FDA Commissioner's Fellowship Program

Class of 2009

FDA Commissioner's Fellowship Program
2009 Fellows

FDA Commissioner's Fellowship Program
2009 Preceptors

FDA Commissioner's Fellowship Program
2009 Preceptors and Fellows by Center

CBER

Preceptor	Fellow
Pradip Akolkar and Elliot Cowan	Bharat Khurana
Abdu I. Alayash	Chad Reiter
Deborah Hursh	Tehyen Chu
Malcolm Moos	Eric Dollins
Donna Przepiorka	Olumide Olajide

CVM

Preceptor	Fellow
Raafat Fahmy	Wenge (Walter) Xie
Joseph C. Kawalek	Peter Jeanettes
Marilyn N. Martinez	Leposava Antonovic
Jennifer Matysczak	Eric Landis
Larisa Rudenko	Malini Mansharamani
Ruby Singh and Jeff Gilbert	Brooke Whitney
Lynn O. Post	Gabriel Davila

OC

Preceptor	Fellow
Timothy Cote, Richard Rodgers, and Menfo Imoisili	Kathryn Burke and Scott Freeman
John W. Gardner	Kosta Makrodimitris and Markus Yap
Norman Marks	Khaled Bouri

ORA

Preceptor	Fellow
Sean Linder	Thilak Kumara Mudalige
Ken Yoshitomi	Joy Waite

CDER

Preceptor	Fellow
Gilbert J. Burckart	Dionna Green
Edward Cox	Nicole Mahoney
John Z. Duan	Kareen Riviere
Jogarao Gobburu	Hui (Helen) Zheng
H.M. James Hung	Rajasri Roy
Baolin Zhang	Joslyn K. Brunelle

FDA Commissioner's Fellowship Program
2009 Preceptors and Fellows by Center, cont…

CFSAN

Preceptor	Fellow
Uma Babu	Kannan V. Balan
Biswendu Goswami	Kaoru Hida
Michael Kulka	Christine Yu
Dan D. Levy	Erika Pfeiler
MaryAnn Principato	Bi-Feng Qian
Debra A. Street	Beverly Wolpert

CDRH

Preceptor	Fellow
Victoria Hitchins	Shanil Haugen
Sally Hojvat	Natalia Comella
Joseph C. Hutter	Angelo Green
Aric D. Kaiser	Jose Moreno
Thomas C. Knott	Charles Anamelechi
John Karanian,	Mark Kreitz and
William Pritchard and	Orlando Lopez
O. Alberto Chiesa	
Frank W. Samuelson	Camille Vidal
Seth J. Seidman	Oxana Pantchenko

NCTR

Preceptor	Fellow
John F. Bowyer	Mark Levi
Richard Beger	Sudeepa Bhattcharyya
Frederick Beland and	Sami Sarfaraz
Igor P. Pogribny	
Deborah Hansen and	Hyung-yul Lee
Jim Kaput	
Robert H. Heflich	Xuefei Cao
Beverly Lyn-Cook	Honggang Wang
Fatemeh Rafii	Sunny Park

Regenerative Medicine Project
(CBER and CDRH)

Preceptor	Fellow
Elias Mallis,	James Bertram, Katherine Kavlock,
Charles N. Durfor,	and Sylva Krizan
Bruce Scheider, and	
Keith Wonnacott	

Charles Anamelechi, D.Phil.

Center for Devices and Radiological Health
Preceptor: Thomas Knott, Ph.D.

Scientific and Professional Background

Duke University, Durham, NC
Postdoctoral Fellow, Biomedical Engineering Department, 2008-2009
Doctor of Philosophy, Biomedical Engineering, May 2008.
Concentration in Tissue Engineering, Certificate in Biomolecular and Tissue Engineering
Master of Science, Biomedical Engineering
Howard University, Washington, DC
Bachelor of Science, Chemistry, with minor in Mathematics and Allied Health, May 2001

Research Interests

My general research interest is in the area of improving biocompatibility and implant biointegration. My PhD focused on using novel protein formulations to promote neointimal formation in synthetic vascular grafts. My current project focus is on mitigating the foreign body response to implanted biomaterials through immunomodulation using soluble anti-inflammatory cytokines. In both of these projects, the goal has been improving and prolonging the utility of implanted devices.

FDA Commissioner's Fellowship Project Overview
Identification and Analysis of Potential Risks Associated with Synthetic Surgical Mesh

Synthetic surgical meshes have become a routine treatment for various types of hernias. The majority of patients receiving these products greatly benefit from them and have no complications. However, FDA has received reports from some patients who have experienced adverse events associated with the mesh repair. The issues associated with meshes include chronic pain, tissue erosion, adhesions, infections (including sepsis when organs are perforated and in the case of more serious infection), and recurrence of the hernia lesion due to inadequate placement or failure of the mesh. Most patients with complications are either unaware that they have a mesh, are unaware of the type of mesh they have, or are not sufficiently informed about the potential issues that could arise with use.

This project will attempt to answer the following questions: 1. What is the level of public health risk posed by synthetic surgical meshes? 2. What measures can be done to mitigate this risk? 3. What are the issues associated with mesh failure? For example, are failures primarily due to device design, material makeup, surgical placement or technique, or genetic or lifestyle factors native to certain patient groups? These questions will be answered by conducting a thorough analysis of the MDR data in MAUDE and a meta-analysis of the scientific literature. Findings from these two analyses will provide a foundation to speak accurately to the FDA about the risks associated with these devices and recommendations for minimizing them. The potential outcomes from this project would be a public health notice, a device information card that can be given to the patient before or after surgery so they are aware of the kind of mesh they have, and instructions to modify the indications for use of these products by improving manufacturer labeling and physician training. Ultimately, more randomized clinical trials may have to be conducted by the manufacturers to determine the pertinent factors responsible for the issues associated with the use of surgical meshes.

Leposava Antonovic, Ph.D.

Center for Veterinary Medicine
Preceptor: Marilyn N. Martinez, Ph.D.

Scientific and Professional Background

Clinical Pharmacology Fellow - M.D. Anderson Cancer Center, Division of Pharmacy and Pharmaceutical Development Center, Houston, TX (2006-2008)
Ph.D. in Biochemistry and Molecular Biology - University of Texas Graduate School of Biomedical Sciences, Houston, TX (2000-2006)
Research Scholar - University of Texas, Medical School, Houston, TX (1999-2000)
M.S. in Biochemistry - Charles University in Prague, Czech Republic (1995-1998)
B.S. in Chemistry - Charles University in Prague, Czech Republic (1992-1995)

Research Interests

Drug Metabolism, Pharmacokinetics and Pharmacodynamics
Cytochrome P450 Drug Metabolizing Enzymes
Drug Discovery, Preclinical and Clinical Drug Development
Anticancer Therapeutics

FDA Commissioner's Fellowship Project Overview
Pharmacogenetic Cytochrome P450 Variability and its Implications in Veterinary Medicine and Animal Drug Approval

Understanding metabolic diversity in the targeted patient population is fundamental to the generation of population inferences from the data in a new product application at the FDA. Our ability to generate population predictions based upon prior information (i.e., known pharmacogenetic differences associated with drug disposition) and information provided in the investigational new animal drug application (INAD) is invaluable, especially in regulatory science, when trying to anticipate adverse drug events in genetically predisposed subpopulations with the limited study sizes associated with veterinary drug submissions. Similarly, such information may be immensely important in guiding the prescribing practitioner. To expand this effort, the goal of this project is to identify the genetic cytochrome P450 (CYP) polymorphism across canine breeds, to develop computer-based physiologically-based pharmacokinetic (PBPK) models to describe the potential breed-related dispersion of dose-exposure relationships in dogs as a consequence of variations in CYP enzyme kinetics, and to consider the potential impact of this population diversity on the safe and effective use of selected compounds.

Kannan V. Balan, Ph.D.

Center for Food Safety and Applied Nutrition
Preceptor: Uma S. Babu, Ph.D.

Scientific and Professional Background

Senior Research Associate	Pediatrics, Case Western Reserve University, Cleveland, Ohio, 2006–2009
Research Associate	Biology, University of Miami, Florida, 2002–2005
Post Doctoral Fellow	Molecular Biology, Cell Biology and Biochemistry, Brown University, Rhode Island, 2001–2002
Ph.D.	Biology, Howard University, Washington, D.C., 2000
Newborn Screening Assistant	Howard University/District of Columbia, 1994–2000
Quality Control Chemist	E. Merck (I), Bombay, India, 1992–1993
M.Sc.	Biochemistry, University of Bombay, India, 1992
B.Sc.	Microbiology & Biochemistry, University of Bombay, India, 1990

Research Interests

My previous research involved identification of estrogen-induced proteins as markers for ovarian cancer and regulation of estrogen receptors by novel drug analogues in breast carcinoma. In addition, as a member of the drug development group, I have worked on identifying mechanisms associated with apoptosis and senescence in human cancer cells treated with novel drugs. With broad exposures in the field of cancer and respiratory neurobiology, my present research focus involves understanding immune (cytokine) response-mediated brain mechanisms associated with respiratory distress following bacterial endotoxin-induced lung infection and chorioamnionitis-induced preterm birth in the neonatal animal model. My research expertise involves cell biology applications, molecular biology-protein separation and identification by 2-DE/Mass spectrometry and *in vivo* physiological measurements. The FDA Commissioner's Fellowship program will provide me with an opportunity to further channel my research experience and enrich it by bringing in a dimension of regulatory interpretation.

FDA Commissioner's Fellowship Project Overview

An in vitro study of Salmonella-induced apoptosis in chicken macrophages: Probiotics mediated immuno-resistance to Salmonella infection

Salmonella enteritidis (SE) is the leading cause of bacterial foodborne illness in the United States. Shell eggs are a primary source of human SE infection. While environmental route for Salmonella contamination of eggs is very common, SE can also infect the ovaries and oviducts of egg-laying hens, permitting contamination of the interior of the egg. Macrophages are phagocytic cells, and serve as a primary line of defense against infection. It has been shown that induction of macrophage death is an important step in Salmonella infection and pathogenesis in hens. Probiotics are beneficial bacteria and have been used in feeds to reduce Salmonella burden in live poultry. Our working hypothesis is to investigate the mechanisms of probiotic-mediated enhancement of the innate immune functions of macrophage, resulting in the clearance of Salmonella by the host.

James Bertram, Ph.D.

Center for Biologics Evaluation and Research and
Center for Devices and Radiological Health
Preceptors: Charles Durfor, Ph.D., Elias Mallis, B.S.,
Bruce Schneider, M.D., and Keith Wonnacott, Ph.D.

Scientific and Professional Background

Yale University	Ph.D. - Biomedical Engineering	2009
Yale University	M.S. - Biomedical Engineering	2005
Pennsylvania State University	B.S. - Mechanical Engineering	2003

Research Interests

To date, my research has been directed towards the synthesis and development of polymer constructs for applications in hemostasis. In particular, efforts have focused on optimizing cell/polymer interactions while addressing blood loss following traumatic injury. Other areas of interest include drug/polymer interactions with the ultimate goal of sustained ocular delivery.

FDA Commissioner's Fellowship Project Overview

The evaluation of combination (device/biologic) product applications by sponsors to CBER/ CDRH: Assessing commonalities in deficiencies and identifying measures for improved FDA review and guidance for multidisciplinary technologies

The ability to characterize and evaluate stand-alone device properties and device-patient interactions (biocompatibility) is well established; however, my project will focus on the increased and growing need to evaluate the interactions between the delivery device, and the biologic that it is administering (e.g. cell therapy). These non-specific interactions may result in variable dosing (e.g. sub-potent) as well as the delivery of a non-specifically altered final product (e.g. shear induced differentiation of stem cells). The goal of this multicenter project will be to assimilate the latest scientific and regulatory expertise from CBER (biologic characterization) and CDRH (device characterization), and develop recommendations on how best to integrate this knowledge in a manner which facilitates the most effective approach in developing these products.

Sudeepa Bhattacharyya, Ph.D.

National Center for Toxicological Research
Preceptor: Richard Beger, Ph.D

Scientific and Professional Background

Scientist, Bioinformatics Research	Stemina Biomarker Discovery Inc, Madison, WI, 2008-2009
Post-Doctoral-Fellow	Center for Orthopedic Research, UAMS, 2007-2008
Ph.D. in Bioinformatics	Univ. of Ark. at Little Rock/ Univ. of Ark for Med. Scs. (Joint Bioinformatics Program), 2007
Research Assistant	Center for Orthopedic Research, UAMS, 2002-2003
Bioinformatics Analyst	Alberta Cancer Board, Alberta, Canada, 2002
M.S. in Proteomics	University of Alberta, Canada, 2001
Graduate Research Assistant	Dept. of Genetics, Texas A&M University, 1995-1996
M.S. in Biochemistry	Calcutta University, India, 1992
B.Sc. (Honors) in Chemistry	Calcutta University, India, 1990

Research Interests

Over the years, I have been privileged enough to be exposed to many cutting edge fields of research under the broad umbrella of bioinformatics--like protein engineering, structural proteomics using NMR and molecular modeling, genomics, SNP analysis, biomarker discovery using mass spectrometry based proteomics and of late metabolomics. My educational and professional expertise have provided me with a broad knowledge base to generate, process, and analyze high throughput *'omics data'* to detect hidden patterns using various statistical and data mining algorithms. My strong computational background in programming, relational databases, data mining and statistical analysis along with my roots in biology, have prepared me well to plunge into the world of integrated systems biology. This, in turn, has led to *my primary interest in studying the biological mechanisms of action underlying the toxicity of different products including drugs and human diseases with a holistic approach.* I have extensive experience in detecting biomarkers of different diseases using mass spectrometry based proteomics and metabolomics and am also very interested in developing assays for minimally-invasive diagnosis of different diseases using these techniques.

FDA Commissioner's Fellowship Project Overview
Quality control for focused and unfocused LC-MS based metabolomic profiling of serum samples

Mass-spectrometry based metabolomics technology has a broad scope of potential applications in analyzing biofluid samples for the discovery and evaluation of safety biomarkers, monitoring of patient response to drug treatment, studies of biochemical pathway in cells (animals and humans), stratification of patients, tracking of mechanisms associated with disease onset and following therapeutic intervention etc. Regardless of these potential applications, the challenges in the complexity of the biological systems and the experimental variability associated with the use of highly sophisticated and sensitive instruments have limited the full commercial application of mass-spectrometry based metabolomic experiments. Currently there are no well-established and standardized methods for quality control when evaluating preclinical or clinical blood samples during metabolomic analyses. Therefore, the goal of my project is to set up a quality control procedure to ensure the reliability of information generated in metabolomic experiments. Using a set of over 40 chemical standards for a synthetic quality control (QC) sample that was developed by NUGO (The European Nutrigenomics Organization) and pooled human serum samples we will develop and use intra-lab and inter-lab QC for quantitative analyses of bile acids, amino acids, vitamins in serum samples from several preclinical and clinical protocols as well as semi-quantitative global LC/MS metabolomic profiles of serum samples. Adding QC methods to LC/MS-based metabolomics data may make such data more consistent for evaluation in IND and NDA submissions to the FDA and improve the identification and validation of biomarkers useful to improve public health.

Khaled Bouri, Ph.D., M.P.H.

Office of the Commissioner
Preceptor: Norman Marks, M.D.

Scientific and Professional Background

2008 M.P.H.	Health communication and Marketing, George Washington University
2006 - 2008	Senior fellow, George Washington University School of Public Health
2000 - 2006	Research associate, Children's National Medical Center, Washington D.C.
1996 - 2000	Post-doctoral fellow, University of Pittsburgh School of Medicine
1996 Ph.D.	Pharmacology, University Louis Pasteur, Strasbourg, France
1985 B.Sc.	Biochemistry, University of Damascus, Syria

Research Interests

I have over twelve years of experience in cutting edge biomedical and public health research. The overarching goal of my most recent research interest is to integrate genomic technologies into public health practices. I served as a principle investigator on a project to study public perceptions and attitudes towards genomic technologies, and to design and disseminate culturally appropriate health communication and prevention programs for chronic diseases targeted to minority populations.

FDA Commissioner's Fellowship Project Overview
Direct-To-Consumer Genetic Testing: Evaluation of the Risks and Benefits, and Adverse Event Reporting System

Direct-to-Consumer (DTC) genetic testing is a service provided by private companies hoping to inform consumers about the presence of genetic variations associated with high risk to common diseases. Several experts have raised concerns about the validity and clinical implications of the results of these tests, and also expressed concerns about potential harms to consumers associated with the premature use of these tests. We will assess the current perspectives on potential risks and benefits of DTC genetic testing, and we will investigate the needs to establish post-marketing surveillance system to detect potential adverse events related to the use of DTC genetic testing. The outcome of this study will clarify the regulatory standards required for DTC genetic testing, and the appropriate level of FDA oversight if necessary.

Joslyn K. Brunelle, Ph.D.

Center for Drug Evaluation and Research
Preceptor: Baolin Zhang, Ph.D.

Scientific and Professional Background

2006 - 2009	Postdoctoral Fellow, Dana Farber Cancer Institute/Harvard University, Boston, MA
2000 - 2005	Ph.D., Northwestern University, Integrated Graduate Program in the Life Sciences, Chicago, IL
1996 - 2000	B.A. (Biology), Albion College, Albion, MI

Research Interests

My research interests are focused on the various aspects of cancer biology, including oncogenes, tumor suppressors, signal transduction, programmed cell death (apoptosis) and angigenesis. My graduate work involved studying tumor cell responses to low oxygen conditions (hypoxia) and oxygen deprivation (anoxia), including the mitochondrial pathway of apoptosis, activity of transcription factor Hypoxia Inducible Factor (HIF-1), and mitochondrial metabolism. During my postdoctoral research, I worked with genetically defined mouse models of leukemia as a tool for the development of a diagnostic technique which can identify cancer cells that depend on anti-apoptotic Bcl-2 family members for survival. In addition, I tested the response of leukemia cells to chemotherapy drugs in order to compare drug response with the diagnostic results. My long term career goals include discovering novel cancer therapeutics, defining mechanism of action of small molecules or biologics, determining mechanisms of drug resistance, and discovering new biomarkers to aid in diagnosis and treatment decisions.

FDA Commissioner's Fellowship Project Overview
Developing a novel apoptosis assay for high throughput measurement of the potency of cancer therapeutics

The FDA regulates a large number of cancer therapy products aimed at inducing apoptosis (programmed cell death) in cancer cells. However, the potency assays used for determining the bioactivity of these products are generally cell viability assays which do not distinguish between cell death and growth inhibition. There are a number of commercial assays available to measure apoptosis; however, many of these assays are not appropriate for high throughput drug testing due to low robustness and high variability. The goals of my project will be: A.) Write and publish a review article to provide background information on apoptosis pathways in cancer development and treatment, including a summary of the strengths and weaknesses of the commercial assays currently available to measure cell viability, cell death and apoptosis. B.) Develop a novel apoptosis assay that could be used by pharmaceutical industry for measuring the potency of anticancer drug products.

Kathryn Burke, Ph.D.

Office of the Commissioner
Preceptor: Dr. Timothy Coté, Dr. Richard Rodgers, and
Dr. Menfo Imoisili

Scientific and Professional Background

2009	Research Fellow, University of Maryland, Baltimore SOM
2003 - 2009	University of Maryland, Baltimore School of Medicine (Ph.D., Neuroscience)
1999 - 2003	Loyola College (B.S.)

Research Interests

For the past four years I have been investigating the role of the prefrontal cortex (PFC) and its interactions with sub-cortical structures such as the amygdala and the striatum in goal-directed learning. The ability of both humans and animals to use information in their environment is critical in adaptive behavior. Conversely, an inability to use such information would result in inappropriate or perhaps habit-driven behaviors, such as was the case in the classic case study of Phineas Gage in the mid-1800s. After an injury to the PFC, Phineas Gage's behavior became erratic and destructive, irreverent to the consequences surrounding his choices or actions. This case study began to unfold a critical function of the prefrontal cortex, and specifically the orbitofrontal cortex (OFC), in forming associations between environmental events and consequences/ outcomes that follow them. My research began on characterizing basic learning functions of the OFC in rodents. Since this area in highly conserved across species, the studies done under my thesis will undoubtedly translate to human behavior. Using both behavioral and neurophysiological techniques, my research has specifically demonstrated how the OFC is required for acquiring associations between environmental events and outcomes to then use these associations to guide adaptive behavior. As I am currently transitioning out of this field, I am very excited to parlay my bench knowledge into a new field of science at the FDA.

