medical product technologies.

Danica Marinac-Dabic, M.D., Ph.D.
Chief, Epidemiology Branch
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

Fellow: Art Sedrakyan, Ph.D.

Scientific & Professional Background
University of Belgrade, School of Medicine, M.D., 1984
University of Belgrade, School of Medicine, University Hospital for Obstetrics and Gynecology, Specialization in Obstetrics and Gynecology, 1986-1990
University of Belgrade, School of Medicine, Master's Degree, Human Reproduction, 1991
(Master Thesis: Effects of Diagnostic Ultrasound on the Feto-Placental Unit)
University of Belgrade, School of Medicine, Ph.D., (Perinatal Epidemiology), 2003 (Dissertation: Effects of Diagnostic Ultrasound on Fetal Growth and Development)

Research Interests
Develop postmarket research and surveillance infrastructure and capabilities that would contribute to sciencebased medical device regulatory decision-making. Design and apply innovative methodological solutions to bridge premarket and postmarket evidence of device safety and effectiveness. Expand collaboration with national and international epidemiologic programs, including those within the FDA, to promote better designed psotmarket studies of medical devices.

Brent McCright, Ph.D.
Division of Cellular and Gene Therapies
Office of Cellular, Tissue, and Gene Therapy
Center for Biologics Evaluation and Research

Fellow: Danielle Turley, Ph.D.

Background
Ph.D. Oncological Sciences, University of Utah
M.S. Molecular, Microbial, and Cellular Biology, George Mason University
B.S. Electrical Engineering, University of Maryland
Post-doctoral Fellow: The Jackson Laboratory 1999 - 2002

Research Interests
The primary purpose of cell and tissue engineering is to address the growing need for tissues and organs required to treat patients with degenerative diseases. To avoid treating patients with poorly engineered, uncharacterized collections of transplanted cells that will not function reliably and may damage other organ systems in a patient, we are developing methods for predictable characterization of these products, and for evaluating the safety and efficacy of these novel cell-based therapies.

Patrick F. McDermott, Ph.D.
Division of Animal and Food Microbiology
Center for Veterinary Medicine
Office of Research

Fellow: Aparna Singh, Ph.D.

Background
B.S., Ph.D., University of Arkansas for Medical Sciences, Little Rock AR

Research Interests
The use of antimicrobial agents in food animals can select for antimicrobial resistant foodborne pathogens. This may render foodborne enteric disease less responsive to therapy in cases resulting from animals exposed to antimicrobials. Dr. McDermott's research examines the evolution of resistance in animals exposed to antimicrobials, the molecular mechanisms underlying resistance, and the spread of these pathogens through the retail food supply. In addition, he is interested in the development of standardized in vitro antimicrobial susceptibility testing methods. Dr. McDermott's research examines the genetic bases of multiple antimicrobial resistance in common foodborne bacteria. These strains are acquired from retail meat samples collected for NARMS. Molecular methods such as PCR and microarray, in addition to gene transfer studies, are used to identify the constellation of genes conferring resistance, and their capacity to spread horizontally to other bacteria. This information can be used to help determine the magnitude of resistance spread via foods.

Amit Mukherjee, Ph.D.
Division of Molecular Biology
Office of Applied Research and Safety Assessment
Center for Food Safety and Applied Nutrition

Fellow: Zonglin Hu, Ph.D.

Background
Birla Institute of Technology and Science, Pilani, India
Calcutta University, Calcutta, India
University of Edinburgh, Scotland, U.K.
University of Kansas Medical Center, Kansas City, Kansas
Previous Employment:
Research Assistant Professor,
University of Kansas Medical Center, Kansas City, Kansas

Research Interests
Research in this laboratory is directed toward metabolic profiling of foodborne outbreak strains of pathogenic enteric bacteria, *E. coli*, *Shigella*, and *Salmonella*. The ultimate goals of this research undertaking are: to identify novel phenotypic markers that distinguish isolates within a food outbreak and among different food outbreaks; to identify the genetic basis of the phenotypic variation; and finally, to develop molecular assays that detect this genetic/phenotypic variation.

Theresa Mullin, Ph.D.
Associate Director for Planning and Business Informatics
Center for Device Evaluation and Research

Fellow: Dongyi (Tony) Du, M.D., Ph.D.

