Pranvera Ikonomi, Ph.D.

240-402-0272; pranvera.ikonomi@fda.hhs.gov

Professional Experience

Food and Drug Administration **August 2013-Present**
CDER/Office of New Drugs/Office of Nonprescription Drugs
Division of Nonprescription Drug Products II
Silver Spring, MD

Interdisciplinary Scientist/Biologist

- Serves as a biologist on a multidisciplinary team, evaluates and makes decisions on over the counter
- (OTC) drug submissions and applications which request FDA regulatory approval for clinical research, human testing, and manufacture of human drugs
- Evaluates New Drug Applications (NDAs), Investigational New Drug Applications (INDs), Supplemental New Drug Applications (sNDAs), amendments, and reports for OTC drug products
- Drafts primary reviews on the submitted data and prepares background materials for both internal and external meetings. Evaluates comments, data and studies submitted to the Health Care, Consumer, and Food Handler Antiseptics rulemaking
- Drafts and develops OTC drug monographs for publication in the *Federal Register*; works with OTC advisory review panels to assure that findings and recommendations are in scientific, medical, and legal compliance; evaluates the impact of proposed monograph standards on the drug industry and consumer population; and provides policy guidance on OTC drug products

Key Accomplishments:

- Prepared the "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use", Final Rule (81 FR 61106) including several scientific reviews on topics related to finalizing the criteria for the efficacy evaluation of consumer antiseptic active ingredients. The review work conducted for publication of his rule led to a major CDER public health initiative to encourage daily use of consumer antiseptics only when they provide a benefit in prevention and reduction of illness due to infections greater than that provided by soap and water
- Initiated and led a multidisciplinary team among CDER and CFSAN experts for issuing "Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information" (83 FR 63168), a potentially new category of antiseptic products. Primary lead in preparing materials for an advisory committee meeting planned for March 6, 2020 on the same topic. Summarized scientific publications and prepared discussion platform for evaluation of efficacy in food handler antiseptic products
- Provided scientific expertise in establishing efficacy testing criteria for applications submitted under emergency use application for treatment and/or prevention of COVID-19. Shared scientific publications and provided information on surrogate viruses currently available for evaluating the efficacy of COVID-19 treatment and/or prevention products
- Served as expert witness in a successful unapproved new drug injunction case, United States v. Innovative BioDefense, Inc. et al., which included preparing an expert report, assisting the government's attorneys, and testifying in a deposition regarding the safety and efficacy of antiseptic products with claims outside of health care and consumer OTC monograph in a federal injunction case
- Currently leading efforts for preparation of a training platform for incoming ONPD staff on OTC Monograph Reform and introducing modernization of the OTC drug review via presentation sessions across CDER review divisions and offices

PHARMACEUTICAL PRODUCT DEVELOPEMNT (PPD) **July 2011-December 2011**
Richmond, VA

Senior Group Leader
- Managed staff of 30 scientists in GMP laboratory performing cell-based assays for development of pneumococcal conjugate vaccine; led cell line optimization for opsonophagocytic assay (OPA); oversaw clinical trials, managed research, and development projects
- Ensured GMP compliance, established criteria for completion of development projects, wrote, reviewed, and approved application methods, development protocols, QA/QC documents; assisted client with scientific presentations and project reports

AMERICAN TYPE CULTURE COLLECTION (ATCC) **October 2001-November 2011**
Manassas, VA

Lead Scientist/Research Scientist III
- Managed the Molecular Authentication Resource Center (MARC) and Molecular Biology R&D group with staff of 15 scientists and combined operating budget of more than $800K
- Managed projects, planned and coordinated contracts and services, assisted clients with experimental design, technical challenges, and customized services
- Established immuno-PCR assay for organism detection; developed quantitative and qualitative controls, used pathogenic *E. coli O157:H7* and Staphylococcus *aureus* as proof of concept
- Developed of high throughput qPCR assay for rapid detection of panel of human viruses in cell lines to complete full array of identification and authentication services
- Led genomic team for biomarker discovery in type 2 diabetes; conducted gene and protein profiling in animal models and diabetic patients, established panel of patented markers for disease detection
- Developed relationships with customers from academia, industry, and government; initiated and maintained collaboration with FDA to establish mycoplasma reference standards for development of new guidelines using nucleic acid technologies for mycoplasma detection; organized and conducted scientific workshops with external collaborators (NIST, FDA)
- Expanded core facility technology offerings to include SNPs, STR, MLVA, MLST fingerprint, microarray, gene, and protein expression analysis for internal and external customers
- Developed patented assay for high throughput speciation and detection of cross-species contamination for cell lines and stem cells using cytochrome oxidase I (COI) as identification target
- Led R&D team and served as project manager for development of commercial mycoplasma detection kit; worked with production, regulatory and marketing teams for successful transfer of project to manufacturing and product launch
- Introduced automation using liquid handling (Biomek FX) and robotic DNA/RNA purification (BioRobot EZ1, QIAsymphony); Increased efficiencies through process consolidation and automation resulting in 45% operational cost reduction for over 20,000 tests annually
- Prepared articles, reviewed scientific proposals, provided technical details for product line marketing materials and new product commercialization
- Performed assessment of new technologies and research programs in support of business development; worked closely with sales, marketing teams