FDA Commissioner's Fellowship Project Overview
An Analysis of Development and Approval Times for Orphan Products

While approved products for rare or "orphan" diseases make up approximately one-third of all drug and biologic approvals, a comprehensive analysis on their total development time has yet to be fully examined. My fellowship project will focus on how orphan products differ from non-orphan products in both clinical development time (CDT) and time to approval (TA). Many rare diseases can be extremely debilitating and life threatening. Therefore, the timely availability of orphan products is extremely critical to these patients and, in general, to the promotion of public health. Unfortunately, barriers exist that hamper their development, such as small patient populations and diverse geographical dispersion. Based on these handicaps as well as the extreme importance of orphan approvals, it is important to understand the CDT and TA of these agents. If orphan products have faster CDTs or TAs than non-orphans, this may prompt investors to venture into orphan development- most likely in virgin orphan territories- for quick financial returns. In turn, this would provide new initiatives in these areas while at the same time assisting both the Office of Orphan Products Development and Food and Drug Administration in their overall missions.

Xuefei Cao, Ph.D.

National Center for Toxicological Research
Preceptor: Robert H. Heflich, Ph.D.

Scientific and Professional Background

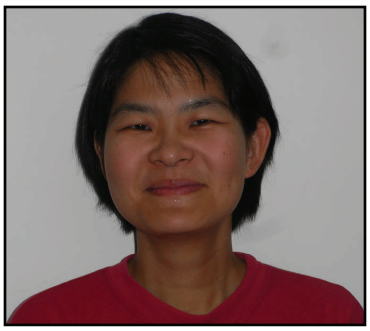
2007 - 2009	Post-doctoral Research Fellow Department of Pharmacology & Pharmaceutical Sciences School of Pharmacy, University of Southern California
2006 - 2007	Post-doctoral Research Fellow Department of Hematology and Oncology Children's Hospital of Los Angeles
2001 - 2005	Doctor of Philosophy Department of Pharmaceutical Sciences School of Pharmacy, University of Southern California
1999 - 2001	Master of Science Department of Chemistry University of Cincinnati
1995 - 1999	Bachelor of Science Department of Biochemistry & Molecular Biology School of Life Sciences, Nankai University, P.R. China

Research Interests

My post-doctoral research focused on the design and pre-clinical development of novel small molecule anti-cancer therapeutics that are orally active and useful for clinical trials. During my post-doctoral training, I have successfully identified and validated the molecular targets of several lead compounds using molecular biology, cell biology, and microarray technology. I also participated in the *in vivo* pharmacology and toxicology studies in collaboration with other research fellows and PK/PD scientists. My research project at the FDA involves application of my experiences to elucidate the genotoxicity of ethyl methanesulfonate (EMS). I hope that my research will help resolve the concerns on the regulation of mutagenic carcinogens.

FDA Commissioner's Fellowship Project Overview
Dose-response Genotoxicity of Ethylmethane Sulfonate (EMS) in Mice Using the Pig-a and Transgenic Gpt Delta Assays

In 2007, contamination of a batch of the AIDS drug Viracept with ethylmethane sulfonate (EMS) prompted the manufacturer, Hoffman La Roche of Basel Switzerland, to conduct additional genotoxicity testings in order to estimate the cancer risk to patients exposed to the contaminated drug. Consistent with recent *in vitro* and *in vivo* experimental findings, Roche's studies also demonstrated that EMS had a practical no-effect threshold of at least 25 mg/kg/day based on a number of genotoxicity endpoints. Nevertheless, the US FDA raised several concerns about the validity of Roche's study and suggested that a more thorough investigation to determine better ways to study dose-response genotoxicity be in the best interests of making future regulatory decision. The goal of this project is to improve human health risk assessment by studying the low-dose genotoxicity of EMS using novel assays with low simultaneous mutation frequencies in mice.



Tehyen Chu, Ph.D.

Center for Biologics Evaluation and Research
Preceptor: Deborah Hursh, Ph.D.

Scientific and Professional Background

Postdoctoral fellow at Harvard University, Department of Molecular and Cellular Biology
Ph.D., Biochemistry, SUNY at Stony Brook, 2000.
B.Sc., Medical Technology, National Taiwan University, 1992.

Research Interests

I am interested in early development, and more specifically how cell trafficking is regulated to affect the developmental process. As a postdoctoral fellow, I focused on the transport of Hedgehog (Hh) protein in the developing visual system in *Drosophila*. Hh is a well studied signaling molecule that is involved in many early patterning processes. In the developing fly eye, Hh is required at both the apical end (for eye development) and the basal lateral end (for brain development). Hh protein is produced near the cell body which is at the apical end and thus an active transport mechanism has to be in place to deliver Hh to the axon terminal, which is the basal lateral end. Our study has shown that Hh protein contains an axon targeting signal which is necessary for targeting the protein to the axon terminal. A single amino acid change at this targeting motif can eliminate its function. I am interested in how such signal is recognized by the cellular machinery as well as exploring other signaling molecules that exhibit targeted expression or secretion.

FDA Commissioner's Fellowship Project Overview
The Role of Extracellular Matrix Protein in the Signaling of Transforming Growth Factor-β/Bone Morphogenetic Protein

A clear understanding of context dependent cell development is critically important in tissue/organ engineering and cellular based replacement therapies. Currently, most cell therapies, with few exceptions, have failed to show the ability to permanently restore function. The transplant cells either die off or become cancerous. This largely reflects the deficiencies of our understanding of how cells differentiate, and maintain proper growth and function. Despite the explosion of knowledge in the past few decades, our lack of understanding in the detailed mechanism of cell development has prevented us from generating more effective cell therapy products for clinical use. In an effort to narrow this knowledge gap, my research emphasis is to examine the role of various extracellular matrix components in effecting cell differentiating. More specifically, I will focus on how extracellular matrix and proteins modulate the signal transduction of Bone Morphogenetic Proteins (BMP). BMPs are powerful morphogens and widely used in the manufacturing of cell therapy products for differentiation induction.

Natalia Comella, Ph.D.

Center for Devices and Radiological Health
Preceptor: Sally Hojvat, Ph.D.

Scientific and Professional Background

U.S. Department of State – Office of the Global AIDS Coordinator
(August 2008 - September 2009)
U.S. Department of State – Office of International Health and Biodefense
(September 2006 – August 2008)
AAAS Diplomacy Fellow – U.S. Department of State
(September 2004 – August 2006)
Massachusetts Institute of Technology - Ph.D. Candidate
(Fall 1998 – Spring 2004)
Beth Israel Deaconess Medical Center – Department of Pathology
(July 1996 – August 1998)
Wellesley College – Graduated in 1996

Research Interests

My research interests focused on how bacteria regulate certain physiological processes, such as biofilm formation, and antibiotic production, by monitoring their population density through the accumulation of chemical cues (a.k.a. quorum sensing). In addition to my scientific interests, an interest in the underlying policy decisions driving (or impeding) global health efforts led me to transition into the policy-making arena. Between 2004 and 2008, I worked at the intersection of health and security – strengthening international cooperation and global preparedness against naturally emerging diseases and bioterrorism. I represented the U.S. at bilateral and multilateral meetings on a range of issues, coordinated the 2004-05 U.S. efforts in the G-8 Bioterrorism Experts Group (BTEX) and spearheaded the Asia Pacific Economic Cooperation (APEC) Food Defense Initiative (2006-2008). Before moving to FDA, I helped coordinate the completion of the first bilateral, HIV-related Partnership Framework.

FDA Commissioner's Fellowship Project Overview

Addressing Regulatory Issues Relating to the Clearance or Approval of Multiplex Assays

Multiplex in vitro diagnostic assays are anticipated to play a more prominent role in future diagnostic practice. Multiplex assays are defined as those assays in which two or more targets (also known as analytes) are assayed through a common process of sample preparation, amplification, and/or detection, and interpretation, allowing for the simultaneous detection, identification and differentiation between various analytes (e.g., pathogens). While these devices provide many benefits, they also raise questions regarding their regulation and their appropriate use. My work will address some of the regulatory challenges raised during the review process.

Gabriel Davila, D.V.M.

Center for Veterinary Medicine
Preceptor: Lynn O. Post, D.V.M., Ph.D., D.A.B.V.T.

Scientific and Professional Background

University of Florida, College of Veterinary Medicine, D.V.M., 2009
University of Florida, B.S. in Animal Science, 2005

Research Interests

During my veterinary medicine program, I conducted a research project that evaluated the prevalence of a previously rare ascarid parasite of ruminants in North Central Florida. The efficacy of fenbendazole in the control of this parasite was also evaluated. I have also been involved in research involving reproductive endocrinology of the cow. My interests include regulatory medicine and food animal production medicine. I hope to apply my knowledge and training in veterinary medicine to solve problems that affect the health of food-producing animals as well as to maintain the safety of the animal food supply.

FDA Commissioner's Fellowship Project Overview
Drug residues: Factors associated with the risk of veterinarian caused drug residue violations in dairy beef

My FDA Commissioner's Fellowship project evaluates how management factors and dairy practitioners influence the occurrence of drug residues in dairy beef. The study consists of two parts. First, dairy management information collected by the FDA CVM drug residue program will be compared with management information from the USDA's National Animal Health Monitoring System in order to evaluate practices that may contribute to the occurrence of drug residues. Second, a survey-based case-control study of dairy practitioners will be carried out to better understand the role of veterinarians in residue avoidance. The information gathered will help the agency's efforts to promote drug residue avoidance in the dairy industry.

Eric Dollins, Ph.D.

Center for Biologics Evaluation and Research
Preceptor: Malcolm Moos, M.D., Ph.D.

Scientific and Professional Background

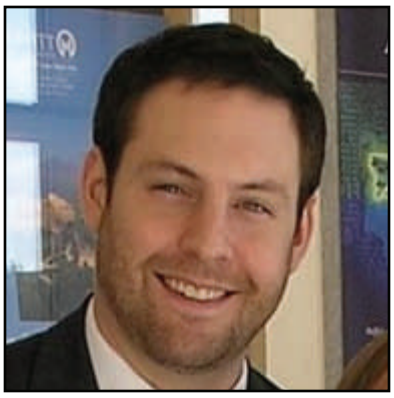
Post-doctoral Fellow, Duke University & Howard Hughes Medical Institute, 2007-2009.
Ph.D., Biochemistry, Duke University, 2007.
Research Technician, Oklahoma Medical Research Foundation, 2001-2002.
B.S., Biochemistry, Oklahoma State University, 2001.
B.S., Psychology, Oklahoma State University, 1997.

Research Interests

My doctoral and post-doctoral research focused on the biology of the Hsp90 family of protein chaperones and a specific cell communication network known as the inositol signal transduction pathway. Each of these systems is essential for life and contributes to human disease when normal function is altered. To understand these systems on the molecular level and gain insight into the pathophysiology associated with them, I've predominately employed a structure-function approach to study the proteins involved in each system. I have utilized techniques ranging from x-ray crystallography to enzyme kinetics and I expect that my training will be broadly applicable to studies of biological systems. I am excited to have the opportunity to apply my training to a problem related to regulatory science and view the FDA Commissioners Fellowship as an excellent way to transition into regulatory review.

FDA Commissioner's Fellowship Project Overview
Improving cell product characterization--defining mechanisms that control cell fate in lineage-restricted (ectodermal) stem cells

Among new therapeutic products being developed, few hold as much promise or present as many challenges as cell-based therapies. The inherent complexity of experimental cell-based products, combined with inadequate understanding of the underlying biology, has led to great difficulty defining the parameters critical for the design, manufacture, and testing of these products. This has become apparent from the lack of predictability of product performance *in vivo* by product manufacturing schemes as well as by in-process and release testing. Therefore a more detailed understanding of the molecular mechanisms and underlying biological processes that control the performance of these products will be essential. To address this problem, we are working to identify specific points of cell fate control that determine the safety and effectiveness of cell based products.



Scott N. Freeman, Ph.D.

Office of the Commissioner
Preceptors: Timothy Coté, Ph.D.,
Richard Rodgers, Ph.D., and Menfo Imoisili, Ph.D.

Scientific and Professional Background

Postdoctoral Fellow, H. Lee Moffitt Cancer Center and Research Institute Departments of Experimental Therapeutics and Thoracic Oncology, 2007-2009

Ph.D., Cancer Biology, H. Lee Moffitt Cancer Center and Research Institute and the University of South Florida Department of Molecular Oncology, 2002-2007

B.S., Major: Pre-graduate/Pre-professional Biology, Minor: Chemistry
Central Michigan University, 1998-2002

Research Interests

My research background consists primarily of basic and translational approaches to improve the understanding of molecular events that initiate and maintain a malignant phenotype towards the end of developing novel therapies and diagnostics to improve cancer outcomes. Many cancers and cancer subtypes constitute orphan diseases, which impressed upon me the importance of promoting the development of products which treat orphan maladies. Given this, my research interests have evolved into the epidemiological analysis of the orphan products program with the intent of deriving information that will lead to the improved development of products designed for the treatment orphan diseases.

FDA Commissioner's Fellowship Project Overview
A Quantitative Analysis of the Contributions of the Orphan Drug Act towards the Development of Products for Orphan Malignancies

The United States legislated the Orphan Drug Act (ODA) in 1983 to provide incentives for the identification and development of products (drugs, biologics, and devices) for rare diseases. Per the Act, a sponsor may apply for an orphan designation for their product which, upon approval, will be entitled to the incentives put forth by the ODA. While orphan malignancies constitute the disease class with the largest number of orphan designations, a quantitative analysis of the contributions of the ODA towards the development of oncological products for has not been conducted. The objective of my project is to quantitatively review designations, approvals, and clinical development time of products for orphan malignancies across several strata. This project aims to identify variables that associate with success and shortcoming that can be utilized to learn from and build upon advancements and guide interest and resource allocation to areas of deficiency. Additionally, it is expected to contribute an important overview of what has been accomplished in the advancement of product development for orphan malignancies through the ODA as well as provide a metric by which future progress may be evaluated. In line with the mission of the FDA, the results of this project seek to contribute towards the betterment of public health by providing evidence that may stimulate the innovation of safe and effective products.

J. Angelo Green, Ph.D.

Center for Devices and Radiological Health
Preceptor: Joseph Hutter, Ph.D.

Scientific and Professional Background

2004 - 2009, Research Fellow, Laboratory of Cell and Developmental Biology, National Institute of Dental and Craniofacial Research, NIH.

1999 - 2004, Ph.D., Molecular and Cellular Biology, Chemistry-Biology Interface Training Program, University of Massachusetts at Amherst.

1994 - 1999, B.Sc., Cum Laude, Chemistry, Biochemistry and Molecular Biology, University of Massachusetts at Amherst.

Research Interests

My past research training has been interdisciplinary, spanning the fields of biology, chemistry and material science. My research interests broadly include the study of biomaterials, cell-surface interactions, cell signaling and extracellular matrix. As a graduate student, I examined the effects of lipid second messengers, and synthetic polymers of different topography and surface chemistry, on cell adhesion and behavior. As a postdoctoral research fellow, I studied both 2-dimensional and 3-dimensional cell-derived biopolymers as in vitro models to investigate the ability of cells to interact with and remodel their extracellular matrix environment. This fellowship experience will further develop my expertise in material science and allow me to contribute to the development of international regulatory standards for testing contact lenses and solutions.

FDA Commissioner's Fellowship Project Overview
Increasing the Safety Margin for Contact Lens Wearers by Enhancing the Disinfection Efficacy Testing of Lens Care Products

As an FDA Commissioner's Fellow, I will be involved in the contact lens critical path project, an interdisciplinary research project aimed at improving pre-market testing of contact lenses and contact lens care products. Between 2004 and 2007, outbreaks of serious ocular infections among contact lens users underscored the need for new premarket test methods to predict disinfection efficacy of contact lens care products. I will study specific physicochemical properties of contact lens materials (hydrogel polymers) that may reduce the ability of care product solutions to disinfect microbial contaminants. In addition, I will be involved in assessing the cleaning effectiveness of contact lens care products with respect to bacterial biofilm removal.

Dionna Green, M.D.

Center for Drug Evaluation and Research
Preceptor: Gilbert Burckart, Pharm.D.

Scientific and Professional Background

2008-2009	Clinical Pharmacology Fellowship – Georgetown University Medical Center, Washington, DC.
2006-2007	Pediatric Internship – Children's Hospital at Sinai, Baltimore, MD.
2001-2005	M.D. – Howard University College of Medicine, Washington, DC.
1997-2001	B.S. in Biology – Bowie State University, Bowie, MD.

Research Interests

As a clinical pharmacology fellow, my research focused on better understanding what contributes to the significant racial disparity seen in endometrial cancer among African-American women versus that of Caucasian women. Clinical research data show that endometrial cancer is much more aggressive in African-Americans than Caucasians. In particular I looked at Sos1, a protein that was found to be significantly up-regulated in the endometrial cancer of African American females versus Caucasian females. Sos1 is a guanine nucleotide exchange factor. It plays a very important role in the activation of the MAP kinase pathway which enhances cell migration and proliferation. siRNA knock down of Sos1 resulted in a dramatic reduction in the proliferation of endometrial cancer cells. Over-expression of Sos1 in the same cell line was also undertaken to further confirm its role in endometrial cancer cell proliferation. The goal of the study is to provide support for the discovery of agents that modulate Sos1 towards developing a targeted therapy for endometrial cancer. My research interests include understanding genetic variation in expression of genes and its role in contributing to the variability of how individuals manifest disease states and respond to treatments, with the goal of using these new findings in drug discovery to develop targeted therapies against disease that are more individually tailored, effective and safe.

FDA Commissioner's Fellowship Project Overview
Pharmacogenomics and Pharmacometrics of Adverse Effects and Dosing of Anti-Proliferative Agents in Children Following Heart Transplantation

For many children with serious cardiac ailments, transplantation is the only option that allows the possibility of long-term survival. The use of immunosuppressive drugs has allowed notable advances in pediatric heart transplantation. However, there remains significant interpatient variability in response to these agents, permitting acute organ rejection to remain a major roadblock to long-term successful transplantation. Genetic polymorphisms affecting genes involved in drug behavior may account for some of the various outcomes seen. Focusing on two immunosuppressive drugs in particular, azathioprine and mycophenolic acid, genotyping data will be used to investigate polymorphisms in thiopurine methyltransferase (TPMT) and multidrug resistance protein 2 (MRP2), respectively, and their affect on drug dosing, outcome, and adverse events. This sum of this information will be used to create a mathematical model relating drug dose and outcome in order to tailor immunosuppressive therapy for the individual patient with the ultimate goals of increasing the number of successful long-term pediatric heart transplantations.

Shanil (Shani) P. Haugen, Ph.D.

Center for Devices and Radiological Health
Preceptor: Victoria Hitchins, Ph.D.

Scientific and Professional Background

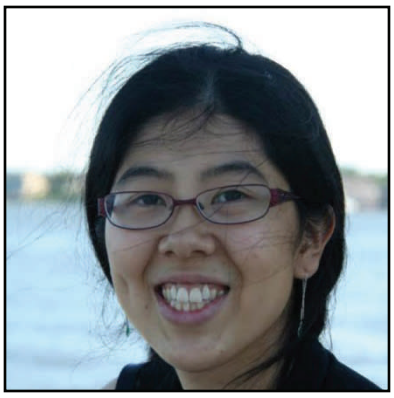
2007-2009 Postdoctoral Research Fellow, NIH
2000-2007 Ph.D. in Microbiology, University of Wisconsin - Madison
1996-2000 B.S. in Microbiology, University of Illinois, Urbana - Champaign

Research Interests

My laboratory experience has primarily been in molecular biology, however, my research interests are very broad. I am interested in mechanisms of genetic regulation, both in microbes and in mammalian cells. I am particularly interested in understanding the factors and conditions that aid bacterial growth.