Background
Dr. Mullin leads CDER's long-range planning and strategic modernization initiatives. Dr. Mullin has expertise in methods of risk benefit and decision analysis, use of quantified expert judgments, regulatory business process analysis, and performance planning. Her knowledge of econometric and other mathematical analysis of scientific data allow the Center to leverage quantitative forecasting to further strategic policy initiatives. Prior to coming to CDER, Dr. Mullin was the Assistant Commissioner for Planning and Director of the Office of Planning, in the Office of Commissioner. As the chief planner, Dr. Mullin led the development of FDA's Strategic Action Plans and performance plans incorporated into agency budget requests. She led special initiatives in performance management and modernization at FDA. She led FDA-industry negotiations for both the 2002 reauthorization and the 2007 reauthorization of PDUFA. Dr. Mullin played a critical role in establishing the new FDA Bioinformatics Board (BiB) and provided early support for the FDA Critical Path initiative through planning and project management to enable development of the 2004 report *Innovation Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.* As head of the Office of Planning, she has also provided oversight of agency cost-benefit analyses to gauge the public impact of agency rulemaking on a wide range of issues, including analysis of proposed or final rules addressing issues such as BSE, condom labeling, bacterial vaccines, MUMS, electronic drug registration and listing, physician labeling, reprocessed single use medical devices, and phenylpropanolamine OTC drugs. Prior to her work at FDA, Dr. Mullin spent over ten years' working as a Principal Scientist with Decision Science Consortium, and as Senior Manager with the Lewin Group, in the design and development of analytic tools and methods for decision support.

Dianne Murphy, M.D.
Director, Office of Pediatric Therapeutics
Office of the Commissioner

Fellow: Ingrid Kohlstadt, M.D., M.P.H., F.A.C.N.

Scientific & Professional Background
1967- Bachelor of Science in Biology: Virginia Polytechnic Institute, Blacksburg, VA
1971- Doctor of Medicine: Medical College of Virginia, Richmond, VA

Training:	Intern, Pediatrics, University Hospital of Jacksonville, FL	1971-72
	Resident, Pediatrics, University of Virginia	1972-74
	Fellowship, Pediatrics, Infectious Diseases, U. of Colorado	1977-79
Military:	LCDR, USN, 1974-77	
	National Naval Medical Center, Pediatrics Unit	
Academic:	1989-Tenured at University of Tennessee-Knoxville, Associate Prof.	
	1997-Tenured at University of Florida-Jacksonville, Professor	

Research Interests
Pediatric infectious diseases; development of therapeutics for pediatrics: clinical trial analysis; international aspect of clinical trial development for pediatrics.

Michael J Myers, Ph.D.
Division of Animal Research
Center for veterinary Medicine

Fellow: Maocheng (Tony) Yang, Ph.D.

Background
B.S., Purdue University
Ph.D., Indiana University

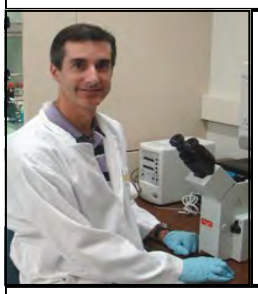
Research Interests
The drug approval process requires the sponsor to demonstrate all claims. For novel non-steroidal anti-inflammatory drugs (NSAID) for swine, the only approved drugs have just claims to reduce fever and not to reduce inflammation. This is because there is no definitive procedure for demonstrating a reduction in inflammation. The current research priority is the identification of biomarkers that can be used to support anti-inflammation claims for non-steroidal anti-inflammatory drugs (NSAID) in swine. An integral part of this project therefore is the development and validation of two inflammation models, with validated biomarkers that can be used by drug sponsors to bring new therapeutics to market. Potential biomarkers will be identified using a combined approach that examined genetic markers (microarray, RT-PCR), biochemical markers (ELISA, LC/MS) and cell surface markers (flow cytometry).

Robert M. Nelson, M.D., Ph.D.
Pediatric Ethicist
Office of Pediatric Therapeutics
Office of the Commissioner

Fellow: John Rossi, V.M.D.

Background
B.A., Wesleyan University
M.D., Yale University School of Medicine
M.Div., Yale Divinity School
Ph.D., Harvard University
(also Professor of Anesthesiology and Critical Care, Univ. of Pennsylvania School of Medicine and Children's Hosp. of Philadelphia)

Research Interests
My research focuses on two broad areas of pediatric research ethics: the ethical aspects of pediatric clinical investigations involving FDA regulated products, and empirical investigations into different aspects of parent and child decision-making concerning research participation. At FDA, specific areas of interest include ethical aspects of different trial designs, the choice of control group (including placebo controls), the use of animal models, the assessment of research risks and the possibility of direct benefit, and ethical aspects of international pediatric research. My academic research has focused on risk perception, voluntary choice, and the balancing of risks and potential benefits in making a decision about the design of clinical trials. My academic research has been funded by the Greenwall Foundation, the National Science Foundation, and the National Institutes of Health.



Tucker A. Patterson, Ph.D.
Division of Neurotoxicology
National Center for Toxicological Research

Fellow: Bradley Schnackenberg, Ph.D.