LIFE TECHNOLOGIES, **Rockville, MD** **October 1999-October 2001**

Staff Scientist, DNA Amplification Group
Salary: $59,000; Hours per Week: 40
- Prepared LUX fluorescent quantitative PCR (qPCR) technology for commercial launch
- Evaluated enzyme performance, optimized buffers, and expanded application to include multiplex qPCR
- Interacted with IT to develop functional algorithm for primer design incorporating LUX technology
- Ensured technology functioned with broad array of available instrumentation platforms

- Managed field-testing phase: established timelines, recruited participants, provided on-going communication and technical support, tracked, and reported progress to product launch team
- Performed competitive audits, developed case studies, and provided technical expertise for the development of marketing materials in support of product launch

LABORATORY of CHEMICAL BIOLOGY **January 1995-September 1999**
NIDDK, NIH, Bethesda, MD

Staff Scientist

- Studied the effect of the GATA-1/GATA-2 expression ratio in the modulation of human embryonic and fetal hemoglobin expression as a potential therapeutic for treatment of sickle cell anemia.
- Established an *in vitro* method to measure hydroxyurea responsiveness using fetal hemoglobin induction of erythroid progenitor cells obtained from patients
- Applied overexpression and antisense technology to determine the quantitative role of GATA-2 in the differentiation and maturation of human pluripotent erythroid progenitor cells using flow cytometry
- Determined the role of GATA transcription factors on fetal and embryonic globin genes in primary cultures and transgenic mice
- Established method for purification and *in vitro* growth of pluripotent erythtthoid progenitors isolated from peripheral blood
- Introduced use of quantitative PCR methods for gene expression profiling of erythroid progenitors
- Managed graduate students and visiting fellows

INSTITUTE of GENETICS and MICROBIOLOGY **September 1990-October 1994**
Orsay, FRANCE

Graduate Fellow

- Determined the specificity of SDC25 in activation of cAMP cascade in yeast *S. cerevisiae* via comparative functional analyses; developed a cloning technique using homologues recombination.
- Presented findings in scientific meetings, published in peer review journals

Education

UNIVERSITY OF PARIS XI, Paris, FRANCE **September 1990-October 1994**
Doctor of Philosophy – Molecular Biology

UNIVERSITY OF TIRANA, Tirana, ALBANIA **September 1986-June 1988**
Master of Science – Biochemistry; Physics

UNIVERSITY OF TIRANA, Tirana, ALBANIA **September 1980-June 1985**
Bachelor of Science – Physics

Other

- Awards: CDER Team Excellence Award "For Superior Antiseptic Work by the Over-the-Counter Antiseptic Team"; September 2017; American Type Culture Collection Award "Leadership and Management Award"; October 2007
- Teaching experience: Faculty professor; George Mason University (2002-Present); Foundation of Advanced Education in the Sciences Graduate School; National Institutes of Health "FDA Perspective on Drug Development" (October 31, 2019)

Patents

1. Composition and methods for diagnosis and treatment of Type II diabetes. # US 2009/0203602 A. Gelber C, Liu L, Xie X, **Ikonomi P**, Sims J, Auge C.
2. Composition and methods for diagnosis and treatment of Type II diabetes. # WO 2009/038689 A2. Gelber C, Liu L, Xie X, **Ikonomi P**, Sims J, Auge C.

3. Composition and methods for diagnosis and treatment of Type II diabetes. # WO 2009/038689 A3R4. Gelber C, Liu L, Xie X, **Ikonomi P**, Sims J, Auge C.
4. Composition and methods for diagnosis and treatment of Type II diabetes. # WO 2009/038689 A4R1. Gelber C, Liu L, Xie X, **Ikonomi P**, Sims J, Auge C.
5. Method for detecting the presence and amount of mammalian organisms using specific cytochrome c oxidase I (COI) and/or cytochrome b subsequences by a PCR based assay. # US 2008/0113349 A1. **Ikonomi P**, Cooper J, Sykes G, Reid Y.
6. Identification of cell culture contaminants among mollicutes species by a PCR based assay**.** # US 2008/0187916 A1. **Ikonomi P**, Polayes D, Cottrill K, Li Q.
7. Composition and methods for diagnosis and treatment of Type II diabetes. # US 2008/0300170 A1. Gelber C, Liu L, Xie X, **Ikonomi P**, Sims J, Auge C.
8. Identification of human pathogens and common cell cultures contaminants among *mollicutes* species by microarray-based assay and DNA sequencing. Application Serial #: 11-702,614. Chizhikov V, **Ikonomi P**, Volokhov D, George J, Anderson C.