FDA Commissioner's Fellowship Project Overview
Medical Device Design Considerations for Infection Control

Many healthcare-associated infections are related to the use of medical devices. My project will explore how medical device design features may contribute to the spread of microbial infections. At the end of this fellowship, the results of my laboratory experiments will provide the FDA, manufacturers of reusable medical devices, and health care workers with information on the effects of design on cleaning, disinfection, and sterilization of devices. These projects will also supply manufacturers with scientific data that can be used to guide the design of medical devices so that the risk of infection associated with devices is minimized.



Kaoru Hida, Ph.D.

Center for Food Safety and Nutrition
Preceptor: Biswendu Goswami, Ph.D.

Scientific and Professional Background

Johns Hopkins University School of Medicine - Ph.D. 2009; Biomedical Engineering
University of California at Berkeley - B.S. 2004; Bioengineering

Research Interests

My interests lie in the broad area of viral pathogens and viral gene therapy vectors targeted at mucosal tissues. My doctoral research has focused on understanding the role of mucus in reducing the risk of infection by mucosal viruses such as HIV, Human Papilloma Virus and Herpes Simplex Virus. This may aid in the identification of methods and strategies to enhance the barrier properties of mucus and minimize viral transmission. In addition, I am interested in the design of improved gene therapy viral vectors targeted at mucosal sites, such as cystic fibrosis. I am interested in utilizing protein engineering methodologies to evolve and characterize novel viral vectors. As such I have a broad expertise in molecular biology, virology and biophysical techniques such as particle tracking and light scattering.

FDA Commissioner's Fellowship Project Overview
Molecular methods for detection of Hepatitis A (and other viruses) from food

Outbreaks of food borne viral infections, including Hepatitis A virus (HAV) have been increasingly reported worldwide. This project aims to explore a microarray based method for the detection of HAV and other viruses that have been isolated from various food matrices. PCR amplification will not be required and thus may be advantageous for the rapid detection of multiple viruses in mixed environmental samples. The second aim is to elucidate the molecular mechanisms behind the differential growth of HAV in different cell lines, especially the role of the anti-viral RNaseL pathway.

Peter T. Jeanettes, D.V.M.

Center for Veterinary Medicine
Preceptor: Joseph C. Kawalek, Ph.D.

Scientific and Professional Background

Doctor of Veterinary Medicine, 2002
Ross University School of Veterinary Medicine, St. Kitts, West Indies
Clinical year at Louisiana State University, College of Veterinary Medicine, Baton Rouge, LA
Bachelor of Science in Biology, 1996, Binghamton University, Binghamton, NY

Research Interests

The FDA Commissioner Fellowship Program will enable me to acquire research and laboratory experience to complement my skill set as a veterinarian. Coming from a private practice background, I will use the FDA training to participate in ongoing veterinary research involving me directly with advancements in animal and public health.

FDA Commissioner's Fellowship Project Overview
Species Comparison of the In Vitro Metabolism of Anthelmintics

The hepatic drug metabolizing enzymes, cytochrome P450 (CYP) and the flavin-monooxygenase enzyme (FMO) systems, catalyze the metabolism of the most commonly used antiparasitic drugs in the ruminant food producing animals. The CYP and FMO isoforms are well characterized in lab animals and humans, but only a few are known in swine and cattle. They remain unknown, for the most part, in the ruminants which are cattle (major species), sheep and goats (both minor species). The project will involve an *in vitro* assessment of these enzyme systems using hepatic microsomal assays. This study will involve the use of several types instrumental procedures including electrophoresis for Western blot analysis, use of microtitre plate readers for measurement of enzymatic activities, and high performance liquid chromatography (HPLC) for analysis of substrate metabolites. These techniques will be used to elucidate the different isoforms of the CYPs and FMOs involved in the metabolism of the antiparasitic drugs. The results will be coupled with a concurrent *in vivo* pharmacokinetic study of the same drugs in these ruminant species. The *in vitro* comparision of these enzyme systems will provide a molecular basis for the different metabolite profiles seen during the pharmacokinetic study. The antiparasitic drugs in this study are already approved and their safety and efficacy have been proven for all of the target animals. In addition, the approval process for drugs used in food animals requires the drug sponsor to demonstrate the safety of any drug residues for the people that consume edible tissues derived from treated animals. This study has important consequences in the veterinary medical field as it pertains to drugs for minor uses and/or minor species. It will enable the development of guidelines for data obtained in major species to be extrapolated to minor species. The results may also lead to new paths for drug discovery in existing and new classes of veterinary antiparasitic drugs which may aid in the near future with the presence of emerging resistances of parasites. In addition procedures developed herein could be applied to the study of other drug classes, e.g. antibiotics.

Katherine Kavlock, Ph.D.

Center for Devices and Radiological Health and
Center for Biologics Evaluation and Research
Preceptors: Keith Wonnacott, Ph.D., Bruce Schneider, M.D.,
Charles Durfor, Ph.D. and Elias Mallis, B.S.

Scientific and Professional Background

Virginia Tech – Wake Forest School of Biomedical Engineering and Sciences, Ph.D. in Biomedical Engineering, May 2009
North Carolina State University, B.S. in Biomedical Engineering, May 2004

Research Interests
My previous research focused on the the effect of mechanical environment, particularly the influence of biomaterial scaffold mechanics and a perfusion flow bioreactor, on the differentiation of adult stem cells for orthopaedic tissue engineering applications.

FDA Commissioner's Fellowship Project Overview
The Modernization of Guidance and Review Practices Regarding Ligament and Tendon Prosthetics: Evaluating the Next Generation of Products

The most recent guidance document for ligament prosthetics was originally published in 1987, was last updated in 1993, and is based on devices that are no longer marketed because of high incidence of implant failure. It does not include considerations for degradable materials, materials of physiological origin (such as xenograft or collagen), or products containing cells or growth factors (i.e., drugs). However, products combining the mechanical benefits of pure prosthetics with the healing and remodeling ability of cells are being actively investigated and advances in both technology and the understanding of ligament and tendon function (e.g. anatomy, composition, biomechanics, and healing) are resulting in increased regulatory submissions in the area of ligament and tendon replacement products. Due to the rapidly evolving regenerative medicine technologies published in scientific literature and/or submitted to the FDA, collaboration between centers will be essential for ensuring efficient and consistent review practices. Therefore, the goal of my project is to work with the review staff in both CDRH and CBER to examine the preclinical and clinical issues associated with ligament prosthetics and to write a white paper evaluating the key elements of review for ligament and tendon products in both centers.

Bharat Khurana, D.V.M., M.B.A, Ph.D.

Center for Biologics Evaluations and Research
Preceptors: Elliot Cowan, Ph.D. and Pradip Akolkar, Ph.D.

Scientific and Professional Background

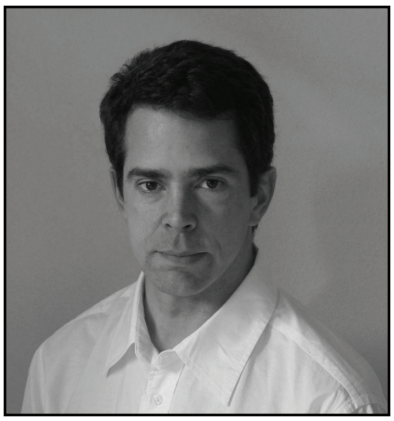
Regulatory Specialist, Technical Resources International, Inc., Regulatory Compliance Center for Division of AIDS, NIAID, NIH, 2007-2009
Staff Scientist, Department of Pathology, Uniformed Services University of the Health Sciences, Bethesda, MD, 2006-2007
Postdoctoral Fellow, Laboratory of Viral Diseases, NIAID, NIH, Bethesda, MD, 2001-2006
M.S. & M.B.A., 2006-2009, Johns Hopkins University, MD
Ph.D., Molecular and Cell Biology, 1997-2001, University of Cologne, Germany
M.S., Veterinary Virology, 1994-1997, CCS Haryana Agricultural University, India
D.V.M., Veterinary Medicine, 1989-1994, CCS Haryana Agricultural University, India

Research Interests

I am particularly attracted by the fact that the FDA Commissioner's Fellowship provides me with an opportunity to hone the necessary skills in science-based and risk-based regulatory strategies to optimize a product's benefit/risk balance and assure that the products are safe and effective. Prior to joining FDA Commissioner's Fellowship, I worked as a Regulatory Specialist at a Regulatory Compliance Center for Division of AIDS, NIAID, NIH. As a Regulatory Specialist, I have gained experience in managing and providing regulatory support for global HIV-1 clinical trials involving microbicides, anti-viral drugs and vaccines. As a scientist, I have an extensive scientific research background in virology, molecular and cellular biology at NIAID/NIH and Uniformed Services University of the Health Sciences.

FDA Commissioner's Fellowship Project Overview
Development and Analysis of New Regulatory Paradigm(s) for Bringing the Screening Tests for Emerging Infectious Diseases to Market in a Timely Manner

The safety of blood and blood products is one of the public health priorities of CBER/FDA. Blood and blood products carry an inherent risk of transmitting infectious agents through transfusion. Though zero risk may be unattainable, the role of CBER/FDA is to drive that risk to the lowest level reasonably achievable without unduly affecting the availability of these life saving products. Stringent and extensive review of blood donor screening tests by the Division of Emerging and Transfusion Transmitted Diseases (DETTD) in the CBER, Office of Blood Research and Review (OBRR), have a profound impact on the safety of the blood supply in the United States. However, the perceived notion of an extensive regulatory approval process may hinder test manufacturers in the development of new assays, especially when a screening test is not required to be used universally – as is the case with emerging infectious disease agents which are geographically sporadic and seasonal in nature. The objective of my project is to develop and analyze new regulatory paradigm(s) for bringing the screening tests for emerging infectious diseases to market in a timely manner.



Mark Kreitz, Ph.D.

Center for Devices and Radiological Health
Preceptors: Alberto Chiesa, D.V.M., Ph.D., John Karanian, Ph.D., and William Pritchard, M.D., Ph.D.

Scientific and Professional Background

1999	Ph.D. Brown University	Medical Science
1988	B.S. Northeastern University	Sensory and Neuropsychology
Brown University		Providence, RI
Molecular MS Diagnostics		Cranston, RI
Therapyx, Inc.		Buffalo, NY
Spherics, Inc.		Lincoln, RI
Schepens Eye Research Institute		Boston, MA

Research Interests

My graduate training focused on the use of erodible and non-erodible polymer-based drug delivery systems, specifically controlled heparin delivery from synthetic vascular grafts. I have subsequently worked on the oral delivery of controlled-release formulations of chemo- and other therapeutics, such as paclitaxel. I have a wide range of scientific interests, including controlled drug delivery and associated analytical techniques, nerve regeneration research involving the nerve-prosthesis interface, general medical science supporting these fields, and regulatory review and documentation systems.

FDA Commissioner's Fellowship Project Overview
Post-balloon Angioplasty Response of Swine Coronary and Peripheral Vessels to Extended Perivascular Release of Paclitaxel

Balloon angioplasty, alone or in combination with stent placement, is widely used to treat vessels substantially narrowed by coronary or peripheral artery disease. However, a significant number of patients require revascularization due to re-closure of these vessels (restenosis). The addition of drugs , such as paclitaxel, to these devices have further reduced restenosis rates while introducing additional patient safety concerns. The objective of this project is to evaluate the long-term safety profile (kinetics and toxicology) and healing response of locally delivered paclitaxel following balloon angioplasty in coronary and peripheral vessels of an established swine model. These findings should provide important safety information regarding the use of anti-restenotic drugs and help guide both the FDA and industry in the appropriate testing and use of anti-restenotic drugs combined with devices for the treatment of coronary and peripheral vascular disease.

Sylva Krizan, Ph.D.

Center for Devices and Radiological Health and
Center for Biologics Evaluation and Research
Preceptors: Keith Wonnacott, Ph.D., Bruce Schneider, M.D.,
Charles Durfor, Ph.D. and Elias Mallis, B.S.

Scientific and Professional Background

University of Michigan: Doctor of Philosophy (Biomedical Engineering), 2009
University of Michigan: Master of Science in Engineering (Biomedical), 2004
McMaster University: Bachelor of Chemical Engineering & Society, 2002

Research Interests

I have a combination of training in chemical and biomedical engineering, study in the social context of technology, as well as several years of research in the areas of adult stem cell biology and cell-biomaterial interactions for orthopedic tissue engineering. In particular, I am interested in the role of mechano-chemical material properties on stem cell differentiation as it pertains to both further understanding of mechanism and how this might relate to in vivo function. The connection between in vitro and in vivo studies will be important for the advancement of regenerative medicine applications and new biomaterial design. Further, I am interested in the social impact that these new regenerative technologies might have, on both developed and developing nations.

FDA Commissioner's Fellowship Project Overview

Improving understanding at the interface of biologics and devices for cartilage repair products: a multi-center (CBER/CDRH) study of preclinical review and knowledge integration both within FDA and across academia and industry

The goal of my fellowship project is to improve understanding of the development and regulation of cartilage repair products by conducting a CBER- and CDRH-based study of pre-clinical review and knowledge integration, both within FDA and across academia and industry. The focus will include the study of cell-biomaterial analysis that is common to cartilage repair products and how this is correlated to current scientific knowledge. Additionally, pre-clinical outcome measures for cartilage repair products reviewed in either center will be followed. Finally, an effort will be made to enhance the sharing of ongoing knowledge about cartilage repair products between CBER and CDRH review staff, as well as externally with academia and industry.

Eric Landis, Ph.D.

Center for Veterinary Medicine
Preceptor: Jennifer Matysczak, V.M.D.

Scientific and Professional Background

2007 – 2009	National Research Council Post Doctoral Fellow; NOAA Northwest Fisheries Science Center, Seattle, WA
2006	Ph.D. Molecular Medicine; University of Maryland, Baltimore
2001	B.S. Molecular Biology; University of California, San Diego

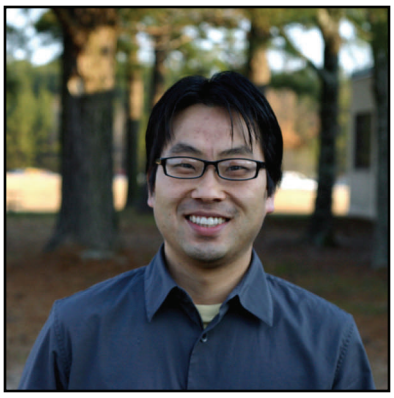
Research Interests

As demand for aquatic resources continues to grow beyond what wild stocks can sustain leading to the expansion of the size and scope of aquaculture (cultured fish and shellfish), it is important to maintain regulatory controls that ensure the health and safety of the animals as well as the American consumer. I have studied fish and aquaculture throughout my undergraduate, graduate, and professional career, and have increasingly focused on the animal and human health issues surrounding fish and shellfish production. I have specific research experience in finfish immunology and the detection of human pathogens in shellfish.

Drug approval for aquaculture presents significant challenges due to the industry's short history of drug development and its small market size in comparison to other animal production industries. There are also novel biological and physiological questions to be addressed when dealing with aquatic hosts and pathogens in an aquatic environment. As a Commissioner's Fellow at the FDA Center for Veterinary Medicine I plan to address these issues while working to adapt study design guidelines from terrestrial animal systems to fish and shellfish culture.

FDA Commissioner's Fellowship Project Overview
When can I stop counting? Developing standards for the evaluation of antiparasitic drugs in aquaculture

The Aquaculture Drugs Team in the Office of New Animal Drug Evaluation at FDA's Center for Veterinary Medicine has identified the specific need for a review of the factors that go in to the design and evaluation of studies for fish antiparasitic drug effectiveness. My approach will be to conduct a thorough review of FDA policies on the evaluation of antiparasitics for animal species and to review scientific literature that addresses the unique aspects of aquatic host and pathogen species that may influence drug evaluation studies. In addition to these reviews I will be communicating with experts in the field in order to understand the practical issues surrounding the use, need for, and evaluation of aquaculture drugs. This inclusive approach will provide the Aquaculture Drugs Team with a more complete understanding of potential approaches for quantifying aquatic parasites and demonstrating the effectiveness of new antiparasitic drugs.



Hyung-yul Lee, Ph.D.

National Center for Toxicological Research
Preceptors: Deborah K. Hansen, Ph.D. and Jim Kaput, Ph.D.

Scientific and Professional Background

Postdoctoral Research Fellow, 2007-2009
Harvard Medical School, MGH/Shriners Hospitals for Children, Boston, MA
Postdoctoral Research Fellow, 2005-2007
Harvard Medical School, Joslin Diabetes Center, Boston, MA
Ph.D. in Molecular & Integrative Physiology, 2005
University of Illinois at Urbana-Champaign, Urbana, IL
B.S. in Biology, 1995
Emory University, Atlanta, GA

Research Interests

I obtained my Ph.D. in the field of reproductive biology. My research interests also include insulin signaling pathway, obesity-related health problems, neutrigenomics, stem cell biology and neuro-toxicology.

FDA Commissioner's Fellowship Project Overview
Development of an in vitro stem cell-based screening of chemical compounds for their neurotoxicity

The overall objective of my project is to develop an *in vitro*, high-throughput stem-cell based assay system to evaluate large sets of developmentally neurotoxic as well as non-toxic chemicals with greater sensitivity and predictability. It is crucial that I utilize cell culture models that accurately recapitulate early embryonic development of the nervous system *in vivo*. To this end, I seek to es-tablish stem cell-based *in vitro* models of rodent and human origin (induced pluripotent stem cells) that can be easily expanded to their differentiated neuronal lineages (i.e. mature neurons, astrocytes, and oligodendrocytes). Once the "normal" course of differentiation is established and extensively characterized, various chemical compounds will be added to undifferentiated cells to test the effects of these compounds on the differentiation process, thereby providing information on possible neurotoxicity. It is ultimately envisioned that my fellowship project can be adapted for a high-throughput *in vitro* assay to facilitate chemical screening and drug discovery processes and prioritizing candidate compounds for additional testing.

Mark Levi, Ph.D.

National Center for Toxicological Research
Preceptor: John Bowyer, Ph.D.

Scientific and Professional Background

Scientist	J. Thomas May Center for ALS Research, 2008-2009
Research Instructor	Univ. of Arkansas for Medical Sciences, 2004-2009
Lecturer	Univ. of Auckland, New Zealand, 2003
Post-doctoral Fellow	Univ. of Auckland, New Zealand, 2003
Ph.D., Medicinal Chemistry	Univ. of Mississippi, 2002
B.S., Chemistry	Harding Univ., 1997

Research Interests

My research interests include *de novo* drug design as well as developing the methodology for the automated synthesis of small molecules and peptides. The small molecules were designed to combat cocaine addiction while the peptides were initially designed for trials as vaccines and neuroprotective agents. I have also worked on developing novel small molecules as neuroprotectants, in hopes of slowing the progression of ALS. I very much enjoy the business aspects of science.

FDA Commissioner's Fellowship Project Overview
Studies comparing the neurotoxicology of amphetamine with methamphetamine and methylphenidate

With the increasing use of proprietary formulations of amphetamine (Vyvanse®, Adderall®) for treating ADD/ADHD, in place of methylphenidate (Ritalin®), there remain doubts (at present) as to whether amphetamine is as safe of a drug as current advertizing portrays. My fellowship project will compare the neurotoxicities of amphetamine, methamphetamine (FDA-approved, Desoxyn®) and methylphenidate by measuring hyperthermia and hypertension. Gene expression studies will also be performed.

Orlando Lopez, Ph.D.

Center for Devices and Radiological Health
Preceptors: Alberto Chiesa, D.V.M., Ph.D.,
John Karanian, Ph.D., and William Pritchard, M.D., Ph.D.