Background
B.S. Chemistry, University of Arkansas, Fayetteville, AR (1982-1986)
Ph.D. Pharmacology, University of South Carolina, Columbia, SC (1986-1992)
Fellow, Center for the Neurobiology of Aging & Dept. of Pharmacodynamics, U. of Florida (1992-1994)
Postgraduate Research Appointment (ORISE), NCTR/FDA (1994-1996)
Staff Fellow, NCTR/FDA (1996-1998)

Research Interests
Dr. Patterson's primary research interests include development and validation of animal models to predict neurotoxicity in humans, using both pharmacodynamic and pharmacokinetic approaches; developing novel assays to measure neurotoxic compounds and their metabolites in the blood and brain, and determining their effects on neurotransmitters; and implementing and validating genomic techniques utilizing laser capture microdissection (LCM) to search for biomarkers of neurotoxicity. Dr. Patterson has utilized the most recent molecular biology techniques (LCM, real-time PCR, RNA amplification, microarray, etc.) and has incorporated this technology into the cadre of other well-established techniques used in his laboratory. Dr. Patterson also is a study director for a Good Laboratory Practice (GLP) nonhuman primate study which assessed the effects of chronic dopaminergic agonist administration on complex brain functions utilizing the NCTR Operant Test Battery (OTB).

Hina M. Pinto, M.S.E.
Biomedical Engineer, Scientific Reviewer
Office of Device Evaluation
Center for Devices and Radiological Health

Fellow: Francesca Dolcimascolo, M.D.

Background
M.S.E., Biomedical Engineering, Tulane University
B.S.E., Applied Science (conc. Biomedical Materials Science), University of North Carolina-Chapel Hill

Regulatory Interests
As a senior scientific reviewer in the Interventional Cardiology Devices Branch (ICDB), Ms. Pinto provides leadership in the area of pediatric device development. Specifically, she provides lead and engineering reviews for various pediatric cardiovascular devices, including cardiac occluders and stents for aortic coarctation and pulmonary artery stenosis. Despite the recent implementation of new legislation directed at pediatric device development (FDAAA), there remains a significant unmet need for new devices designed for pediatric patients and for devices currently used off-label to be studied and appropriately labeled for use in pediatric patients. To help address this unmet need, Ms. Pinto has established and leads a biweekly Cardiovascular Pediatric Working Group, during which clinicians, statisticians, and other interested scientific reviewers work to develop alternative study designs and methodologies by which pediatric devices may be made available to patients more readily. She has initiated discussions with the American College of Cardiology regarding potential partnership with FDA on a planned national database of congenital cardiac catheterization procedures, which could provide data to speed premarket development of new devices as well as provide valuable postmarket information about marketed devices. Ms. Pinto has also initiated outreach to the clinical community and medical device industry to address the problem of the use of off-label cardiovascular devices for pediatric use. To ensure that her efforts at the Division level are consistent with the Agency, Ms. Pinto participates in the CDRH Pediatric Steering Committee meetings.

Igor P. Pogribny, M.D., Ph.D.
Division of Biochemical Toxicology
National Center for Toxicological Research

Fellow: Athena Starland-Davenport, Ph.D.

Background
M.D., Ivano-Frankivsk Medical University
Ph.D., Kyiv National Medical University
FDA Experience - 17 years

Research Interests
The role of genetic and epigenetic changes in the etiology of cancer. Classically, the development of cancer in human has been viewed as disease driven by the progressive genetic alterations. However, current evidence indicates that not only genetic but also epigenetic alterations are similarly important in carcinogenesis. Presently, cancer is recognized as both genetic and epigenetic disease, which is evident from every aspect of tumor biology, and genetic and epigenetic components cooperate at every stage of cancer development. It is widely accepted that carcinogenesis is initiated by permanent heritable changes in the genome caused by endogenous and environmental agents. However, initiation alone is not sufficient for tumor formation; rather it is a necessary prerequisite for tumor development. Additionally, genetic alterations alone cannot explain the extremely diverse phenotypic changes observed in preneoplastic cells at the promotion and progression stages of carcinogenesis as well as in neoplastic cells. This has led to a suggestion that evolution of preneoplastic cells during promotion and progression stages may be driven primarily by epigenetic mechanisms. Furthermore, it has been proposed that epigenetic alterations during carcinogenic process may precede and provoke genetic changes suggesting that epigenetic events may be primary events while genetic changes may be a consequence of disrupted epigenomic state. Many important questions in the field of carcinogenesis remain to be answered. Among them, questions whether or not carcinogens cause epigenetic changes during carcinogenesis and the precise relationship between carcinogen-induced genetic changes and epigenetic alterations in carcinogenic process, are the most important. In view of these considerations, the goal of these proposal is to identify the exact role of genotoxic and epigenetic alterations in rat liver carcinogenesis induced by a variety of chemicals and drugs (furan, tamoxifen, antiretroviral drugs) that are important to the FDA.

Renate Reimschuessel, V.M.D., Ph.D.
Division Animal Research, Office of Research
Center for Veterinary Medicine

Fellow: Cynthia Stine, Ph.D.