Scientific and Professional Background

Postdoctoral Fellow, March 2007 – September 2009
Magnetic Resonance Imaging and Spectroscopy Section
National Institute on Aging, NIH, Baltimore, Maryland
Ph.D. Biomedical Engineering, September 1999 – February 2007
Magnetic Resonance Imaging Research Laboratory
Mayo Clinic College of Medicine, Rochester, Minnesota
Research Assistant, July 1998 – August 1999
Departments of Orthopedics & Cardiology Division
Harvard Medical School & Beth Israel Hospital, Boston, Massachusetts
B.S. Biomedical Engineering – June 1998
Boston University, Boston, Massachusetts

Research Interests

My research interests cover the development of engineering, imaging and analytical technologies that enable noninvasive characterization of biological systems and enhance our capabilities for early diagnosis and speed to new treatments. Some of my previous work has involved the development of magnetic resonance imaging based systems to assess the biomechanical properties of articular cartilage to provide an early detection of degeneration in tissue integrity. Other work has involved the development and application of imaging and spectroscopic technologies to provide noninvasive assessments in preclinical studies of cardiovascular function and muscle bioenergetics in animal models.

FDA Commissioner's Fellowship Project Overview
Predictive modeling of biomechanical vascular characteristics important for swine-to-human translation of peripheral vascular interventional therapeutics

Biomechanical factors play key roles in the function of the cardiovascular system, from vascular growth to adaptation, disease and treatment outcomes. The combination of imaging and computational technologies has enabled a better understanding of parameters associating biomechanical vascular characteristics and vascular biology which in turn provide new insights to improve on the design, development and regulatory evaluation of cardiovascular interventional therapeutics. The goal of my project is to establish predictive, image-based, computational modeling techniques of vascular characteristics in swine to gain better understanding of site specific implant environments and the ability to establish safety and effectiveness guidelines for preclinical testing and regulatory review of vascular interventional therapeutics.

Nicole M. Mahoney, Ph.D.

Center for Drug Evaluation and Research
Preceptor: Edward Cox, M.D., M.P.H.

Scientific and Professional Background

I joined the FDA Commissioner's Fellowship program after working in the Office of Technology Development at the National Institute for Allergy and Infectious Diseases (NIAID) since 2006. At NIAID, I managed emerging technologies in immunology and parasitic disease by providing patentability and marketability assessments, negotiating clinical trial agreements and facilitating collaborative research and the exchange of resources (equipment, funds, reagents) between NIAID and partners from academia, nonprofit organizations, and industry.

Prior to this, I was an American Association for the Advancement of Science Policy Fellow working in the Office of Legislative and Public Affairs at the National Science Foundation (NSF) (2004 - 2005) and the National Heart Lung and Blood Institute's (NHLBI) Office of Science and Technology (2005 - 2006). At NSF, I communicated agency specific research results and policies to various stakeholders via press releases, newsletters, and legislative testimony. My projects at NHLBI included analyzing the NIH childhood obesity grant portfolio and helping craft a new funding initiative to address research gaps in this field.

I earned my Ph.D. in 1999 from the Albert Einstein College of Medicine where I analyzed the structure and function of profilin—an actin binding protein involved in cell division and motility—using x - ray crystallography and other biophysical techniques. As a postdoctoral fellow at the University of California at San Francisco from 1999 - 2004, I studied centrosome formation and mitosis in cultured cells using RNAi and microscopy.

Research Interests

I am particularly interested in translating basic science discoveries into new medical products and treatments. I have strived to understand the various factors—scientific, economic and policy - related—that influence this process.

FDA Commissioner's Fellowship Project Overview
Trends in Antibacterial Drug Development from 1980-Present

The goal of this project is to conduct a comprehensive review of FDA data, including New Drug Applications and Investigational Drug Applications, in order to examine trends in antibacterial drug development over the last 30 years. The data gathered will allow us to better understand the current status of antibacterial drug development and address important questions in the field. We intend to publish the results of this study as a white paper or manuscript and expect that the insights provided will help inform future antibacterial drug development efforts.

Kosta Makrodimitris, Ph.D.

Office of the Commissioner
Preceptor: John Gardner, M.D., Dr.PH.

Scientific and Professional Background

Dr. Makrodimitris finished his Ph.D. in Europe (National Technical University of Athens, graduate scholarship award by National Centre of Scientific Research Demokritos 2002). His dissertation was on simulations of materials and membranes and he has been awarded the best scientific project by European Membrane Society. Kosta holds a Bachelor and Master of Science degree in Chemistry (University of Athens, 1995) with minors in Food science and diploma in Wine Chemistry. He attended Psychology and Philosophy(Science, Logic, Ethics) at University of Athens. Kosta continued his career as a research associate at University of Virginia and visiting scientist at Johns Hopkins designing simulations of biomolecules in chromatography to optimize processes in drug industry(2003-5). As a research scientist (Johns Hopkins, 2005-7), he described the molecular recognition of salivary proteins in teeth collaborating with Rosetta Commons institutes. He acquired managerial, IT and analytics experience the last years working in industry(Fannie Mae, Sentrana/SYSCO). As entrepreneur (president, cofounder), he led MAKROnanoKosmos, Inc. on web and research projects to educate and inform about nutrition, food safety and bioinformatics (2007-9). He collaborates with Johns Hopkins (Physiology) on qualitative data-driven multiscale methods for biological networks (insulin-diabetes). Kosta has certificates in Business for Scientists (Kellogg Mgmt, 2007), Project Management (PMI, 008) and Competent Communication (TI, 2009).

Research Interests

I have a lifetime goal of contributing to agencies such as the FDA, universities and organizations with missions of promoting and protecting public health, making drugs, devices and foods more effective, safer and affordable and helping the people to get biomedical and health information and knowledge.

FDA Commissioner's Fellowship Project Overview
Regulatory Scientific Systems: Architecture, Intelligence & Analytics in a Global e-Health Network

The goal is to improve the architecture, analytics and intelligence of Regulatory Scientific (RS) systems at FDA in a global electronic medical and health arena, to address the needs about the quality and transparency of reviews and decisions, the efficiency in data access and analytics, the advanced mining of clinical trials and adverse events, the effective comparison and response on safety and efficacy issues, and the availability of electronic scientific information across time and products. The objectives are to: a) *Draw (envision)* the ideal target image for the FDA enterprise RS informatics by linking research, pre- and post-market RS Data, Information, Knowledge and Understanding (DIKU) across time and products, by revealing and promoting the interfaces and health information exchange of FDA with the HHS, other US agencies and healthcare, the Office of the National Coordinator and the National Health Information Network, the bilateral-multilateral collaborations, and the open access, academic networks worldwide. *b) See (evaluate)* the current status of RS-DIKU at FDA and the global e-Health network by collecting, analyzing and presenting their views, architecture, analytics and intelligence in collaboration with subject matter experts and leaders. c) *Think and Plan* a strategic-operational framework and capability maturity model for the FDA RS-DIKU architecture and analytics by establishing metrics, priorities and targets (data model, standards and federation, Health IT policy and adoption, systems principles, comparative effectiveness, competitive analytics, product lifecycle and harmonization).

Malini Mansharamani, Ph.D.

Center for Veterinary Medicine
Preceptor: Larisa Rudenko, Ph.D., D.A.B.T.

Scientific and Professional Background

Johns Hopkins School of Medicine, Postdoctoral Fellowship (Cell Biology); 2007
Texas Tech University Health Sciences Center, TX; Ph.D. (Biomedical Sciences); 2001
University of Pune, India; M.S. (Biotechnology); 1994

Research Interests

With experience in the assessment of biotechnology manufacturing processes for their ability to remove or inactivate viruses or transmissible spongiform encephalopathy agents in biologics derived from mammalian cells, blood and plasma, I am interested in learning more about the FDA regulatory and evaluation process. The goal is to achieve this by focusing on the development of regulations and guidance's for evaluation of genetically engineered animals and their products.

FDA Commissioner's Fellowship Project Overview

Multiple heritable rDNA constructs in a single genetically engineered (GE) animal and the implications for safety assessment of these GE animals

My fellowship project aims to determine the effect of gene stacking in genetically engineered (GE) animals and how the introduction of multiple heritable recombinant DNA constructs in a single animal affects the safety assessment of the health of the animal and the effects on humans and the environment. This corresponds well with my interest in exploring risk assessment methods and participation in policy development while furthering the development of the agency's science-based approaches to the regulation of GE animals containing multiple DNA constructs.

Jose L. Moreno, Ph.D.

Center for Devices and Radiological Health
Preceptor: Aric D. Kaiser, M.S.

Scientific and Professional Background

2006 - 2009	Assistant Professor, University of Maryland, Baltimore, MD.
2004 - 2006	Postdoctoral Fellow II, CVID, University of Maryland, Baltimore, MD.
2002 - 2004	Postdoctoral Fellow II, American Red Cross, Rockville, MD.
1999 - 2002	Postdoctoral Fellow I, American Red Cross, Rockville, MD.
1997 - 1998	Postdoctoral Fellow, University of Iowa, Iowa City, IA.
1996	Ph.D. Cell Biology, University of Navarra, Pamplona, Spain.
1992	B.S. Biology, University of Navarra, Pamplona, Spain.

Research Interests

My training has been focused on the study of the musculoskeletal system and especially the bone tissue. I am especially interested in the mechanisms regulating bone destruction (osteolysis) associated with inflammatory pathologies and in the development and application of new bone grafting materials.

FDA Commissioner's Fellowship Project Overview
Analysis of the standards for clearance and approval of bone void fillers to improve future reviews and applications: Evaluation of the need for new regulatory strategies to assess the impact of emerging technologies on the development of bone void filler devices

Bone grafting is an essential technique in the daily practice of orthopaedics. However, the amount and sources of bone autograft is very limited and the harvesting process results in associated morbidity. Unfortunately the use of bone allograft is hampered by the risk of disease transmission. These limitations have prompted an increasing interest in the generation of alternative synthetic bone void fillers devoid of complications and with an unlimited supply. These devices are generally regulated as Class II medical devices in accordance with the premarket notification (510(k)) regulations.

The first phase of my project consists of the analysis of the existing standards for clearance and approval under the guidance of my Preceptor Mr. Aric Kaiser. My main aim is to analyze the need for revision of the existing guidance document and review practices in order to improve the process. In a second phase of the project, I intend to analyze the need for new regulatory strategies and guidance documents for bone void fillers that, as a result of incorporating emerging technologies in their manufacturing process, acquire new biological properties that may raise new safety and effectiveness questions.

Thilak Kumara Mudalige, Ph.D.

Office of Regulatory Affairs
Preceptor: Sean Linder, Ph.D.

Scientific and Professional Background

Postdoctoral Research Associate (2007-2009) Center for Functional Nanomaterials, Brookhaven National Laboratory
Ph.D. in Chemistry (2007) Western Michigan University
B.S. in Chemistry (2001) University of Colombo

Research Interest

Synthesis and characterization of metallic and semiconductor nanoparticles
Application of bio-molecules such as DNA & protein for ordered assembly of nanoparticles
Method development for the characterization of nanomaterials within complex matrices

FDA Commissioner's Fellowship Project Overview
Development of Characterization Techniques for the Determination and Speciation of Nanosilver in FDA Regulated Products

It has been documented that over one thousand commercially available products contain nanomaterials. Some examples include food packing materials, cosmetics, sunscreens, medical devices, and dietary supplements. FDA is faced with the challenge of regulating products containing nanomaterials, where the isolation and characterization of nanomaterials in complex matrices, can be extremely difficult. Currently I am working on methodologies for the characterization of silver nanoparticles within FDA regulated products. This research utilizes the state of the art nanomaterials characterization capabilities located within the NCTR/ORA Nanotechnology Core Facility.

Olumide Olajide, M.D.

Center for Biologics Evaluation and Research
Preceptor: Donna Przepiorka, M.D., Ph.D.

Scientific and Professional Background

Olumide trained and received his MD degree from the University College Hospital, College of Medicine, University of Ibadan, Nigeria in 1998. While in medical school, he worked on the pharmacological and clinical efficacy of antimalarial drugs with the Institute of Health, a WHO-sponsored program. After graduation, he interned at the Lagos University Teaching Hospital and majored in Oncology and Hematology. He worked as a medical officer of oncology with the hospital where he designed and implemented the system to audit blood products and improved transfusion-related documentations. He joined the Cancer Center, Clinical Trials department of the Johns Hopkins/ Greater Baltimore Medical Center in 2007 where he utilized his knowledge and expertise in oncology, working on gastrointestinal and breast cancers, and clinical trials process, guidelines and compliance.

Research Interests

Having worked in clinical trials, Dr. Olajide has research interests in clinical trials design, monitoring and compliance. He is also interested in tumor vaccines and stem cell research (embryonic and adult) for novel therapies of some hereditary and acquired diseases without a cure.

FDA Commissioner's Fellowship Project Overview
Identification of Safe Starting Doses for Adenoviral Vectors in Phase 1 Clinical Trials

First-in-man studies represent several potential safety concerns that are mitigated in part by preclinical testing. For small molecules, there is extensive literature that supports the conversion of drug dose from animal model to human, ensuring maximal safety in the starting dose and planned dose range. There are currently no available data aggregated for converting doses of biologics in animals to humans. It is therefore difficult to establish starting doses precisely, in terms of anticipated biological effect.

On the basis of the aforementioned, my fellowship project will support the hypothesis which states that a safe starting dose and dosing range for adenoviral-based gene therapy dose in animals should be equal to that in humans when corrected by weight, or volume of organ/lesion for intraorgan or intralesional administration. The project will compare dose-toxicity relationships between animal species in order to establish the best conversion factor which may vary by viral serotype, transgene, viral modification, and route of administration.

Oxana S. Pantchenko

Center for Devices and Radiological Health
Preceptor: Seth Seidman, M.S.

Scientific and Professional Background

Ph.D. Electrical Engineering (with a concentration in Medical Devices)
University of California at Santa Cruz, Expected 2012
M.S. Electrical Engineering, University of California at Santa Cruz, 2008
B.S. Electrical Engineering, University of California at Santa Cruz, 2006

Research Interests

I am interested in building and prototyping medical devices that meet current electromagnetic compatibility standards. I am also interested in analyzing and modeling electromagnetic fields around emitting devices and how they alter function of medical devices on the market. I would like to participate in developing a structured set of test methods for current medical devices, such as implantable pacemakers and defibrillators.

FDA Commissioner's Fellowship Project Overview
Electromagnetic Compatibility between Radio Frequency Identification and Active Medical Devices

At the Food and Drug Administration, Center for Devices and Radiological Health, Office of Science and Engineering Laboratories, I'm currently working on investigating the level of electromagnetic compatibility between Radio Frequency Identification (RFID) Systems and implantable neurostimulators. Also, I'm in the process of developing an RFID simulator for testing at various parameters of RFID technology.

Sunny Park, Ph.D.

National Center for Toxicological Research
Preceptor: Fatemeh Rafii, Ph.D.

Scientific and Professional Background

Commissioner's Fellow, 2009 – present
Division of Microbiology, NCTR
Postdoctoral research fellow, 2005-2009
Channing Laboratory, Brigham and Women's Hospital/Harvard Medical School, Boston, MA
Ph.D. in Microbiology, 2005. University of Illinois at Urbana-Champaign, Urbana, IL

Research Interests

My postdoctoral research has focused on bacterial pathogenesis and host immune response, specifically the role of innate immunity in the Type 1 and Type 2 diabetic host to *Staphylococcus aureus* hindpaw and systemic infection. I have also worked with *Staphylococcus saprophyticus* to characterize structure and function of capsular polysaccharides. My doctoral research was in the field of microbial physiology, focusing on the mechanisms of oxidative DNA damage in *E. coli* and identification of its defense mechanisms against oxidative stress. Additionally, I studied iron metabolism and hydrogen peroxide toxicity and resistance of *Salmonella enterica* serovar Typhimurium and *Streptococcus pneumoniae*. My current interest involves antibiotic resistance of *Clostridium perfringens*.

FDA Commissioner's Fellowship Project Overview
Analysis of gene expression changes associated with fluoroquinolone resistance in two strains of Clostridium perfringens

Understanding the effects of antibiotics on bacteria, particularly the gene mutations associated with antibiotic resistant strains of pathogens, is of the utmost concern to the FDA and public health professionals. The main focus of my project is to evaluate the association between fluoroquinolone resistance selection and virulence of a colonic anaerobic bacterium, *Clostridium perfringens*. The current hypothesis is that fluoroquinolone resistance is associated with alteration in the expression of a variety of genes involved in resistance, virulence, and metabolic activities of *C. perfringens* and that this alteration is strain specific. I plan 1) to profile genes in two different *C. perfringens* strains, in which transcription has been altered as the result of fluoroquinolone resistance selection, and 2) to investigate regulation of the genes for toxins and other virulence factors in these *C. perfringens* strains. The result of the study will provide insight into the effects that fluoroquinolone resistance may have on multiple cellular functions that affect virulence, survival and growth of *C. perfringens.* This information will be valuable for understanding the reason for the emergence and recurrence of more virulent strains of some clostridia after treatment with certain fluoroquinolones.

Erika Pfeiler, Ph.D.

Center for Food Safety and Applied Nutrition
Preceptor: Dan Levy, Ph.D.

Scientific and Professional Background

North Carolina State University, 2009 - Ph.D., Functional Genomics
The University of Tennessee, 2004 - B.S.

Research Interests

Members of genus *Lactobacillus* are a diverse group of microorganisms that are useful to humans in a variety of ways. Their ability to produce lactic acid as a primary metabolic byproduct makes them useful in dairy, meat, cereal, and vegetable fermentations. In recent years, many lactobacilli have gained attention for their potential as probiotics (defined by the World Health Organization as 'live microorganisms, that, when administered in adequate amounts confer a health benefit on the host'). The interaction of these species with the human gastrointestinal tract is currently the subject of much research. My research interests involve using functional genomics techniques to analyze how lactobacilli interact with their environment. I completed my dissertation research on the genomic basis of bile tolerance in *Lactobacillus acidophilus* NCFM, a strain that is considered to be a probiotic, and is found in a number of yogurts and dietary supplements. While in the commissioner's fellowship program, I will participate in regulatory decisions involving new probiotic strains, as well as research on probiotic and commensal species.

FDA Commissioner's Fellowship Project Overview
Use of genomic and culture based techniques to define parameters for the safety assessment of probiotic microorganisms

Foods and dietary supplements live microorganisms are increasing in popularity among consumers. Safety assessments of live microorganisms for human consumption examine a number of criteria, including virulence potential, toxin production, antibiotic resistance, and retention of the strain in the gastrointestinal tract. Despite numerous studies to examine phenotypic characteristics of these strains, there is limited experimental evidence with which to define parameters for the appropriate safety assessments of these microorganisms. The goal of this project is to utilize genomic and culture-based techniques to experimentally define parameters for the safety assessments of live microbial ingredients through three distinct objectives:

1) Identification of gene mutations in strains exhibiting high levels of antibiotic resistance and development of a protocol to identify similar mutations in other strains; 2) Examination of the potential for transfer of antibiotic resistance genes from a live microbial ingredient; 3) Assessment of the effects of gastrointestinal passage on molecular strain typing methods for live microbial ingredients.

Bi-Feng Qian, M.D., Ph.D.

Center for Food Safety and Applied Nutrition
Preceptor: MaryAnn Principato, Ph.D.

Scientific and Professional Background

BiFeng Qian obtained her MD degree from Southeast University Medical College in China and completed six years of clinical training in internal medicine and gastroenterology. She next pursued a strong research interest in the field of immunology and earned a Ph.D. in Medicine/Immunology from Umeå University in Sweden. Her post-doctoral immunology-based research was performed at the Department of Medicine, University of North Carolina at Chapel Hill followed by research at the Oral Infection and Immunity Branch, NIDCR at the NIH.

Research Interests

BiFeng Qian's interests lie in the pathogenesis of inflammatory and mucosal diseases, including allergen-induced airway inflammation (asthma) and commensal bacteria-induced intestinal inflammation (ulcerative colitis and Crohn's disease). She has designed and performed both *in vitro* and *in vivo* studies utilizing a variety of animal models of autoimmune and inflammatory diseases, and her expertise includes a broad range of molecular biological and immunological techniques.

FDA Commissioner's Fellowship Project Overview

Development of new biomarkers for staphylococcal enterotoxin B (SEB) contamination in foods: in vivo analyses of the superantigenic activity following ingestion of native and thermally-processed SEB in gut associated lymphoid tissues

BiFeng Qian's research effort at CFSAN, in the FDA will focus on Staphylococcal enterotoxin B (SEB) as a superantigen and food contaminant. She will be involved in studying the basic cellular and molecular events triggered following ingestion of the superantigen and the consequences of this exposure upon health and autoimmunity induction. In particular, BiFeng Qian will work to develop a complementary approach to existing projects for the analysis of SEB-induced T cell receptor-mediated signaling cascades and the superantigen-induced gene expression patterns in the mammalian immune system. The molecular and cellular biomarker data obtained in her study will be assessed for its value as indicator of SEB contamination in foods.

Chad Reiter, Ph.D.

Center for Biologics and Evaluation Research
Preceptor: Abdu I. Alayash, Ph.D.

Scientific and Professional Background

2005 - 2009		Post-Doctoral Fellowship	Diabetes Unit, National Center for Complementary and Alternative Medicine (NCCAM), NIH, Bethesda, MD
2004	Ph.D.	Physiology	Penn State University College of Medicine, Hershey, PA
1998	B.S.	Biochemistry	North Central College, Naperville, IL

Research Interests

My research interests are in metabolic disorders such as diabetes, obesity, and endothelial dysfunction, and the development of novel therapies to treat them. Under the Richter Fellowship Program, my first research experience as an undergraduate student examined beta-cell mass dynamics in diabetic animal models. My doctoral work centered on understanding the insulin receptor signaling pathway in retina tissue and the development of utilizing pro-survival growth factors to treat the eye and inhibit neurodegeneration that occurs in diabetic retinopathy. As a post-doctoral fellow, I studied the gene regulation and cell signaling effects of the green tea polyphenol, EGCG, on endothelium to better understand its beneficial effects on cardiovascular health.

FDA Commissioner's Fellowship Project Overview
Molecular mechanisms of HIF-1α control as a biomarker of tissue oxygenation

A sensor of tissue oxygenation is the transcription factor hypoxia-inducible factor (HIF)-1α, which binds DNA to initiate a genetic program to counteract insufficient oxygen delivery to cells. Hemoglobin-based oxygen carriers (HBOCs) are utilized for treatment of traumatic blood loss or anemia. However, whether HBOCs deliver sufficient oxygen remains a critical issue. Suppression of HIF pathway activation occurs following oxygen delivery by HBOCs or red blood cells; therefore, oxygen transport and sensing mechanisms are amenable for manipulation to optimize tissue oxygenation in ischemic diseases. The induction and/or stabilization of HIF-1α under normoxic conditions also has the potential to enhance HBOC therapy, treat blood disorders, or improve adaptation to high altitude. Thus, the overall goals of this proposal are to gain a greater understanding of mechanisms involved in HIF-1α-driven gene expression and to develop HIF-1α expression as an oxygen biomarker to improve HBOC function and analyze hemoglobin allosteric control mechanisms.

Kareen Riviere, Ph.D.

Center for Drug Evaluation and Research
Preceptor: John Z. Duan, Ph.D.

Scientific and Professional Background

2004 - 2009 Ph.D. Pharmaceutical Sciences and Pharmacogenomics
University of California, San Francisco

1999 - 2003 B.S. in Chemical Engineering
Brown University

Research Interests

My doctoral research focused on investigating the enhancement of anti-cancer drug synergism by co-delivery via targeted liposomes. I am interested in drug discovery, development & delivery, nanotechnology and public health. I am passionate about facilitating the development and regulatory approval of novel, safe, and effective therapies for unmet medical needs.

FDA Commissioner's Fellowship Project Overview

Evaluation and Enhancement of Quality by Design Approaches from a Biopharmaceutics Perspective

Since the institution of the Quality by Design (QbD) initiative, it has been challenging for industry to implement QbD approaches to drug manufacturing due to lack of understanding and successful examples of applying this new concept. Particularly, there is limited comprehensive understanding of how the design and manufacturing of a product affects its clinical quality. The objectives of my research are to: 1) provide examples of applications of QbD approaches; 2) evaluate and establish various methods to link manufacturing attributes to clinical performance under a QbD context; 3) promote implementation of QbD approaches by industry; and 4) facilitate regulatory review and evaluation of QbD submissions. This research project will significantly contribute to FDA's Critical Path Initiative and 21st Century Quality Initiatives.

Rajasri Roy, Ph.D., M.P.H.

Center for Drug Evaluation and Research
Preceptor: M. James Hung, Ph.D.

Scientific and Professional Background

Before joining the FDA Commissioner's Fellows Class of 2009, Dr. Rajasri Roy was working as an Epidemiologist in the Department of Defense-Patient Safety Center (DoD-PSC), Silver Spring, MD, since 2003. After finishing her Master's degree in Public Health Sciences (2001-2003) from George Washington University, Washington DC, she joined the DoD-PSC. In this position she continuously served in reviewing, analyzing, and deploying various research projects related to error reporting systems of medication and medication safety, laboratory and radiology, as well as errors in medical and patient safety reporting systems of the military health population of the United States-Department of Defense (US-DoD). In the US-DoD, Dr. Roy developed taxonomies of error causation; trends of patient care errors, and addressed the integrated processes for how to minimize adverse events and errors or how to take corrective actions by the respective US military facilities for enhancing patient safety.

Dr. Roy received her Ph.D. degree in Behavioral Psychology (1990-1994) from the University of Calcutta Science and Technology, India, and her Master's Degree (1988-1990) in Applied Psychology from Calcutta University, India. Before coming to the state of Maryland, Dr. Roy briefly worked as a fellow in the Psychiatric Division of the Memorial Sloan-Kettering Hospital, NY. In the initial phase of her stay in Maryland she also worked as a data base manager for the Food and Drug Administration. During her MPH studies she also worked as a part-time grant coordinator for the Center for Scientific Review, National Institutes of Health.

Research Interests

Dr. Roy was attracted to a career in serving the general public through epidemiological surveillance systems to improve the health of all. She enjoys the experiences in addressing various adverse events in public health reporting systems, analyzing disease surveillance systems, and improving active safety surveillance programs for serious medical adverse events. Her future goals include the development of survey materials for the change in behavioral health related to medication, as well as advancements of measurable parameters of regulatory requirements into achievable program interest. Dr. Roy's long-term career goal is to participate, develop, and promote adverse event reporting systems that encourage health institutions and health practitioners to report all sorts of adverse events in care giving systems more often.

FDA Commissioner's Fellowship Project Overview
Evaluating the Risk of Weight Gains Associated with Exposure to Antidepressant Medications

Many studies in literature seem to have indicated that patients experience undesirable adverse effects during their treatment of major depressive disorder. My project aims to investigate the relationship between antidepressant use among individuals and increased weight gain, and to identify key baseline covariates and potential prognostic variables, such as gender, age and race. This study will assess the relationship between use of medication due to depression and possible adverse effect such as weight gain at any time of the study time period and sustained weight gain at the end point. The data on antidepressant use and its adverse side effects are to be derived from the double blind randomized placebo controlled clinical trials data submitted by the pharmaceutical industries to FDA electronic document room. The results of this analysis may help it predict the probability of weight gain associated with drug dose(s) when it is used for treatment of depressive symptoms.

Sami Sarfaraz, Ph.D.

National Center for Toxicological Research
Preceptor: Igor Pogribny, M.D., Ph.D.

Scientific and Professional Background

2009 - Present	FDA Commissioner's Fellow, Division of Biochemical Toxicology, FDA-National Center for Toxicological Research, Jefferson, AR.
2008 - 2009	Cancer Research Training Award (CRTA Fellow), National Cancer Institute (NCI/NIH), Bethesda, MD
2003 - 2008	Assistant Researcher, University of Wisconsin, Madison, WI
2003	Consultant, United Nations Children's Fund (UNICEF) Patna, India
2002	Ph.D., Kanpur University, Kanpur, India
1996	MS., Lucknow University, Lucknow, India

Research Interests

I am interested in the area of cancer and tumor biology focusing on the development of novel therapeutic strategies against cancer. I have worked with various in vivo cancer models like transgenic adenocarcinoma of mouse prostate (TRAMP), Nude mice, SENCAR mice, SKH-1 hairless mice and have experience in the area of cell culture, immunohistochemistry, immunocytochemistry, molecular biology, radioactive isotopes. I have also worked at the National Cancer Institute, NIH on characterization and isolation of lung cancer stem cells from tumors samples obtained from patients after surgery to support drug testing and clinical development of lung cancer stem cell directed therapies. My research interest at FDA is to understand the science behind regulation in combination with my scientific expertise to ensure safe and efficacious products are available to the public.

FDA Commissioner's Fellowship Project Overview
Role of genetic and epigenetic changes in acrylamide and glycidamide-induced lung carcinogenesis in mice

Acrylamide, a probable human carcinogen formed during high-temperature cooking of many commonly consumed foods, poses a significant danger to human health. The results of epidemiological studies have demonstrated positive associations between dietary acrylamide intake and the risk of several major human cancers. Acrylamide is metabolized *in vivo* to the epoxide, glycidamide. It is widely believed that carcinogenicity of acrylamide is due to its metabolism to glycidamide, which reacts with DNA resulting in formation of DNA adducts. The goal of this study is to elucidate the role of genetic and epigenetic events in acrylamide and glycidamide carcinogenicity and create new approaches and tools, termed epigenetic biomarkers, that can be used for early detection of tumorigenesis and carcinogenicity testing. We anticipate that the U.S. FDA will ultimately be able to incorporate the knowledge gained from this study into guidelines that consider the impact of epigenetic changes in evaluating susceptibility to human diseases, including cancer.

Camille Vidal, Ph.D.

Center for Devices and Radiological Health
Preceptor: Frank W. Samuelson, Ph.D.

Scientific and Professional Background

Post-Doctoral Fellow, Biomedical Engineering, Johns Hopkins University, 2008-2009
Ph.D. Applied Mathematics, Université des Sciences et Technologies de Lille, France, 2008
M.S. Applied Statistics, AgroParisTech, France 2004
B.S. Bioengineering, AgroParisTech, France 2003

Research Interests

My research combines developing efficient algorithms to automatically extract meaningful information from complex data and developing statistical methods to analyze this information for the detection and analysis of disease. I have worked on computational methods for pattern recognition and image matching. I have built a system for detecting anatomical landmarks in brain MR images to analyze the structural variability of the brain. More recently, I have been involved in the development of a system to quantitatively assess the evolution of *M. Tuberculosis* induced inflammation *in vivo* in a longitudinal study, combining anatomical information from CT scans with functional images (PET, SPECT).

FDA Commissioner's Fellowship Project Overview
Controlling the Bias due to the Reuse of Testing Data in the Evaluation of Computer-Assisted-Diagnostic Devices

Computer-Assisted Diagnostic (CAD) devices rely on mathematical functions that analyze image patterns and classify normal from abnormal findings. The level of accuracy of CAD devices is usually assessed on a testing set of images that were not used for developing the device. It is frequent that, after receiving approval for an initial version, a sponsor seeks approval for successive versions of the device. Since it is time-consuming and costly to assemble an independent testing set for each submission, the new versions of the device are usually tested on the same testing set as the initial device. However, such repeated use of a single testing set introduces a positive bias in performance evaluation, which may lead, if disregarded at the time of review, to the approval of devices whose performance is overestimated. Although, it is certainly acceptable to use a large testing set a few times, it is not known how many times it may be reused before bias becomes significant. The purpose of our research is to investigate different methods to mitigate the bias due to the reuse of testing data by replacing parts of the testing set each time it is used. We are also working on adequate testing procedures to compare the performance of several versions of a device while minimizing the bias due to the partial reuse of data.

Joy Waite, Ph.D.

Office of Regulatory Affairs
Preceptor: Ken J. Yoshitomi, Ph.D.

Scientific and Professional Background

Post-doc Researcher, 2008-2009 - The Ohio State University, Department of Food Science
Ph.D., 2007, Food Science and Nutrition - The Ohio State University
M.S., 2004, Microbiology - Oregon State University, Department of Microbiology
B.S., 2002, Food Science and Technology - Oregon State University, Department of Food Science and Technology

Research Interests

I have been trained as a food microbiologist with my research predominantly focused on methods to inactivate foodborne spoilage and pathogenic microorganisms using non-thermal technologies, with particular emphasis on high pressure processing. I have also been working on comparing, adapting, and designing protocols for the identification and/or enumeration of specific microorganisms in food products for instructional purposes in a classroom laboratory setting. On this angle, I am interested in developing new approaches for efficacious detection of foodborne pathogens in commercial food products.

FDA Commissioner's Fellowship Project Overview
Rapid detection of foodborne pathogens in fresh produce

Recent large-scale foodborne disease outbreaks associated with fresh produce have highlighted the need for improved testing protocols to rapidly identify microbiological hazards that pose a health risk to the consumer. Large quantities of fresh produce are imported and these products require rapid analysis to minimize product losses before they are released for distribution in the United States. My research will focus on the continued development, evaluation, and improvement of rapid, cost-effective, and sensitive detection methods of pathogens in food products. The specific focus of my fellowship project is to develop high-throughput DNA extraction and Real-Time Multiplex PCR protocols to screen enrichment cultures for Shiga-toxin producing *Escherichia coli* for use in the FDA mobile laboratories. Once developed and validated in the laboratory, microbiology analysts will be trained to use these protocols in the mobile laboratory in addition to fixed field laboratory locations.

Honggang Wang, M.D., Ph.D.

National Center for Toxicological Research
Preceptor: Beverly Lyn-Cook, Ph.D.

Scientific and Professional Background

Research Scientist, Department of Medicine, University of Washington 2009
Research Associate, Department of Pharmaceutics, University of Washington, 2003 - 2009
Fellow, Department of Endocrinology, Metabolism and Nephrology, Kochi Medical School, Kochi University, Kochi, Japan, Ph.D. 1998 - 2003
Fellow, Department of Nephrology, Juntendo University, Tokyo, Japan 1992 - 1993
Physician, Department of Nephrology, Medical School Hospital, Qingdao University, Qingdao, China, 1986-98
School of Medicine, Qingdao University, Qingdao, China, M.D., 1986

Research Interests

My career began as a physician in China for twelve years. I performed several clinical and basic medical research projects in Japan during my Ph.D. training. Recently, my research has focused on an ATP-binding cassette membrane transporter, breast cancer resistance protein (BCRP). BCRP plays a significant role in drug disposition and in conferring multidrug resistance in cancer cells. Recent studies support the notion that BCRP plays a significant role in the placental-to-maternal transport of drugs. My in vivo work demonstrated that expression of BCRP in the various tissues is altered by pregnancy. My in vitro data suggested that the pregnancy-related hormones regulate BCRP expression during pregnancy. I also elucidated some mechanism by which pregnancy related hormones regulate BCRP expression. My research interest at the FDA is to understand the effect of polymorphism of drug transporters in chemoresistance and chemosensitivity. Recently, I passed the United States Medical Licensing Examination (USMLE). It is my hope that both my medical knowledge and research experience can be applied to facilitate the implementation of personalized medicine in patient care.

FDA Commissioner's Fellowship Project Overview
Genotyping human equilibrative nucleoside transporter 1 (hENT1) polymorphisms in normal and pancreatic cancer tissues: Assessing gemcitabine and the role of indole-3-carbinol in chemosensitivity and chemoresistance in pancreatic cancer

Improving the effectiveness of cancer drug treatment continues to be a worldwide challenge. In recent years, gemcitbine has become the first line drug for patients with pancreatic cancer. However, a substantial number of patients fail to respond to therapy due to gemcitabine resistance. Gemcitabine is transported into cells mainly by a transporter protein located at cell membrane called the human equilibrative nucleoside transporter 1 (hENT1). It has been reported that variations in hENT1 gene play a critical role in the adsorption distribution, metabolism and elimination of numerous drugs. Therefore, variations in hENT1 gene may also profoundly affect effectiveness and safety of gemcitabine. During this fellowship program, the influence of genetic variations on hENT1 gene expression, protein function, and gemcitabine chemosensitivity will be investigated. This study may provide new genetic biomarkers to predict pancreatic cancer patient's responses to gemcitabine. Indole-3-carbinol (I3C), a naturally occurring component of cruciferous vegetables, has shown a number of anti-cancer properties in experimental studies. Additional studies will be conducted to determine whether the use of indole-3-carbinol can enhance the efficacy and safety of gemcitabine in pancreatic cancer therapy.

Brooke Whitney, Ph.D.

Center for Veterinary Medicine
Preceptor: Ruby Singh, Ph.D.

Scientific and Professional Background

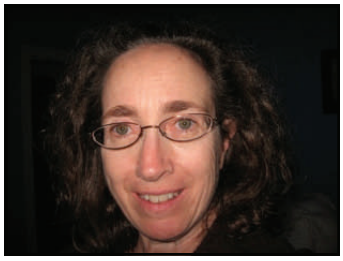
Doctorate of Philosophy, Food Science, September 2009
Minor: Biotechnology
North Carolina State University, Raleigh, NC
Center for Veterinary Medicine
Laurel, MD, May 2007-August 2007
Master of Science, Food Science and Technology, July 2005
Virginia Tech, Blacksburg , VA
Bachelor of Science, Biochemistry and Biology, Biotechnology option, May 2003
Minor: Chemistry
Virginia Tech, Blacksburg, VA
Internship, Dr. David White and Dr. Heather Harbottle, US FDA

Research Interests

Brooke's research interests are focused on food safety. Previous research endeavors have focused on *Vibrio* spp. in Gulf Coast Oysters as well as *Salmonella* and *E. coli* O157:H7 in unpasteurized fruit juices. During her Ph.D. studies, Brooke had the opportunity to work at the FDA Center for Veterinary Medicine. While there, she designed DNA microarray probes to characterize strains isolated through the National Antimicrobial Resistance Monitoring System (NARMS).

FDA Commissioner's Fellowship Project Overview
Macrolide Use in Food Animals: Implications on Human Health

Antimicrobial agents are used in food-producing animals for treatment, control, and prevention of diseases, as well as at non-therapeutic levels for production purposes (e.g., improved feed efficiency and increased weight gain). In recent years, public awareness of antimicrobial resistance has increased with particular regard to uses in food-producing animals. To address public concerns over antimicrobial resistance in food-producing animals, congress appropriated funds to the FDA's Center for Veterinary Medicine (CVM) in 2001. Currently, CVM is reviewing previously approved antimicrobial products to assess their safety in light of increasing scientific evidence of antimicrobial resistance in agriculture. Of particular concern is the use of antimicrobials at low doses in food-producing animals for prolonged periods of time as this affords selective pressure, allowing resistance to mount within reservoir animals. This project focuses on the macrolide class of antimicrobials, which the World Health Organization (WHO) has identified as "critically important" in human health. Specific aims of this project are to develop a comprehensive review manuscript on non-therapeutic uses of macrolides in animals and its impact on human health, develop a user-friendly chart of approved uses and dosage of macrolides in food-producing animals and participate in the review process of currently approved macrolide antimicrobials drugs for non-therapeutic uses.



Beverly Wolpert, Ph.D.

Center for Food Safety and Applied Nutrition
Preceptor: Debra A. Street, Ph.D., M.P.H

Scientific and Professional Background

Ph.D. (2009) & M.S. (2009), Epidemiology & Preventive Medicine, University of Maryland, Baltimore, School of Medicine

M.S. (2003), Biological Sciences, George Washington University, Washington, DC

B.A. (1980), English Language & Literature, University of Virginia, Charlottesville, VA

Research Interests

My research interests include the effects of foods and supplements on human health. I look forward to applying the appropriate analysis methods to the data that the CFSAN collects by electronic and paper channels from consumers, producers, and health care providers, as well as other groups and individuals, to characterize adverse events.

FDA Commissioner's Fellowship Project Overview

Characterization of CFSAN Adverse Events Reporting System (CAERS) energy drink data, 2004-2009

US energy drink (ED) consumption has risen consistently over the past 5 years, with annual sales surpassing $2 billion in 2005 and projected at >$9 billion by 2011. Acute and chronic effects of caffeine and other energy drink ingredients alone and in combination are not well understood, and this knowledge gap has prompted concern over potential risks to public health. My research project involves characterizing 2004 to 2009 adverse event (AE) and ED data from the Center for Food Safety and Nutrition Adverse Events Reporting System (CAERS), including establishing working definitions and categories of EDs to be used for descriptive analysis and then refined in subsequent analyses, as well as applying appropriate epidemiologic methods to test the hypothesis that the data indicate significant variation in AEs by ED category and to assess whether or not any of the ED categories pose greater risk than others.