Background
B.A., University of Pennsylvania, Philadelphia
V.M.D. University of Pennsylvania School of Veterinary Medicine, Philadelphia
Ph.D., University of Maryland, Baltimore
Previous Employment: University of Maryland School of Medicine (Asst./Assoc. Professor (1986-1999)
Veterinarian, Pennsylvania (1981-1986)

Research Interests
Dr. Reimschuessel's research focuses on the development of new animal drugs for aquatic animals while promoting human food safety. As a result, her laboratory has fostered numerous collaborative studies which examine the safety, efficacy and residue withdrawal of drugs that may be used in aquaculture. These studies have provided the FDA with much needed information necessary for evaluating drugs for potential approvals, making significant contributions to fulfill CVM's mission to develop drugs for Minor Species. Dr. Reimschuessel recently developed an on-line database on fish pharmacokinetics containing residue information for over 90 different fish species and over 200 chemicals. In addition, her laboratory routinely provides tissues of market sized fish exposed drugs for collaborators to develop new detection methods. She has successfully coordinated a large number of studies with multiple FDA Centers throughout the United States. This work has resulted in new methods being used to identify illegal drugs in fish being imported for human consumption. Dr. Reimschuessel is also a leader in standardization and global harmonization of antimicrobial susceptibility testing methods for aquatic bacteria. Her international, multi-laboratory trials were the first successful studies to support the new guidelines for testing aquatic pathogens recently published by the Clinical and Laboratory Standards Institute. Dr. Reimschuessel has also successfully implemented a research program focusing on the effects of antimicrobials on aquatic animal microbiology and non-target species effects, significantly contributing to CVM's goal to evaluate the effects of antimicrobials in food producing animals. She is a graduate faculty member of the several universities, where she co-advises graduate and veterinary students. She serves on numerous FDA and outside professional committees and serves as an ad hoc reviewer and section editor for many peer-reviewed journals.

William J. Rodriguez, M.D., Ph.D.
Office of Pediatric Therapeutics
Office of the Commissioner

Fellow: Haihao Sun, M.D., Ph.D.

Background
B.S., Georgetown University Washington D.C.
MD., Georgetown Medical School
Internship and Pediatric Residency. University Hospital San Juan P.R.
Fellowship Ped. Infect. Dis., Children's National Med. Center, Wash. D.C.
Ph.D. Dept. Microbiology, Georgetown U. Grad. School, Wash. D.C.
Prof. Peds 1985-2000, then Prof emeritus Peds, GW University Wash. D.C.
Science Director Office of Pediatric Therapeutics FDA, 2000-present

Research Interests
The interest of this researcher has previously included the areas of new antibiotic development, the treatment of middle ear infections, and the study of monoclonal antibodies in the prevention and treatment of respiratory syncytial virus in infants and young children. More recently, he has participated in the pediatric initiatives which have encouraged pediatric drug development. Information from some of the initiatives' early findings has been communicated in scientific journals. However, a wealth of data remains currently available for extraction and analysis at the FDA on drugs studied in pediatrics. The studies could be converted into data bases accessible for analysis in a variety ways and to address a variety of questions . We plan a novel program, that would include assigning a researcher in the program to work on areas of significant public health, mine and manage data currently available in the pediatric domain, conduct scientific analysis and develop pertinent research under the direction of the appropriate FDA supervisor(s).

Larisa Rudenko, Ph.D., DABT
Senior Advisor, Biotechnology
Center for Veterinary Medicine
Office of New Animal Drug Evaluation

Fellow: Brinda Dass, Ph.D.

Background
Ph.D., Cellular and Molecular Pharmacology
Diplomate of the American Board of Toxicology
FDA Experience - 8 years

Research Interests
The focus of our group is providing science-based direction via guidances and regulations towards the safe and effective use of genetically engineered (GE) animals. Ensuring consumer safety and confidence in GE therapeutics, food or animals, relies on a consistent, rigorous, transparent, science-based approval process. The Animal Biotechnology group at the Center for Veterinary Medicine is the first government agency to implement pre-market mandatory approval for GE animals. Towards this end we have proposed draft guidance for the regulation of GE animals containing heritable rDNA constructs as a first step towards assisting sponsors involved in this process as well as educating consumers of safety issues. We are interested in ensuring animal welfare, food safety, human health and environmental safety through the continuing promulgation of guidance's and regulations and discussions with industry, scientific researchers and consumers.

Larry Schmued, Ph.D.
Sr. Staff Scientist, Division of Neurotoxicology
National Center for Toxicological Research

Fellow: Sumit Sarkar, Ph.D.