Wenge (Walter) Xie, Ph.D.

Center for Veterinary Medicine
Preceptor: Raafat Maher Fahmy, Ph.D.

Scientific and Professional Background

Organic Chemist, Senior Staff Scientist, Project Leader and Project Manager
Eli Lilly, Memory Pharmaceuticals and Progenics Pharmaceuticals
Post-Doctoral Research Fellow
University of Illinois at Chicago, and Georgia Institute of Technology
Joint Ph.D. in Synthetic Organic Chemistry, 1994
Lanzhou University and Shanghai Institute of Organic Chemistry, P.R. of China
B.S. and M.S. in Organic Chemistry, 1988 and 1991
Lanzhou University, P.R. of China

Research Interests

CNS, anti-virus and oncology drug research and discovery.
Medicinal chemistry and CMC regulatory science, parameters and reviews.

FDA Commissioner's Fellowship Project Overview
Implementation of QbD (Quality by Design)in Pharmaceutical Development: Putting Principles into Practice

The program will help me to explore a specific aspect of FDA regulatory science, and an in-depth understanding of the science behind regulatory review, public policy, FDA law. My fellowship project will develop and practice the conceptual Quality by Design (QbD) approach in the pre-formulation, formulation, manufacturing process and the analytical method development. Also, I will explore how to define variables and critical manufacturing parameters and how to monitor and control them. The expectation of this project: to get fully scientific understanding of all Critical Quality Attributes, to develop Design Space methodology, and process controlling, to implement QbD from principle into practice with more clear definitions and flexible regulatory guidance.

Markus Yap, Ph.D.

Office of the Commissioner
Preceptor: John W. Gardner, M.D., Dr. PH.

Scientific and Professional Background

M.P.H. Global Health, Harvard 2011 (expected)
Ph.D. Bioengineering, University of Illinois at Chicago 2006
M.B.A. Finance, Marketing and Health Administration & Policy, Univ. of Chicago 2005
M.S. Electrical Engineering, Caltech 1992
A.B. Chemistry, Occidental College 2003

Life Sciences Strategy Management Consultant 2002-2009
- Senior Consultant - Arthur D. Little, Boston MA
- Associate - PRTM Management Consultants, Chicago ILS
- Independent Consultant – Sole Proprietorships, Chicago IL

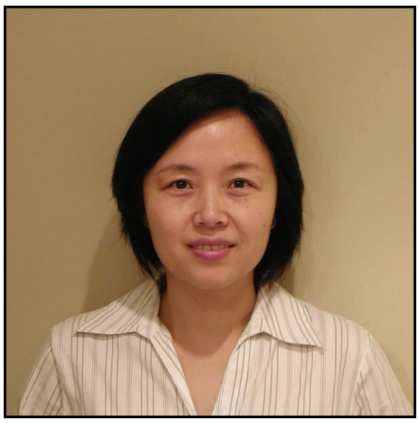
Marketing and R&D Professional, Medical Device Industry 1994 – 2002
- Market Manager - Smith & Nephew Endoscopy, Andover MA
- Global Product Manager - G.E. Healthcare, Mount Prospect IL
- Fellow in Endo-Surgery Engineering - Duke University, Durham NC
- Project Manager – Stryker Endoscopy, Santa Clara CA
- Research Engineer – Conductus, Sunnyvale CA

Research Interests

Application of data mining and visualization tools to facilitate better clinical and business decisions for FDA reviewers and industry submitters working with FDA's clinical trial databases and Venture Capital for Global Health social entrepreneurship – development and distribution of low-cost medical devices in underdeveloped regions.

FDA Commissioner's Fellowship Project Overview
Visual Analytics and Business Intelligence for New Medical Product Application Reviewers

My project aims to evaluate and demonstrate user-friendly, workflow-oriented and customizable graphical visualization software tools for reviewing and data-mining clinical data residing in FDA databases.



Christine F. Yu, M.D.

Center for Food Safety and Applied Nutrition
Preceptor: Michael Kulka, Ph.D.

Scientific and Professional Background

Lentiviral Gene Therapy, Virxsys Corporation (2008 – 2009)
HIV Drug Discovery and Development, Gilead Sciences Inc. (2000 – 2005)
Cancer Genomics, Chiron Corporation (1999 – 2000)
M.S. in Biochemistry and Virology, Cornell University (1999)
M.D., Peking Union Medical College, China (1995)

Research Interests

My research interests are mainly focused on viruses. I worked on retroviral assembly and morphogenesis during my graduate studies. My industry experiences included five years on developing HIV‐1 Integrase inhibitors. Most recently, I was part of a team to develop safe and efficient HIV‐ and SIV‐based lentiviral vectors for clinical applications of gene therapy and vaccines. Working in biotech industry has exposed me to a variety of novel technologies in drug development and other fields. My areas of expertise include molecular biology, cell biology, and virology.

FDA Commissioner's Fellowship Project Overview
The Role of OAS3 in the Activation of the 2-5OAS/RNase L Pathway during HAV/18f Infection

One of the major obstacles in detecting infectious viruses isolated from food matrices is the lack of effective culture methods. My project will investigate certain cellular genes that govern the restricted growth and phenotype of wild-type and mutant hepatitis A virus (HAV) strains in selected cell lines. Relevant cell signaling pathways will be explored, and knowledge gained from this project will ultimately facilitate the development of sensitive and efficient detection methods for HAV as a foodborne contaminant.

Hui (Helen) Zheng, Ph.D.

Center for Drug Evaluation and Research
Preceptor: Jogarao V. S. Gobburu, Ph.D.

Scientific and Professional Background

Ph.D. in Pharmaceutical Science, Ohio State University, 2004

Seven years of pharmaceutical industrial experience in supporting pharmacokinetics, pharmacodynamics, toxicokinetics and metabolism studies in drug discovery and clinical development.

Research Interests

Both my educational and professional experience has equipped me with in-depth working knowledge in clinical pharmacokinetics. The therapeutic areas I had worked include diabetes, obesity, neuroscience, and oncology. My current research interests involve application of modeling and simulation strategy in clinical trial design. Through this fellowship training, I hope to gain invaluable knowledge and new perspective in drug discovery and development.

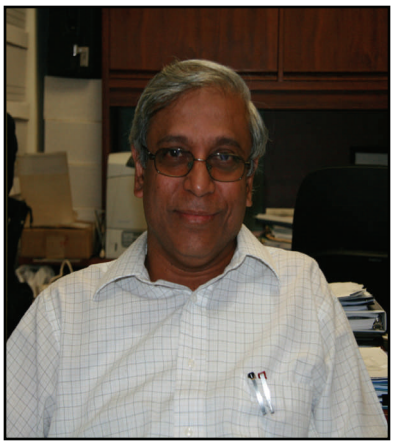
FDA Commissioner's Fellowship Project Overview

Application of Pharmacometrics in Drug Safety Evaluation and Dose Optimization

My current research interests involve application of modeling and simulation strategy in clinical trial design. Examples include dose optimization for special population, exposure-response relationship in support of effectiveness. The specific aim of this project is to apply pharmacometrics analysis in various case studies with the goal to better understand the utility and impact of this approach in regulatory decision making.

FDA Commissioner's Fellowship Program

2009 Preceptors



Pradip Akolkar, Ph.D.

Division of Emerging and Transfusion Transmitted Diseases
Officer of Blood Research and Review
Center for Biologics Research and Evaluation

Fellow: Bharat Khurana, D.V.M., Ph.D.

Scientific and Professional Background

Ph.D., M.S. University of Baroda, Baroda, India
M.Sc., M.S. University of Baroda, Baroda, India
B.Sc., M.S. University of Baroda, Baroda, India

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.

Abdu I. Alayash, Ph.D.

Principle Investigator and
Chief of Laboratory of Biochemistry and Vascular Biology
Division of Hematology,
Office of Blood Research and Review,
Center for Biologics Evaluation and Research

Fellow: Chad Reiter, Ph.D.

Scientific and Professional Background

Ph.D., Essex University, Essex, England
B.S., Baghdad University, Iraq

Research Interests

Hemoglobin-based oxygen carriers (HBOCs), also referred to as "blood substitutes," have the potential to reduce need for blood transfusion and to deliver oxygen; however, they have shown evidence of toxicity. Improved in vitro and in vivo biomarkers to better predict and monitor toxicity is the focus of our ongoing research. Such biomarkers could enhance the potential for safe use of these investigational products in clinical trials.

Uma Babu, Ph.D.

Immunobiology Branch
Division of Virulence Assessment
Center for Food Safety and Applied Nutrition

Fellow: Kannan Balan, Ph.D.

Scientific and Professional Background

Ph.D. from University of Maryland
Worked at FDA since 1991

Research Interests

Several food-borne pathogens cause infectious illnesses for which the immunobiology is not completely understood. These pathogens may modify functions of different immune cells, which may include secretion of inflammatory or immune cytokines or other bio-markers. The purpose of our studies is to examine the role of immunomdulators and other factors, including several commonly consumed nutrients on the immune responses and clearance of food-borne pathogens by animal tissues (in vivo) or cells (in vitro). Some of these interventions may alter colonization of animal tissues or cellular infection and clearance of pathogens. These studies will help find appropriate models for different pathogens.

Richard Beger, Ph.D.

Branch Chief, Center for Metabolomics
Division of Systems Toxicology
National Center for Toxicological Research

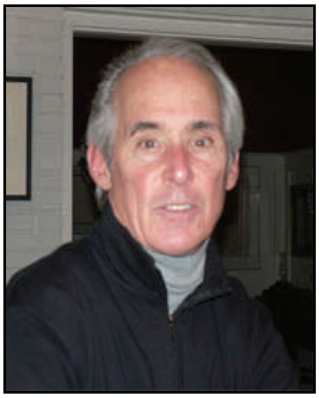
Fellow: Sudeepa Bhattcharyya, Ph.D.

Scientific and Professional Background

Ph.D. Purdue university
M.S. Marquette University
FDA - 10 years

Research Interests

The Center for Metabolomics focuses on FDA Critical Path research to develop translational metabolic biomarkers of disease, toxicity, and susceptibility. The metabolomic facility uses state of the art NMR, LC/MS, and GC/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 Metabolomics center has a Waters UPLC-Qtof Premier mass spectrometer system that will evaluate metabolites in biosamples from toxicity and personalized medicine studies and an Agilent GC mass spectrometer system that will be used to evaluate metabolic fluxes from fully 13C labeled glucose and palmitic acid in biofluid and tissue samples from toxicity and personalized medicine studies. The metabolomics group is focused on the development of translational metabolic biomarkers of toxicity, susceptibility, and health status. Metabolomics technology is readily applicable to cross-species comparisons and for both preclinical and clinical studies.



Frederick A. Beland, Ph.D.

Division of Biochemical Toxicology
National Center for Toxicological Research

Fellow: Sami Sarfaraz, Ph.D.

Scientific and Professional Background

Ph.D., Montana Sate University
M.S., Montana Sate University
B.A., Colorado College
FDA Experience - 33 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.

John F. Bowyer, Ph.D.

Research Pharmacologist
Division of Neurotoxicology
National Center for Toxicological Research

Fellow: Mark Levi, Ph.D.

Scientific and Professional Background

FDA Experience - 26 years

Research Interests

My research over the past ten years has had a primary focus on the investigation of the molecular mechanisms (gene expression) involved in neurotoxic insults, particularly amphetamine and substituted amphetamines, and the recovery from such insults. Amphetamines are a good model to study the physiological and molecular mechanisms behind neurotoxicity because they can affect multiple neurotransmitter systems and regions of the brain without producing widespread non-specific necrosis. As well, a long-term recovery process occurs which can be investigated using molecular biology tools. The development of these techniques has allowed me to apply them to other types of potential neurotoxic insults (evaluating acrylamide as a neurotoxin, e.g.).

Gilbert J. Burckart, Pharm.D.

Associate Director for Regulatory Policy
Office of Clinical Pharmacology
Office of Translational Science
Center for Drug Evaluation and Research

Fellow: Dionna Green, M.D.

Scientific and Professional Background

FDA Experience - 2 years

Research Interests

Gil Burckart is presently Associate Director for Regulatory Policy, Office of Clinical Pharmacology, U.S. Food and Drug Administration. Dr. Burckart received his Pharm.D. from the University of Kentucky in 1975, and did his pediatric residency at UK in Lexington and Norton Children's Hospital in Louisville. He served on the faculties of the State University of New York at Buffalo at Buffalo Children's Hospital, and the University of Tennessee at LeBonheur Children's Hospital before joining the faculty at the University of Pittsburgh in 1982. He was at the University of Pittsburgh and the Pittsburgh Children's Hospital from 1982 to 2002 where his research focused on drug therapy in organ transplant patients. He has been Principle Investigator on NIH grants in both liver and lung transplantation. At Pitt, he was a Professor of Pharmacy, Pediatrics and Surgery, and served as Director of Research for the Division of Cardiothoracic Surgery.

In 2003, he moved to the University of Southern California in Los Angeles, where he was Director of the Clinical Pharmacogenomics Laboratory, Professor of Pharmacy and Professor of Pediatrics. He was also an investigator at the Children's Hospital of Los Angeles.

Dr. Burckart has previously served as the President of the American College of Clinical Pharmacy, and as President of the American College of Clinical Pharmacology.

Dr. Burckart moved to the US FDA in February of 2008. His duties include membership on the FDA's Pediatric Review Committee, and direction of the pediatric group within the Office of Clinical Pharmacology.

Alberto Chiesa, D.V.M., Ph.D.

Laboratory of Cardiovascular and Interventional Therapeutics
Division of Biology
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Fellows: Mark Kreitz, Ph.D. and Orlando Lopez, Ph.D.

Scientific and Professional Background

D.V.M., Buenos Aires, Argentina
Ph.D., Universidad Autonoma de Barcelona, Spain
M.S., Universidad Autonoma de Barcelona, Spain

Research Interests

Image-guided interventions represent a major component of therapeutic technologies available to the clinical community with new developments having greater clinical promise for the treatment and prevention of vascular disease and cancer. These two disease categories account for the majority of deaths within the US, while related devices account for the majority of regulatory submissions to CDRH. The Laboratory of Cardiovascular and Interventional Therapeutics (LCIT) investigates a range of these interventional therapeutics, including minimally invasive devices and related adjunctive agents. The research includes the development and application of new imaging and analytical technologies to our pre-clinical investigations. The imaging tools are used to guide the delivery of diagnostic or therapeutic devices to the target location, monitor devices during implantation, monitor the delivery of therapeutic interventions, such as local or targeted drug delivery, embolization or thermal ablation and sample tissues in vivo for analysis. The analytical tools are used to assess drug kinetics and the responses to interventions and for computational analysis of imaging data, including the dynamics of arterial motion. These combined imaging and analytical technologies are used to evaluate the safety and effectiveness of emerging therapeutic devices and agents and develop recommendations for pre-clinical study design.

Tim Cote, M.D., M.P.H.

Office of Orphan Products Development
Office of the Commissioner

Fellows: Katherine Burke, Ph.D. and Scott Freeman, Ph.D.

Scientific and Professional Background

Dr. Timothy Cote has served as the Director of FDA's Office of Orphan Product Development since September, 2007. He received a bachelor's degree from Syracuse University, a Medical Doctorate from the Howard University College of Medicine, and a Masters in Public Health from Harvard School of Public Health. He has completed residencies and is Board certified in both Preventive Medicine and Anatomic Pathology. Dr. Cote began Federal service in 1989 with the CDC's Epidemiology Investigation Service (EIS) and has since continued as an officer in the US Public Health Service Commissioned Corps assigned to wide variety of positions at CDC, NIH, USDA and FDA. Most recently he served as CDC Chief of Mission in Kigali, Rwanda where he implemented the Presidents Emergency Plan for AIDS Relief. He has authored or co-authored over 60 publications on infectious and neoplastic disease.

Elliot P. Cowan, Ph.D.

Office of Blood Research and Review
Division of Emerging and
Transfusion Transmitted Diseases
Center for Biologic Evaluation and Research

Fellow: Bharat Khurana, Ph.D.

Scientific and Professional Background

Dr. Elliot Cowan received a B.A. from Williams College in 1977 and a Ph.D. in Biology and Biomedical Sciences (Cellular, Developmental, and Systemic Biology) from Washington University in St. Louis in 1983. He trained as a Staff Fellow at the National Institute of Allergy and Infectious Diseases, studying the molecular basis of immune recognition. In 1986 he joined the National Institute of Neurological Diseases and Stroke as a Senior Staff Fellow and Special Expert where he studied the molecular immunology of multiple sclerosis and molecular mechanisms surrounding neurological disease associated with human T-lymphotropic virus type I (HTLV-I). Dr. Cowan came to the Center for Biologics Evaluation and Research at the Food and Drug Administration in 1993 to work on issues related to HTLV and blood safety, serving as Chief of the HTLV Section in the Division of Emerging and Transfusion Transmitted Diseases (DETTD), Office of Blood Research and Review, responsible for all issues related to HTLV and blood safety at FDA, including the licensing of blood donor screening tests for HTLV. He also assumed major responsibility for all issues related to rapid HIV testing, including device approval and drafting of policy.

Dr. Cowan now serves as Chief of the Product Review Branch in DETTD, responsible for the review of all blood donor screening tests and retroviral diagnostics. He has represented the FDA to discuss tests and testing in many different forums, including the Centers for Disease Control and Prevention, federal advisory committees, industry and professional roundtables, briefings for the Secretary of Health and Human Services, and meetings sponsored by the World Health Organization. He is also a member of the Laboratory Technical Working Group in the Office of the Global AIDS Coordinator for the President's Emergency Plan for AIDS Relief, serving as Chair of the HIV Diagnostics Subcommittee.

Edward Cox, M.D., M.P.H.

Director, Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

Fellow: Nicole Mahoney, Ph.D.

Scientific and Professional Background

M.D., Univ. of North Carolina School of Medicine
M.P.H., Johns Hopkins School of Hygiene and Public Health
FDA Experience – 11 years
Medical Officer in the Division of Special Pathogen and Transplant Products
Deputy Director of Office of Antimicrobial Products
Director of Office of Antimicrobial Products
Board Certifications – infectious diseases and internal medicine (ABIM)

Research Interests

Dr. Cox is interested in antimicrobial drug development, issues in clinical trial design and antimicrobial resistance.

John Z. Duan, Ph.D.

Biopharmaceutics,
Office of New Drug Quality Assessment
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Fellow: Kareen Riviere, Ph.D.

Scientific and Professional Background

Ph.D. in Pharmaceutical Science
FDA Experience - 13 years

Research Interests

Dr. Duan has special interest in biopharmaceutics, especially IVIVC analyses. With his programming expertise, he found that the review practice involved a lot of repetitive activities and one of the solutions he has been pursuing is automation. His current project is developing a review tool for biopharmaceutics review, which will be a collection of modules and each of them is a combination of knowledge base, review template, and training tool for a particular type of biopharmaceutics study. The research project titled "Biopharmaceutics Review Tool Development" is in line with following three key opportunity areas identified in critical path initiatives: Better Evaluation Tools, Harnessing Bioinformatics and Moving manufacturing into the 21st century.

Charles N. Durfor, Ph.D.

Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Fellows: James Bertram, Ph.D.,
Katherine Kavlock, Ph.D., and Sylva Krizan, D.Phil.

Scientific and Professional Background

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

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.

Raafat Maher Fahmy, Ph.D.

Division of Manufacturing Technology
Center for Veterinary Medicine

Fellow: Wenge (Walter) Xie, Ph.D.

Scientific and Professional Background

FDA Experience - 9 years

Research Interests

Achieve quality by design for tablet dosage form product by developing scientific understanding to the material attributes and critical manufacturing process which impact the critical quality attribute of tablet drug products. Monitoring and controlling all the critical material and process attributes using Near Infrared with chemometric modeling. Study Design Space methodology, define the best practice for Design Space applications and develop specific examples of Design Space methodology that can be used for the educational purposes.