Background
Ph.D. UC Irvine, Dept. of Anatomy, 1987
Post-Doctoral Fellow: University of Virginia, Dept. of Neurosurgery, 1988-91

Research Interests
Since conceptual revolutions often follow technical innovations, Dr. Schmued's laboratory has a history of developing an improved histochemical tracer and then applying it to resolve specific neuroanatomical or neuropathological questions. Early innovations include the development of the fluorescent axonal tract tracers Fluoro-Gold and Fluoro-Ruby. These respective retrograde and anterograde axonal tract tracers were then used to help resolve the connectivity of the basal forebrain. Dr. Schmued established the Neurohistochemistry Laboratory within the Division of Neurotoxicology. His group has developed a number of histochemical markers of toxicant induced brain pathology, including the Fluoro-Jade dyes for the demonstration of degenerating neurons, and Black-Gold II, a marker of myelin pathology. The lab routinely also uses variety of other markers to demonstrate brain pathology including the use of GFAP immunohistochemistry for localizing astrocytic hypertrophy, Isolectin B-4 for detecting activated microglia, Capsase-3 for identifying apoptosis and labeled anti-host IgG for assessing blood-brain barrier integrity. These methods were used to characterize the pathologies associated with a variety of different classes of neurotoxicants including: kainic acid, domoic acid, 3-NPA, isoniazid, PCP, MK-801, ketamine, ibogaine, aurothioglucose, amphetamine, methamphetamine, d-fenfluramine and MDMA. By doing so, it is possible to correlate the histo-path pattern of damage with the mode of action of a particular neurotoxicant. The most recent project will use these technologies to follow the potential of proposed neuroprotectants for use in Alzheimer's disease therapy. Both the toxicity and efficacy of these potential AD therapeutics will be evaluated in the amyloid plaque expressing

No photo available

Bruce S. Schneider, M.D.
Clinical Evaluations Branch
Office of Cellular, Tissue and Gene Therapy
Center for Biologics Evaluation and Research

Fellows: Jeremiah Wille, D.Sc., Caitilin Hamill, Ph.D.

Background
A.B., Harvard College
M.D., Harvard Medical School

Research Interests
Dr. Schneider regulates clinical development of gene and cell therapies for a variety of indications. He has broad interests and experience in endocrinology and metabolism. His major focus at CBER is the clinical development of islet cell products for treatment of diabetes. Dr. Schneider also serves on the NIH-FDA Interagency Artificial Pancreas Working Group, as well as on the Metabolic Steering Committee of the Biomarkers Consortium.

Badar Shaikh, Ph.D.
Research Chemist
Center for Veterinary Medicine

Fellow: Donglei Yu, Ph.D.

Background
B.S., Sind University
Ph.D., The American University, Washington D.C.
Previous Employment:
Frederick Cancer Research Center, Frederick, MD
(Staff Scientist 1972-1980)

Research Interests
Aquaculture or the farming of aquatic organisms is a world wide growth industry and many cultured fish species are imported to U.S. as food for human consumption. Compared to many drugs used in aquatic species internationally, there are very few drugs approved by the FDA for use in U.S. aquaculture. The drug use in aquaculture/minor species is analogous to human orphan drug use for which the market is insufficient to justify costly research expenditures by pharmaceutical firms to generate data, necessary to obtain FDA approval. The focus of current research is to conduct comparative metabolism and residue depletion studies of selected veterinary drugs in various fish species of importance to U.S. aquaculture. This will allow the establishment of a potential common marker residue (MR) in inter-species of fish as well as facilitate the development of analytical methods for regulatory monitoring. This research is designed to address the shortage of drugs for minor food animal species by encouraging the drug companies to sponsor limited-demand animal drugs. Additionally, the research will support an active surveillance program to monitor illegal use of drugs in imported and domestic aquaculture products destined for human consumption.

Stanley H. Stern, Ph.D.
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs
Center for Devices and Radiological Health

Fellow: Thalia Mills, Ph.D.

Background
B.A., Rutgers University, Physics
M.S., Ph.D., New York University, Experimental radiation and condensed-matter physics.
FDA, 1992 - Present
US Naval Surface Warfare Center, 1983-1992

Research Interests
Dr. Stern's primary research interest is the control of medical x-ray exposure to patients. Organ-dose handbooks promote quality assurance of radiation use and facilitate informed risk communication between clinical staff and patients by providing authoritative, publicly accessible reference values of tissue doses associated with different radiological modalities. In particular, there has been a long-standing need for a Handbook of Radiation Doses Absorbed in Tissues of Patients undergoing X-Ray Computed Tomographic (CT) Studies, especially in view of the surge of CT interventional procedures and the prospective advent of CT screening. Such studies may include, for example, coronary-artery calcium scoring, CT angiography, virtual colonoscopy, lung exams and other protocols expected to be used in screening, as well as routine CT procedures used to visualize the abdomen, pelvis, chest, and head, where these routine diagnostic studies comprise the vast majority of CT contributing so much to the population's collective radiation dose.

Ben D. Tall, Ph.D.
Division of Virulence Assessment
Office of Applied Research and Safety Assessment
Center for Food Safety and Applied Nutrition

Fellow: Lan Hu, M.D., Ph.D.

Background
B.S.: Salisbury State College, (Biology), 1979
Ph. D.: University of Maryland, Baltimore, Maryland,1988
Postdoctoral Training:
Center For Vaccine Development, 1988-1989
University of Maryland School of Medicine

Research Interests
1) Study of the pathogenic mechanisms of food borne enteric bacteria; Characterization and expression of adherence factors; fimbriae ultrastructure, effects of environmental influences on bacterial attachment/invasion mechanisms associated with foodborne enteric pathogens such as enterotoxigenic and enteropathogenic *Escherichia coli, Salmonella* sp. and *Vibrio* sp.such as *V. cholerae, V. vulnificus* and other marine pathogenic *Vibrio* spp.; and identification and characterization of virulence factors expressed by *Enterobacter sakazakii* and the development of molecular assays based on these factors for the isolation and detection of *E. sakazakii* from foods. 2) The development of protocols and methods for the detection of *Bacillus anthracis, Yersina pestis, Francisella tularensis, Brucella* spp.and *Burkholderia* spp. from foods.

William H Tolleson, Ph.D.
Research Chemist, Division of Biochemical Toxicology
National Center for Toxicological Research

Fellow: Kiet Nguyen, Ph.D.

Background
B.S. Biology and Chemistry, University of South Carolina
Ph.D. Chemistry and Biochemistry, U. of South Carolina
Postdoctoral U. South Carolina School of Medicine, 1990-1993
Postdoctoral/Staff Fellow NCTR, 1993-1996/1996-1997

Research Interests
Food safety and food defense are ongoing concerns of the FDA and several *Select Agents* are subject to intense study to characterize their behaviors when placed in foods. Ricin and abrin produced by the castor bean plant (*Ricinus comminis*) and the rosary pea plant (*Abrus precatorius*), respectively, are highly toxic seed proteins with histories of use as homicidal and biological warfare agents. Shiga toxin (Stx1) and Shiga-like toxin (Stx-2) are produced by *Shigella dysenteriae* and the *Escherichia coli* Shigatoxigenic group, which includes the serotype O157:H7 that is notorious for causing severe food-borne illnesses and deaths. Stx1 and Stx2, along with ricin and abrin, are classified as Type II ribosome-inactivating proteins toxins due to their shared site-specific rRNA depurinating capabilities and have been designated Category B Potential Bioterrrorism Select Agents by the USDA and HHS. Staphylococcal enterotoxin B (SEB) is another Category B Select Agent with food safety relevance that is noted for its resistance to heat inactivation and for its ability to induce a toxic shock-type syndrome via its superantigen activity. Pet foods also may be contaminated with toxins. In 2007 a large number of pet food products had reached the market contaminated by melamine, cyanuric acid, and related triazine compounds and that the consumption of contaminated food was associated with a fatal acute renal failure syndrome in pets.

Frank M. Torti, M.D., M.P.H.
Acting Commissioner, FDA

Fellow: Kevin Whittlesey, Ph.D.

On May 15, 2008, Dr. Frank M. Torti was appointed FDA's first Chief Scientist, a position established by the Food and Drug Administration Amendments Act of 2007. He was simultaneously appointed Principal Deputy Commissioner. The appointment of a Chief Scientist signaled a new emphasis on the importance of science in the agency. It also enhanced the FDA's ability to direct and manage the complex and interrelated aspects of the regulatory science of medical product development from conception through post-marketing, as well as regulatory science related to human and animal food and nutrition, food additives and cosmetics.

In his presentation at the 100th Anniversary of the American Association for Cancer Research in Roswell Park, Dr. Torti stated, "The future of the FDA will be written in the quality of FDA science and scientists".

Dr. Torti received his B.A. and M.A. degrees from Johns Hopkins University, his M.D. from Harvard Medical School (cum laude), and his M.P.H. from the Harvard School of Public Health, where he trained in cancer epidemiology and nutrition. He was an intern and resident at the Beth Israel Hospital, Boston and a fellow in medical oncology at Stanford University. While on the Stanford faculty, he served as Executive Officer of the Northern California Oncology Group and Associate Director of the Northern California Cancer Program, and was instrumental in the development and oversight of the data management functions and overall administration of that clinical cooperative group and its regional network in northern California. He was tenured at Stanford, where he led one of the most active genitourinary programs in the country. He joined Wake Forest University School of Medicine in 1993 as the Charles L. Spurr Professor of Medicine, Director of the Comprehensive Cancer Center, and Chair of the Department of Cancer Biology. At Wake Forest, he developed and is principal investigator on a training program in cancer biology for Ph.D. students and M.D. and Ph.D. postdoctoral fellows.

He has published in *Science*, *the Journal of Biological Chemistry*, *Molecular and Cellular Biology*, *Proceedings of the National Academy of Sciences of the United States of America (PNAS)*, *The Journal of Immunology*, *Journal of Clinical Oncology*, *Cancer Research*, *The New England Journal of Medicine*, *Annals of Internal Medicine*, *Cell*, and other highly respected journals. He has served on or chaired a number of national study sections, including those of the National Institutes of Health (NIH), Department of Veterans Affairs, Department of Defense, and American Institute of Clinical Research. He also served on the NIH Council for the National Center for Complementary and Alternative Medicine.