John W. Gardner, M.D., Dr.P.H.

Office of Information Management
Office of the Commissioner

Fellow: Kosta Makrodimitris, Ph.D. and Markus Yap, Ph.D.

Scientific and Professional Background

Dr.P.H., Epidemiology & Biostatistics, Harvard University
M.D., University of Utah
M.S., Physical Chemistry & Biochemistry, Brigham Young University
M.P.H., Epidemiology & Biostatistics, Harvard University
FDA Experience - 4 years

Research Interests

Data systems for epidemiologic research and regulatory purposes to enhance the public health protection of the public.

Jogarao (Joga) V.S. Gobburu, Ph.D.

Division of Clinical Pharmacology
Center for Drug Evaluation and Research

Fellow: Hui (Helen) Zheng, Ph.D.

Scientific and Professional Background

FDA Experience - 10 years

Research Interests

Quantitative Clinical Pharmacology or Pharmacometrics; modeling and simulation of clinical trials; clinical trial design; dose optimization using Pharmacometrics.

Biswendu B. Goswami, Ph.D.

Division of Molecular Biology, OARSA
Center for Food Safety and Applied Nutrition

Fellow: Kaoru Hida, Ph.D.

Scientific and Professional Background

Ph.D., University College of Science, University of Calcutta
B.S., M A College, University of Calcutta

Research Interests

Dr. Goswami, Research Virologist, has over 30 years experience in the areas of virus –cell interaction, antivirals including Interferon response, and virus detection using molecular methods, some developed in FDA/CFSAN. Currently, he is working on the mechanism behind virus induced apoptosis mediated by a latent cellular ribonuclease called RNase L. His work shows how hepatitis A virus and some other enteric viruses following infections of host cells subvert the Interferon based cellular defense mechanism to their own advantage through the activation of RNase L.

Dr. Goswami is also working in the area of molecular detection methods for food borne viruses using an advanced array based technique, that is capable of detecting multiple viruses in the same sample, as well as identify the genotype of the virus. He has published over 40 peer-reviewed articles in these areas including eight book chapters and review articles. He is also an internationally recognized expert on the development of molecular-based methods for the detection and identification of food borne viruses using reverse transcription and PCR, and oligonucleotide array technology.

His current efforts center on the identification of closely related strains of food or water borne viruses using simultaneous detection and identification down to the strain level in one single hybridization experiment. Generally virus detection and strain identification are not run concurrently with the current most widely used molecular methods, resulting in loss of time. His laboratory is developing a high density oligonucleotide array hybridization system that incorporates thousands of oigonucleotide probes to scan a number of viral targets simultaneously. Integral to this approach are the development of closely related techniques of target synthesis using modified protocols not currently routinely used. It is believed that the project will lead to extensive improvement to array design, as well as new methods of target synthesis and labeling protocols. An additional goal is to make the protocol realistic in sensitivity that will be applicable to detection of very low concentrations of viruses in food and water samples, a main goal of the CFSAN virus detection program.

Deborah K. Hansen, Ph.D.

Division of Personalized Nutrition and Medicine
National Center for Toxicological Research

Fellow: Hyung-yul Lee, Ph.D.

Scientific and Professional Background

Ph.D., Indiana University
FDA Experience - 24 years

Research Interests

My research interests are in the area of developmental toxicology, particularly the effects of nutrition on normal and abnormal embryonic development. Furthermore, I'm interested in the interaction of the genetic constitution of the embryo and environmental influences, such as chemical (or drug) exposure.

Robert H. Heflich, Ph.D.

Division of Genetic and Reproductive Toxicology
National Center for Toxicological Research

Fellow: Xuefei Cao, Ph.D.

Scientific and Professional Background

Ph.D., Rutgers - The State University of New Jersey
FDA Experience - 27 years

Research Interests

Dr. Heflich has conducted research in Genetic Toxicology for approximately 30 years. He is presently working on improving FDA regulatory safety assessments by developing rapid, high throughput methods for measuring gene mutation and chromosomal changes.

Victoria M. Hitchins, Ph.D.

Division of Biology
Office of Science and Engineering Laboratory
Center for Devices and Radiological Health

Fellow: Shanil Haugen, Ph.D.

Scientific and Professional Background

M.S. and Ph.D., Department of Microbiology, Michigan State University
B.A., Wellesley College

Research Interests

There are three major areas of research that I am involved in: 1) biological responses of device materials (e.g. nanoparticles) using an in vitro system (e.g. murine macrophage cells), 2) tissue engineering (chondrocytes), and 3) infection control (e.g. cleaning, disinfection/sterilization of medical devices, endotoxin contamination on devices, infections associated with devices).

Sally A. Hojvat, Ph.D.

Division of Microbiology Devices
Center for Devices and Radiological Health

Fellow: Natalia Comella, Ph.D.

Scientific and Professional Background

Ph.D. Biochemistry
M.Sc. Microbiology
B.Sc (Hons)
Post Doctoral Fellowships. in Pharmacology and Clinical Chemistry
Eighteen years experience in the IVD Industry
Six years experience with FDA as a Division Director in the Office of In-vitro Diagnostics/ CDRH

Research Interests

Regulation of in-vitro diagnostic devices for the detection and diagnosis of infectious diseases.

The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) regulates all aspects of in-home and laboratory diagnostic tests (in vitro diagnostic devices, or IVDs). The Office was formed November 17, 2002, in order to consolidate all regulatory activities for IVDs. OIVD has a dual charge to foster the rapid transfer of new IVDs into the marketplace while preventing marketing of unsafe or ineffective devices. To accomplish this OIVD combines the functions of all the offices within CDRH into one organizational unit for cradle-to-grave regulation of in vitro diagnostic devices (IVDs).

The Division of Microbiology is responsible for the pre-market and post- market review of devices for the detection and diagnosis of infectious diseases. These can range from rapid hand held devices for the detection of influenza or streptococcal infection to complex multiplex devices capable of detecting multiple microorganisms involved in respiratory infections, gastrointestinal infections and systemic fungal disease.

H.M. James Hung, Ph.D.

Division of Biometrics I
Office of Biostatistics, Office of Translational Science
Center for Drug Evaluation and Research

Fellow: Rajasri Roy, Ph.D.

Scientific and Professional Background

FDA Experience - 20 years

Research Interests

Throughout his 20+ years with CDER of FDA, Dr. Hung has been conducting extensive research on factorial design trials, utility of p-value distribution, adaptive design/analysis, non-inferiority trials, and multi-regional trials. His research was supported by a number of CDER RSR funds. In addition to research, Dr. Hung has been contributing to several FDA/CDER working groups such as non-inferiority guidance group, adaptive design guidance group.

Deborah Hursh, Ph.D.

Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Thereapies

Fellow: Tehyen Chu, Ph.D.

Scientific and Professional Background

Ph.D., Indiana University, Bloomington
M.S., University of Denver
B.A., New College, Sarasota, Florida

Research Interests

Cell therapy and the use of engineered tissues are critical emerging areas of medical intervention for repair and regeneration of diseased, damaged or aging tissues. For these therapies to be both safe and effective, it will be necessary to be able to reliably predict the final fate of transplanted immature cells and engineered tissues. Immature cells or tissues that mature along an unpredicted path will not provide effective treatment, and can cause serious adverse consequences, such as tumors.

What kind of cell a precursor cell becomes (i.e., cell fate) after administration as a cell therapy product is largely directed by cellular communication networks. This communication is carried out by proteins called growth factors that are secreted from cells. Many such growth factor networks regulate the maturation of cells, and can work in collaboration or opposition to each other, depending of the cellular context. Thus, to ensure that cell and tissue therapy products manufactured outside an organism can be used effectively, we seek to capture the communication code used by particular cell types and translate this knowledge to predict how transplanted cell and tissue products will respond to the environment into which they are transplanted.

Joseph C. Hutter, Ph.D.

Division of Ophthalmic and ENT Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Fellow: J. Angelo Green, Ph.D.

Scientific and Professional Background

M.S., Ph.D., Pennsylvania State University
B.S.Ch.E., University of Florida
FDA Experience - 10 years

Research Interests

Since 1998, various *silicone hydrogel* contact lenses have been introduced into the US market. At the same time, multi-purpose solutions (MPS or solutions that can be used for cleaning, disinfecting and storing the lenses) have become more complex with additives to facilitate moisture retention, comfort, lubrication, and biocompatibility. This increase in complexity has had the unintended consequence of being linked to two serious infectious outbreaks of fusarium solani and acanthamoeba, which resulted in serious injuries to contact lens users. The outbreaks were believed to be caused by the formation of biofilms and/or preservative depletion (fusarium) and/or possibly conversion of micro-organisms to a resistant cyst form (acanthamoeba). The products linked to the outbreaks performed well in the pre-market testing recommended by the FDA guidance of 1997, which indicated to us that our pre-market testing require updating. The proposed research project will evaluate various lenses and solution products to identify the factors that could contribute to infectious outbreaks with the goal of improving existing premarket testing strategies.

Menfo Imoisili, Ph.D.

Office of Orphan Product Development
Office of the Commissioner

Fellows: Katherine Burke, Ph.D. and Scott Freeman, Ph.D.

Aric D. Kaiser, M.S.

Expert Biomedical Engineer
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Fellow: Jose Moreno, Ph.D.

Scientific and Professional Background

M.S., Mechanical Engineering, University of Cincinnati, 1987
B.S., Biomedical Engineering, Case Western Reserve University, 1985

Research Interests

Aric Kaiser, a biomedical engineer with experience in tissue mechanics and mechanical testing, has regulatory and scientific interests in the design and evaluation of products intended to treat orthopedic disorders. Of particular interest are tissue-engineered medical products (combination products) and devices intended to serve as functional replacements for the diseased or damaged tissue, *e.g.*, products intended to repair/regrow damaged cartilage with functional tissue rather than implantation of synthetic materials as in total joint replacements. Recent work has focused on bone void fillers containing calcium salts, collagen and/or recombinant human proteins or synthetic peptides.

The Division of General, Restorative and Neurological Devices has had a dramatic increase in the number of applications for bone void fillers used in a variety of orthopedic applications in the last several years. The complexity of these fillers, particularly those incorporating recombinant human proteins or synthetic peptides, and their possible risk of immunological and other reactions, would be enhanced by a review and production of a "lessons learned" and/or minimum non-clinical evaluation document based on recent applications. In addition to these types of general documents, a guidance document describing the requirements for submissions investigating fracture healing would also be very useful to agency staff and industry. The fellow would also participate in reviews of pre-IDEs, IDEs, 510(k)s and PMAs on these products and interact with staff from DAGID for products with dental and orthopedic uses, from OSB concerning post-market issues and staff from CDER concerning pre- and post-market issues associated with these products.

Jim Kaput, Ph.D.

Director, Division of Personalized Nutrition and Medicine
National Center for Toxicological Research

Fellow: Hyung-yul Lee, Ph.D.

Scientific and Professional Background

Ph.D., Colorado State University

Research Interests

Current nutritional and genetic epidemiological methods yield "risk factors" based on population studies. Risk factors, however, are statistical estimates of the percentage reduction in disease in the population if the risk were to be avoided or the gene variant was not present. These measures are often assumed to apply to individuals who are likely to differ in genetic make-up, lifestyle, and dietary patterns than those individuals in the study population. Developing individual risk factors in light of the genetic diversity of human populations, the complexity of foods, culture and lifestyle, and the variety of metabolic processes that lead to health or disease are significant challenges for personalizing dietary advice for healthy or individuals with chronic disease.

The FDA/NCTR Division of Personalized Nutrition and Medicine focus on several aspects of the health to disease continuum using laboratory animals and studies in humans. These questions we seek to answer are: how does one define health (and not just the absence of disease)? What is the full phenotypic range of laboratory animal and human metabolic profiles? Can we assign individuals into genotype – environment bins that will allow for the selection of lifestyles (diet and activity) to optimize health and prevent or delay the onset of chronic diseases? What is the optimum intake of nutrients in children of all ancestral backgrounds to allow them to reach their full physical and mental potential?

The technologies underlying these initiatives are re-sequencing of candidate genes (see reference 10 below), whole genome scans to determine genetic ancestry (for epistasis analyses), gene expression analyses, laboratory animal models, micronutrient analyses, and development of software tools and databases for nutrient and physical activity analyses. About half of the members of our division are statisticians and mathematicians who collaborate on the design and interpretation of high dimensional datasets. We also collaborate with experts at NCTR, nationally, and internationally in other omic technologies.

John Karanian, Ph.D.

Laboratory of Cardiovascular and
Interventional Therapeutics
Division of Biology
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Fellow: Mark Kreitz, Ph.D. and Orlando Lopez, Ph.D.

Scientific and Professional Background

Ph.D., Georgetown University
B.S., St. Michaels College

Research Interests

Image-guided interventions represent a major component of therapeutic technologies available to the clinical community with new developments having greater clinical promise for the treatment and prevention of vascular disease and cancer. These two disease categories account for the majority of deaths within the US, while related devices account for the majority of regulatory submissions to CDRH. The Laboratory of Cardiovascular and Interventional Therapeutics (LCIT) investigates a range of these interventional therapeutics, including minimally invasive devices and related adjunctive agents. The research includes the development and application of new imaging and analytical technologies to our pre-clinical investigations. The imaging tools are used to guide the delivery of diagnostic or therapeutic devices to the target location, monitor devices during implantation, monitor the delivery of therapeutic interventions, such as local or targeted drug delivery, embolization or thermal ablation and sample tissues in vivo for analysis. The analytical tools are used to assess drug kinetics and the responses to interventions and for computational analysis of imaging data, including the dynamics of arterial motion. These combined imaging and analytical technologies are used to evaluate the safety and effectiveness of emerging therapeutic devices and agents and develop recommendations for pre-clinical study design.

Joseph C. Kawalek, Ph.D.

Division of Animal Research
Office of Research
Center for Veterinary Medicine

Fellow: Peter Jeanettes, D.V.M.

Scientific and Professional Background

Ph.D., University of Pittsburgh
B.S., St. Francis College

Research Interests

Dr. Joseph C. Kawalek, Research Chemist investigates drug metabolism and disposition in veterinary animals. His research addresses factors that affect drug metabolism, e.g., age, gender, diet/nutrition, physiological states, and disease. He has published several articles on the maturation of hepatic drug metabolizing enzyme activities in several species (sheep, dogs, cattle, and chickens). His current research activities are in support of the Agency's Critical Path Initiatives in the area of Process Analytical Technology (in vitro in vivo correlations) and species bioavailability comparisons in support of developing guidelines for drug approvals under CVM's Minor Use Minor Species Program.

Thomas C. Knott, M.A.

Chief, General Surgery Devices Branch
Division of Enforcement A
Office of Compliance
Center for Devices and Radiological Health

Fellow: Charles Anamelechi, D. Phil.

Scientific and Professional Background

M.A., University of Maryland at Baltimore
B.A., Johns Hopkins University

Research Interests

The Office of Compliance brings together scientific and investigational evidence with the law to determine the regulatory status of devices. On a broader scale, the Center for Devices and Radiological Health (CDRH) has recently launched the Matrix or Network. This draws together scientists, medical doctors, and regulatory experts from all CDRH offices to concentrate on specific public health issues.

One of our concerns involves surgical meshes. Meshes are indicated for supporting hernia repairs and internal organs and treating urinary incontinence. They are manufactured from materials like polypropylene and collagen that are similar to materials used in sutures. Depending on their use they may be multilayered, have various "wings" to attach them, and come in various weaves.

FDA has received numerous reports of adverse events related to the use of these devices. Several patients who have experienced adverse events have contacted FDA individually. These patients experience intense pain, infections, reactions to the mesh as a foreign body, erosion and perforation of organs, inflammation, etc. A Network committee is examining this issue to determine whether further action is warranted.

Michael Kulka, Ph.D.

Research Microbiologist (Virologist)
Division of Molecular Biology
Center for Food Safety and Applied Nutrition

Fellow: Christine Yu, M.D.

Scientific and Professional Background

Ph.D., Department of Microbiology and Immunology, Medical College of Pennsylvania
B.S., Albright College

Research Interests

Dr. Michael Kulka, Research Microbiologist, has over 20 years combined experience in the areas of molecular and cellular biology, molecular virology, and antiviral/immune modification. Upon his arriving at the FDA and joining the Molecular Virology Team (MVT), he applied his knowledge and experience to the team's research aims which focus on the improvement of genomic detection and development of culture methods for foodborne viruses. He has published over 25 peer-reviewed articles, co-authored a book chapter and is recognized for scientific contributions in his field of research. His laboratory has had both intra- and extramural research collaborations and has also made significant contributions in other division and center related issues such as participation in pre-validation round robin testing, application of experimental methods to outbreak samples/investigation, and contribution to the development of Risk Profile (CFSAN) documents on hepatitis A virus and norovirus.

Dan D. Levy, Ph.D.

Acting Supervisor, New Dietary Ingredient Review Team
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition

Fellow: Erika Pfeiler, Ph.D.

Scientific and Professional Background

M.S./Ph.D., Sackler Institute of Graduate Biomedical Studies, New York University
A.B., Chemistry, Oberlin College

Research Interests

Dr. Levy is a molecular biologist with a broad range of interests the application of molecular genetic techniques to problems of regulatory interest. He chairs the Genetic Toxicology Working Group of the Interagency Coordinating Committee for Validation of Alternative Methods and the FDA inter-center working group on live microbial ingredients in FDA regulated products. He transferred from a laboratory research position 5 years ago into a regulatory position. In the last year he has initiated projects within FDA laboratories to advance validation of the Comet assay and to establish methods for genetic identification of *Lactobacillus* and *Bacillus* strains used as ingredients in dietary supplements.

Sean Linder, Ph.D.

Office of Regulatory Affairs
Arkansas Regional Lab

Fellow: Thilak Kumara Mudalige, Ph.D.

Scientific and Professional Background

Ph.D., Bioanalytical Chemistry, University of Arkansas
FDA Experience – 1 year

Research Interests

My primary research interests lie in the development and application of analytical methodologies for the detection of biologically relevant compounds in complex matrices. Over the last seven years, I have focused on the development of extraction and detection protocols in biological tissues, fluids, and foodstuffs. This work has been very diverse in that analytes of interest have been both organic and inorganic in origin. Notable work includes: 1) Analytical techniques for the determination of multiple classifications of anticoagulants in animal tissues at sub parts-per-million (ppm) levels. 2) Determination of elemental compounds, such as lead, arsenic, and selenium in multiple biologically relevance matrices at sub parts-per-million (ppm) levels. 3) Implementation of post-extraction automated cleanup technologies to increase sample throughput and laboratory efficiency. With experience in both organic and inorganic analytical methodologies, the opportunity to develop new methodologies in the evolving field of nanotechnology is of great personal and professional interest.

Beverly D. Lyn-Cook, Ph.D.

Senior Research Scientist
Office of the Associate Director of Regulatory Activities
Women's Health Research Program
National Center for Toxicological Research

Fellow: Honggang Wang, M.D., Ph.D.

Scientific and Professional Background

Ph.D., Atlanta University
FDA Experience - 21 years

Research Interests

Dr. Cook's research areas include epigenomics and nutrition and gender differences in adverse drug reactions and diseases. Although genomics play an important role in adverse drug reactions and the development of diseases, it is also becoming increasingly important to understand the role of nutrition in individuals' response to drugs and susceptibility to diseases. The preceptor has been involved in research examining the effects of micronutrients, dietary agents and their interaction with polymorphisms in critical genes involved in carcinogenesis, metabolism and drug transport. Her laboratory was one of the first to establish a relationship between changes in methylation status and caloric restriction and methylation changes associated with dietary components found in soy. Her laboratory continues to investigate epigenetic regulation of genes involved in Phase II and Phase III detoxification and transport as it relates to drug toxicity and drug-drug interactions. The laboratory is currently investigating polymorphisms in drug transporter genes and inactivation of critical Phase II enzymes such as UDP-glucuronosyltransferases (UGTs) in liver toxicity and pancreatic cancer resistance to various chemotherapeutic drugs. Often clinical applications of new chemotherapeutic drugs are hindered by their low therapeutic index or lack of efficacy in humans. Research in gender differences in expression of drug transporters as it relates to adverse drug reactions are also being conducted in her laboratory.