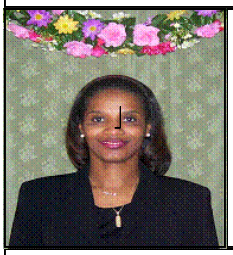
Dr. Torti is a noted clinician and clinical investigator, as well as an accomplished research scientist. He is the recipient of a MERIT award from the NIH, an honor bestowed on only 2% of all NIH grantees.

Wendy C. Weinberg, Ph.D.
Senior Investigator
Division of Monoclonal Antibodies
Office of Biotechnology Products
Office of Pharmaceutical Sciences
Center for Drug Evaluation and Research

Fellow: Stayce Beck, Ph.D.

Background
B.S., University of Illinois, Urbana-Champaign
Ph.D., Northwestern University
Post-doctoral training, National Cancer Institute, NIH

Research/Regulatory Interests: The development of antibody-based therapies comprises one of the most active areas of clinical research in oncology today. Many targeted therapies based on our current molecular understanding of cancer pathogenesis are under development to optimize the treatment outcome of tumors with specific genetic alterations. Despite major advances in identifying rational targets and early promising pre-clinical findings, the majority of cancer treatments proceeding through clinical trials fail. To maximize the predictive value of pre-clinical data supporting clinical trials, the models utilized must reflect the disease etiology as much as possible. Our laboratory applies a variety of approaches to establish biochemical and molecular correlates *in vitro* with pre-clinical *in vivo* models. Our research is specifically focused on elucidating the normal function and effects of dysregulation of particular p53 homologues on keratinocyte growth regulation, differentiation, and neoplasia, and their interactions with p53 and oncogenic pathways in multistep carcinogenesis. The overall goal of our research is to identify biomarkers of tumor progression and responsiveness for monitoring therapeutic efficacy. These approaches may also be applied to assess product potency and comparability following manufacturing changes.



Tonya Alisa Wilbon, B.S.
Office of *In Vitro* Diagnostic Device Evaluation and Safety
FDA Center for Devices and Radiological Health

Fellow: Katherine Serrano, B.S.

Background
B.S., Howard University, Howard University Graduate School
Johns Hopkins University Graduate School of Public Health
FDA Instructor for AAMI Courses
Previous Employment: The Johns Hopkins Hospital, Medical Technologist; Howard University Hospital, Medical Technologist

Regulatory Interests
The Office of In Vitro Diagnostic Evaluation and Safety (OIVD) regulates laboratory testing devices used in medical care of humans. It is estimated that 10 billion laboratory tests are performed in the US per year and that these impact 70 to 80% of medical decision making. There are a number of outstanding policy issues regarding IVDs, many of which are the result of rapidly changing technologies used for testing, and others of which stem from a 30-year old policy of enforcement discretion (i.e., deliberate non-enforcement of applicable regulations) towards certain types of IVDs called laboratory-developed tests (LDTs). This use of non-enforcement has raised issues of science, policy and regulatory parity. In an attempt to protect and promote the public health, I am working to provide a more comprehensive, coherent risk-based framework for regulatory oversight of new molecular diagnostic tests and instruments with the clear objective of clarifying and shortening transfer of new tests from the research lab to the patient bedside. A critical initiative in this work is undertaking an analysis of FDA's Quality System regulation as it relates to laboratory developed tests and determining how it can be integrated with existing regulatory oversight provided by the Clinical Laboratory Improvement Amendments and its application to different facets of testing.

Robert P. Wise, M.D., M.P.H.
Division of Epidemiology
Office of Biostatistics and Epidemiology
Center for Biologics Evaluation and Research

Fellow: Amy Steffey, D.V.M., M.P.H.

Background
B.A., Carleton College;
M.D., Northwestern University Medical School
M.P.H., Harvard School of Public Health
Previous Employment:
U.S. FDA Center for Drug Evaluation and Research
U.S. Centers for Disease Control
Pan American Health Organization
Brigham and Women's Hospital

Research Interests
The Division of Epidemiology monitors the safety of vaccines, blood, tissues, and cell therapies after licensure using the FDA's passive surveillance systems, the Adverse Event Reporting System (AERS) and the Vaccine Adverse Event Reporting System (VAERS). In addition, expanding access to claims and medical encounter databases provides the opportunity to conduct epidemiological studies of safety concerns for CBER regulated products. Research opportunities include both development of methodologies for rapid detection of possible safety problems and conducting evaluations of specific issues. Dr. Wise is especially interested in evaluating predictive modeling, a widely used data mining approach in various industries, for its possible utility in safety surveillance of licensed biological products regulated by CBER.