Elias Mallis

Acting Deputy Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Fellows: James Bertram, Ph.D., Katherine Kavlock, Ph.D., and Sylva Krizan, D.Phil.

Scientific and Professional 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.

Norman S. Marks, M.D., M.H.A.

Medical Director
MedWatch Program
Office of Scientific and Medical Programs
Office of the Commissioner

Fellow: Khaled Bouri, Ph.D.

Scientific and Professional Background

M.D., University of Wisconsin-Madison
M.H.A., University of Colorado
B.Med.Science, University of Wisconsin-Madison

Research Interests

Dr. Marks' professional interests focus on risk communication and biomedical informatics, with a specific interest in studying the application of clinical medical informatics theory and methodologies to drug and device risk management. Research on enhancing medical product risk identification through access to clinical electronic health record data and the use of clinical decision support tools and applications to incorporate new safety information and best practices for use of medical products into point-of-care clinical decisions are of particular interest.

MedWatch has an interest in research that contributes to a better understanding of the extent to which new risk information about regulated products that are disseminated to MedWatch Partners organizations for further dissemination to members and subscribers is received, understood, and acted on by recipients and end-users. FDA is beginning to develop a research capacity, based in the social or behavioral sciences, to assess this process of communicating safety information to point-of-care providers and patients. This qualitative and quantitative research would assess the effectiveness of the messages we communicate - how they are being received and understood, and how they could more optimally be disseminated. The findings will help FDA design communications to more effectively meet the decision-making needs of our provider audiences.

Marilyn N. Martinez, Ph.D.

Center for Veterinary Medicine
Division Of Therapeutic Drugs For Food Animals

Fellow: Leposava Antonovic, Ph.D.

Scientific and Professional Background

Ph.D., Georgetown School of Medicine
FDA Experience - 24 years

Research Interests

Pharmacokinetics and biopharmaceutics. One of the challenges encountered within the Division of Therapeutic Drugs for Food Animals is the problem of assessing the blood concentrations of drugs when administered to animals in feed or drinking water. Oftentimes, sponsors wish to use blood level studies to bridge to existing clinical safety or effectiveness information. In these cases, differences in systemic drug exposure can be due to differences in drug intake in water versus feed (an animal behavior question) or due to formulation differences (a biopharmaceutics question). While the latter can be addressed via assessing blood concentration-time profiles after gavage dosing the two formulations (a relative bioavailability study), exposure differences due to food versus water consumption cannot be easily obtained. In particular, efforts to capture blood levels during such investigations interfere with normal animal behavior. Therefore, we are often left with little option but to conduct additional studies.

Jennifer Matysczak, V.M.D.

Center for Veterinary Medicine
Division of Therapeutic Drugs for Food Animals

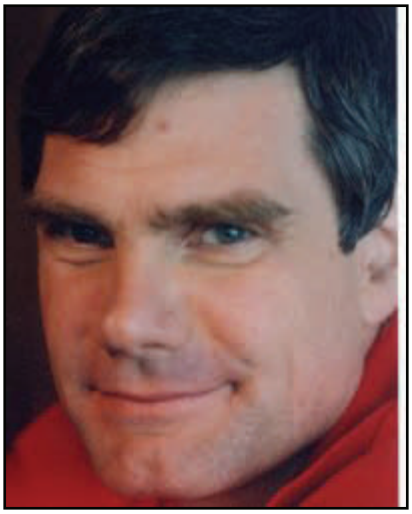
Fellow: Eric Landis, Ph.D.

Scientific and Professional Background

V.M.D., University of Pennsylvania School of Veterinary Medicine
FDA Experience - 4 years

Research Interests:

Dr. Jennifer Matysczak is the Leader of the Aquaculture Drug Team in the Office of New Animal Drug Evaluation in Food and Drug Administration's Center for Veterinary Medicine (FDA/CVM). Dr. Matysczak received a VMD from the University of Pennsylvania's School of Veterinary Medicine with elective training in aquatic animal medicine. Before joining the FDA, she completed a two-year post-graduate veterinary internship with the University of Florida's Tropical Aquaculture Laboratory, providing extension and diagnostic services to the ornamental fish industry, and The Florida Aquarium. Dr. Matysczak joined the FDA/CVM as a reviewer on the Aquaculture Drugs Team, and currently serves as the leader of this team and FDA/CVM's representative to the Joint Subcommittee on Aquaculture, an interagency (federal government) coordinating group. Dr. Matysczak recently participated in the FAO (Food and Agriculture Organization of the United Nations) Expert Workshop on Improving Biosecurity through Prudent and Responsible Use of Veterinary Medicine (Antimicrobials) in Aquatic Food Production.



Malcolm Moos, M.D., Ph.D.

Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapy
Center for Biologics Evaluation and Research

Fellow: Eric Dollins, Ph.D.

Scientific and Professional Background

Ph.D., Pharmacology, University of Minnesota Medical School
M.D., University of Minnesota Medical School
B.S., Stanford University

Research Interests

Tissues and organs can be damaged by accident, battle trauma, or disease. Improved methods of repair, replacement, or regeneration of damaged tissues and organs are an important public health goal. Novel biological products containing living cells show great promise for use as therapies in these settings, but design, manufacture, and testing of these products has proven very challenging. A major obstacle to successful development has been great uncertainty regarding how best to evaluate experimental cell-based products analytically in order to develop process controls and release specifications that predict product performance reliably.

To meet this challenge, we identify the biological processes that cells can use to repair damage within the body, and the components that control these processes. This information will help guide sponsors in the development and regulatory approval of novel therapeutic product approaches, lead to improved manufacturing methods, and guide development of laboratory tests that will help ensure consistent, safe, and effective cellular products. The research program uses a vertebrate embryology model (the South African clawed frog Xenopus) that is particularly useful for identifying the key biological mechanisms that control repair and regeneration and the interactions between these components. We focus on the medically critical, but complicated process of joint development and perform detailed functional analyses of the proteins involved. We have identified several molecules that help control processes such as joint morphogenesis, blood development, and formation of the nervous system. The work has also uncovered ways in which different proteins cooperate to achieve precisely localized control during the formation of complex structures like joints.

Igor P. Pogribny, Ph.D.

Division of Biochemical Toxicology
National Center for Toxicological Research

Fellow: Sami Sarfaraz, Ph.D.

Scientific and Professional Background

M.D., Ivano-Frankivsk Medical University
Ph.D., Kyiv National Medical University
FDA Experience - 18 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.

Lynn O. Post, D.V.M., Ph.D., D.A.B.V.T.

Center for Veterinary Medicine
Office of Surveillance and Compliance
Division of Surveillance

Fellow: Gabriel Davila, D.V.M.

Scientific and Professional Background

D.V.M., Veterinary Medicine, Texas A&M University
Ph.D., Toxicology and Pharmacology, Louisiana State University
Board Certified, American Board of Veterinary Toxicology
M.S., Veterinary Toxicology, Texas A&M University
B.S., Animal Science, Cornell University
B.S., Veterinary Science, Texas A&M University

Research Interests

Toxicology and Pharmacology: Drug interactions, adverse drug events, pharmacogenomics and toxic plants.

MaryAnn Principato, Ph.D.

Immunotoxicology Section/ DivisionToxicology
Center for Food Safety and Nutrition

Fellow: Bi-Feng Qian, M.D., Ph.D.

Scientific and Professional Background

Ph.D., Pathobiology, College of Physicians and Surgeons of Columbia University
M.S., Biochemistry, New York University Basic Medical Sciences, New York
B.A., Natural Sciences, Fordham University, New York

Research Interests

This laboratory has maintained a dual focus upon Staphylococcal enterotoxin B as a superantigen and food contaminant. The research in my laboratory concerns the fundamental events that regulate T cell activation and development during immune responses to super antigenic stimulation by the pyrogenic food toxin, Staphylococcal enterotoxin B (SEB). Efforts have focused on understanding and describing the basic cellular and molecular events triggered following ingestion of the superantigen, and the consequences of this exposure upon health and autoimmunity induction using mouse models of autoimmune disease and aging. Our other emphasis in the laboratory has centered upon the protection and defense of the national food supply. To this end, we developed a variety of methods for the rapid assay and identification of Staphylococcal enterotoxin B in a wide variety of food matrices. In other studies, we have shown that the detection of SEB in thermally processed foods can alter the toxin's ability to be detected by conventional antigen-capture ELISA. To this end, we have developed an *in vivo a*ssay for the detection of occult SEB toxin in thermally processed foods.

William Pritchard, M.D., Ph.D.

Laboratory of Cardiovascular & Interventional Therapeutics
Division of Biology
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Fellow: Mark Kreitz, Ph.D. and Orlando Lopez, Ph.D.

Scientific and Professional Background

M.D., Vanderbilt University
B.S., Massachusetts Institute of Technology

Research Interests

Image-guided interventions represent a major component of therapeutic technologies available to the clinical community with new developments having greater clinical promise for the treatment and prevention of vascular disease and cancer. These two disease categories account for the majority of deaths within the US, while related devices account for the majority of regulatory submissions to CDRH. The Laboratory of Cardiovascular and Interventional Therapeutics (LCIT) investigates a range of these interventional therapeutics, including minimally invasive devices and related adjunctive agents. The research includes the development and application of new imaging and analytical technologies to our pre-clinical investigations. The imaging tools are used to guide the delivery of diagnostic or therapeutic devices to the target location, monitor devices during implantation, monitor the delivery of therapeutic interventions, such as local or targeted drug delivery, embolization or thermal ablation and sample tissues in vivo for analysis. The analytical tools are used to assess drug kinetics and the responses to interventions and for computational analysis of imaging data, including the dynamics of arterial motion. These combined imaging and analytical technologies are used to evaluate the safety and effectiveness of emerging therapeutic devices and agents and develop recommendations for pre-clinical study design.

Donna Przepiorka, M.D., Ph.D.

Medical Officer, Clinical Evaluation Branch
Division of Clinical Evaluation and Pharmacology/Toxicology
Center for Biologics Evaluation Research

Fellow: Olumide Olajide , M.D.

Scientific and Professional Background

M.D. University of Illinois, Chicago, IL
Ph.D. (Microbiology and Immunology) University of Illinois, Chicago, IL
B.S. (Biochemistry) Illinois Benedictine College, Lisle, IL

Research Interests

The products that the Office of Cellular, Tissue, and Gene Therapies (OCTGT) regulates include gene therapies (ex vivo transduction of cells and direct injection of product), tumor vaccines, xenotransplantation, stem cells (embryonic and adult), tissue preparations (fetal and adult), combination products (biologic plus drug or device), and bioengineered tissues. Dr. Przepiorka has a special interest in design and monitoring of early phase clinical trials for novel therapies. She is a member of the RAC Clinical Trial Design Working Group.

Fatemeh Rafii, Ph.D.

Division of Microbiology
National Center for Toxicological Research

Fellow: Sunny Park, Ph.D.

Scientific and Professional Background

Ph.D., Washington State University
M.S., Washington State University
B.S., Tehran University
FDA Experience - 21 years

Research Interests

Determining the effects of antibiotic exposure on resistance development, metabolic activities and virulence factors of bacterial pathogens. Elucidating the molecular mechanisms that govern physiological changes occurring in antibiotic-resistant bacteria. Detecting compounds that increase antibiotic potency.

Detecting bacteria from the human gastrointestinal tract that are involved in the metabolism, activation, and detoxification of food additives, nutritional supplements, environmental contaminants and pharmaceutical drugs, including antimicrobial agents.

Richard Rogers, M.D.

Office of Orphan Products Development
Office of the Commissioner

Fellow: Katherine Burke, Ph.D. and Scott Freeman, Ph.D.

Scientific and Professional Background

R. P. C. Rodgers received training at Harvard College and the University of Utah College of Medicine. He completed postdoctoral programs at the University of London, NCI's Laboratory of Theoretical Biology, and the International Institute of Cellular and Molecular Pathology (Brussels), performing research on computer simulation for the design of bioanalytical chemical assays and the statistical analysis and quality control of these methods. He then completed training in Clinical Pathology within the Department of Laboratory Medicine in the School of Medicine at the University of California, San Francisco, where he subsequently served as a faculty member, with a parallel appointment within the Department of Pharmaceutical Chemistry in the School of Pharmacy. In 1992, he joined the research staff of the Lister Hill National Center for Biomedical Communications of the U.S. National Library of Medicine, where his research program led him to become the first physician dealing with World Wide Web technology at a serious technical level, creating NLM's initial Web services, including the first large catalogued image archive on the Web. Dr. Rodgers served as a Founding Member of the International World Wide Web Conference Committee, was founding Chair of the NSF/NCSA World Wide Web Federal Consortium, served as a member of the NISO Standards Development Committee, and has participated in several Internet Engineering Task Force (IETF) working groups; he has been a strong proponent of open source and open standards. His fostering of multicast technology within the context of the International World Wide Web Conference series led to the formation of a highly successful video-conferencing firm now owned by Google. He has authored articles and books, and made many presentations dealing with clinical pathology, biomedical computing, and network-based information and collaboration systems. He currently works on special projects within the Office of Orphan Products Development of the U.S. Food and Drug Administration, including creation and direction of the online course, "The Science of Small Clinical Trials," which in 2010 had over 1300 registrants.

Larisa Rudenko, Ph.D., DABT

Senior Advisor, Biotechnology
Center for Veterinary Medicine
Office of New Animal Drug Evaluation

Fellow: Malini Mansharamani, Ph.D.

Scientific and Professional 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 premarket 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 guidances and regulations and discussions with industry, scientific researchers and consumers.

Frank W. Samuelson, Ph.D.

Division of Imaging and Applied Mathematics
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Fellow: Camille Vidal, Ph.D.

Scientific and Professional Background

Ph.D., Iowa State University
A.B., Harvard University

Research Interests

The FDA evaluates computer aided diagnosis devices that are intended for clinical use for their safety and effectiveness. Frank Samuelson performs research on statistical methods for the evaluation of such CAD devices. These methods are used to evaluate CAD devices for technical effectiveness as well as clinical and user effectiveness. Some of these methods are directly used by sponsors that submit CAD devices to the FDA. Frank Samuelson utilizes and provides expertise for the OSEL computing cluster. The OSEL computing cluster provides compute power for much of the scientific modeling within the Center.

FDA Fellows participating in this research program will create and evaluate models that describe the statistical change in performance and aggression of users (primarily clinical radiologists) of CAD software. These models are necessary for understanding how CAD devices affect the ability of radiologists to diagnose patients and therefore the safety and effectiveness of these devices. Current models do not estimate or account for some kinds of effects, such as diagnostic aggression, that CAD devices have been demonstrated to have on radiologists.

Bruce S. Schneider, M.D.

Clinical Evaluations Branch
Office of Cellular, Tissue and Gene Therapy
Center for Biologics Evaluation and Research

Fellows: James Bertram, Ph.D.
Katherine Kavlock, Ph.D., and Sylva Krizan, D.Phil.

Scientific and Professional 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.

Seth J. Seidman, M.S.

Research Electrical Engineer
Division of Physics
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Fellow: Oxana Pantchenko, M.S.

Scientific and Professional Background

M.S., Electrical Engineering, University of Maryland, College Park

Research Interests

My research and regulatory duties are related to wireless coexistence and electromagnetic compatibility (EMC) of medical devices. Of special interest to me are intentional wireless emitters such as radio frequency identification (RFID), wireless local area networks (WLAN), and cellular phones. I also enjoy my work in the development of EMC standards for implantable pacemakers and implantable cardiac defibrillators (ICDs).

FDA Fellows participating in this research program will develop laboratory skills in characterizing and exposing radio frequency identification (RFID) signals to critical care medical devices. The research produced in this project will generate peer-reviewed publications and electromagnetic compatibility (EMC) test methods for RFID around medical devices. Fellows having a background in biomedical or electrical engineering are preferred.

Ruby Singh, Ph.D.
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Fellow: Brooke Whitney, Ph.D.

Scientific and Professional Background

Ph.D., University of Maryland Baltimore
FDA Experience – 7 years

Research Interests

Antimicrobial resistance development among bacteria of public health concern in or on food-producing animals, following their treatment with (or exposure to) antimicrobial drugs (or compounds with antimicrobial activities).

Debra A. Street, Ph.D., M.P.H.

Chief, Emergency Response and Surveillance Branch
Division of Public Health
Center for Food Safety and Applied Nutrition

Fellow: Beverly Wolpert, Ph.D.

Scientific and Professional Background

Ph.D., Epidemiology
M.P.H., Epidemiology
B.A., English
FDA Experience - 15 years

Research Interests

- Characterization of adverse events reported by passive surveillance
- Incidence and prevalence of infectious disease
- Risk assessment for food contamination as associated with chronic disease

Keith Wonnacott, Ph.D.

Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapy
Center for Biologics Evaluation and Research

Fellow: James Bertram, Ph.D.
Katherine Kavlock, Ph.D., and Sylva Krizan, D.Phil.

Scientific and Professional Background

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

Ken J. Yoshitomi, Ph.D.

Applied Technology Center
Pacific Regional Laboratory Northwest
Office of Regulatory Affairs

Fellow: Joy Waite, Ph.D.

Scientific and Professional Background

Ph.D., University of Cincinnati
B.A., University of San Diego
FDA Experience – 8 years

Research Interests

Development of rapid, molecular based assays targeting bacterial pathogens in complex food matrices: Design and utilization of nucleic acid based detection technology has greatly enhanced analytical capabilities in food microbiology. Multiplex conventional PCR and real-time PCR probe chemistries can rapidly provide genetic information on pathogens that may be present. These strategies have been successfully employed in the detection and characterization of virulence markers or conserved sequences associated with foodborne pathogens. Much of my interests lie in detection of E. coli O157:H7, as well as other shiga toxin-producing E. coli and Listeria. However, development of molecular assays alone is not sufficient for effective detection of bacterial pathogens from food.

The complexity of the food matrix itself, associated background microflora, heterogeneous distribution of microorganisms in the sample, and nutrient requirements of the target organism presents a portion of the many challenges that must be overcome to successfully detect the pathogen of interest in a timely manner. Thus, we have investigated various enrichment procedures, immunomagnetic separation systems, and nucleic acid extraction techniques to improve specificity and sensitivity in our detection methodologies. Through the integration of rapid molecular screening techniques and standard cultural procedures is it possible to provide comprehensive detection strategies that are rapid, sensitive, and specific.

Baolin Zhang, Ph.D.

Principal Investigator
Division of Therapeutic Proteins
Office of Biotechnology Products
Center for Drug Evaluation and Research

Fellow: Joslyn K. Brunelle, Ph.D.

Scientific and Professional Background

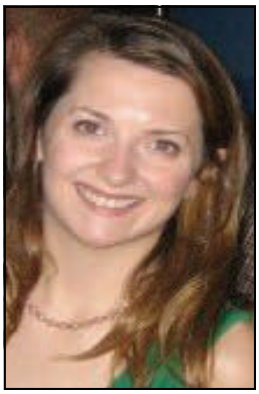
FDA experience – 8 years

Research Interests

Drug resistance is a major obstacle in cancer therapy. We study how chemotherapies kill cancer cells with particular interest in the identification of molecular alterations rendering tumor resistance. Our goal is to identify biomarkers for predicting tumor responsiveness to different types of cancer therapies. The acquired information will aid FDA scientists in making more informed review decisions with respect to drug safety, efficacy, and dosing. In addition to being a Principal Investigator of a laboratory, I am a quality reviewer for protein drug products in treating cancer and other diseases.

Food and Drug Administration
COMMISSIONER'S
Fellowship Program
Protecting Public Health
Through Science and Regulation

Program Staff



Kelly Wilkicki, M.P.P.
Presidential Management Fellow
Commissioner's Fellowship Program Coordinator
Office of the Chief Scientist, Office of the Commissioner

Jeffery B. Rexrode II, B.A.
Management & Program Analyst
Office of the Chief Scientist
Office of the Commissioner

Felicia Evans Long, M.B.A.
Management Analyst
Office of the Chief Scientist
Office of the Commissioner