Keith Wonnacott, Ph.D.
Division of Cellular and Gene Therapies
Office of Cellular Tissue and Gene Therapy
Center for Biologics Evaluation and Research

Fellows: Jeremiah Wille, D.Sc. & Caitilin Hamill , Ph.D.

Background
B.S., Bringham Young Unversity
Ph.D., Pennsylvania State University

Research Interests
Dr. Wonnacott is responsible for oversight of the review and regulation of cell therapy products, devices for manufacture of biological products, and combination products. He has a special interest in pancreatic islet cells and xenogeneic products.

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Fellow: Dongyi (Tony) Du, M.D. Ph.D.

Background

Dr. Woodcock most recently served as the Deputy Commissioner and Chief Medical Officer, 2006-2007, where she oversaw scientific and medical regulatory operations for FDA. Prior to that she served the FDA as the Deputy Commissioner for Operations and Chief Operating Officer,. Dr. Woodcock served as Director, Center for Drug Evaluation and Research at FDA 1994-2005. She previously served in other positions at FDA including Director, Office of Therapeutics Research and Review and Acting Deputy Director, Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School, and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

Li-Rong Yu, Ph.D.
Director, Center for Proteomics
National Center for Toxicological Research

Fellow: Qiang Gu, Ph.D.

Research Interests

Recent developments are making early detection and targeted therapy of cancer a realistic expectation of disease management. Furthermore, while the advantage of targeted therapy is obvious, some treatments have resulted in relapse and drug resistance for advanced cancers. Clinically-validated biomarkers of high specificity and sensitivity are required for effective diagnosis and are sought to stratify patients for personalized therapy that avoids relapse and development of drug resistance. Dr. Yu's laboratory is using novel quantitative proteomic and phosphoproteomic technologies for the identification and validation of protein biomarkers for early cancer detection, toxicity assessment, and efficacy prediction.

Cancer biomarkers are typically present in tissues at very low abundance levels. Dr. Yu's laboratory utilizes highly sensitive mass spectrometry (MS)-based proteomics technologies and he has optimized nanoflow liquid chromatography-tandem MS for a significant increase in detection sensitivity. The technology detects hundreds of proteins from as little as a few nanograms of sample and thousands of proteins (more than 4500 proteins) from ~30 micrograms of proteomic sample. Dr. Yu has used this technology in neuronal cell models to quantitatively measure proteome changes associated with apoptosis (cell death) induced by camptothecin, a DNA damage and anticancer drug. By combining isotope-coded affinity tag (ICAT) labeling of proteins and mass spectrometry, it was found that DNA damage causes a p53-dependent decrease of the protein kinase A (PKA) signaling pathway and induces co-activation of proapoptotic and antiapoptotic processes during p53-dependent neuronal death. Cell surface labeling in combination with mass spectrometry was also developed in Dr. Yu's research to identify potential breast cancer biomarkers. Dr. Yu's group also has developed advanced quantitative phosphoproteomics technology to obtain phosphosignatures of cell signaling pathways to follow changes resulting from drug treatments. Can the advanced proteomic technologies be used to validate candidate biomarkers in the clinical setting? Can mass spectrometers be employed to develop clinical assays that can be used routinely in clinical labs?

Shaohua Zhao, D.V.M., M.P.V.M., Ph.D.
Division of Animal and Food Microbiology
Center for Veterinary Medicine

Fellow: Heather Green, Ph.D.

Background
D.V.M., Guizhou University, China (1982)
M.P.V.M., University of California, Davis (1988)
Ph.D., University of California, Davis (1991)

Research Interests
Dr. Zhao's primary responsibilities within CVM include maintaining molecular genotyping databases, and advancing genotyping technologies for foodborne pathogens. She has established and integrated the CVM PulseNet program into the national molecular subtyping network for foodborne disease surveillance program (PulseNet). This network permits rapid comparison of DNA fingerprint patterns of foodborne pathogens through PulseNet's electronic database. The goal of this program is to reduce the burden of foodborne illness by assisting investigations and improving outbreak detection and intervention. The CVM PulseNet component, spearheaded by Dr. Zhao, focuses on bacterial pathogens recovered from retail food (NARMS), companion animals, and veterinary clinical specimens. The CVM PulseNet program works closely with NARMS to better understand how antimicrobial usage in the animal production environment influences the development and dissemination of antimicrobial resistance in zoonotic foodborne bacterial pathogens. Dr. Zhao also serves as the CVM's liaison with the U.S. Centers for Disease Control and Prevention (CDC). FDA has further acknowledged her accomplishments as a research microbiologist through several awards she has received. To date, Dr. Zhao has published 66 peer-reviewed journal articles, 6 review articles, 7 book chapters, and 125 research abstracts which have been presented at numerous national and internationals meetings. In addition she has served on the editorial board of the Journal of Food Production and as an ad hoc reviewer for several other peer reviewed scientific journals. Dr. Zhao is the recipient of the FDA's Scientific Achievement Award for 2008.

FDA Commissioner's Fellowship Program

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