Selected Publications

1. Dabrazhynetskaya A, Volokhov DV, David SW, **Ikonomi P,** Brewer A, Chang A, Chizhikov V. (2011). "Preparation of reference strains for validation and comparison of mycoplasma testing methods" Journal of Applied Microbiology 111(4), 904-14.
2. Leslie D, Sohrabi A, **Ikonomi P**, McKee M, Landers J. (2010). "Size-based separations as an important discriminator in development of proximity ligation assay for protein or organism detection". *Electrophoresis10, 1615-22.*
3. Nims R, Sykes G, Cottrill K**, Ikonomi P**, Elmore E "Short tandem repeat profiling: part of an overall strategy for reducing the frequency of cell misidentification"**.** *In Vitro Cellular & Developmental Biology - Animal 46, 811-9.*
4. Cooper J, Sykes G, King S, Cottrill K, Ivanova N, Hanner R, **Ikonomi P** (2007). "Species identification in cell culture: a two-pronged molecular approach". *In Vitro Cellular & Developmental Biology - Animal 43, 344-351.*
5. Chantangsi C, Lynn D, Brandl M, Cole J, Hetric N, **Ikonomi P** (2007) "Barcoding ciliates: a comprehensive study of 75 isolates of the genus Tetrahymena". *International Journal of Systematic Evolutionary Microbiology 57, 2412-23.*
6. Kong H, Volokhov D, George J, **Ikonomi P**, Chandler D, Anderson C, Chizhikov V (2007) "Application of cell culture enrichment for improving the sensitivity of mycoplasma detection methods based on nucleic acid amplification technology (NAT)". *Applied Microbiology and Biotechnology 77(1), 223-32.*
7. Volokhov D, George J, Liu S, **Ikonomi P**, *Anderson C, Chizhikov V (2006)* "Sequencing of the intergenic 16S-23S rRNA spacer (ITS) region of Mollicutes species and their identification using microarray-based assay and DNA sequencing". *Applied Microbioogy and Biotechnology 10, 1-19.*
8. Han j, Farnsworth R, Tiwari J, Tian J, Lee H, **Ikonomi P,** Byrnes A, Goodman J, Puri R (2006) "Quality prediction of cell substrate using gene expression profiling". *Genomics 87, 552-559.*
9. Baker S, Bauer S, Beyer R, Brenton J, Bromley B, Burrill J, Causton H, Conley M, Elespuru R, Fero M, Foy C, Fuscoe J, Gao X, Gerhold D, Gilles P, Goodsaid F, Guo X, Hackett J, Hockett R, **Ikonomi P,** Irizarry R, et al. External RNA Controls Consortium: a progress report. ". *Nat Methods. 2005 Oct 2, 731-734.*

10. **External RNA Control Consortium** (2005). Proposed methods for testing and selecting the ERCC external RNA controls. *BMC Genomics 2005, 6:150.*
11. Hay, R. J, **Ikonomi, P,** Julio E. (2004) "Detection of Microbial and Viral Contaminants in Cell Lines, in "Cell Biology: A Laboratory Handbook"; Celis *(Ed.), Academic Press, New York.*
12. Smith R.D, Brown B, **Ikonomi P**, Schechte A.N (2003) "Exogenous reference RNA for normalization of real-time quantitative PCR*". Biotechniques. (34), 88-91.*
13. Nazarenko I, Lowe B, Darfler M, **Ikonomi P,** Schuster D, Rashtchian A (2002) "Multiplex quantitative PCR using self-quenched primers labeled with a single fluorophore". *Nucleic Acids Res. (1), 30-37***.**
14. Kawabata H, Nakamaki T, **Ikonomi P**, Smith R D, Germain R S, Koeffler H. P (2001) **"**Expression of transferrin receptor 2 in normal and neoplastic hematopoietic cells**".** *Blood. (98), 2714-19.*
15. **Ikonomi**, P, Noguchi C T, Miller W, Kassahun H, Hardison R, Schechter A N (200) "Levels of GATA-1/GATA-2 transcription factors modulate expression of embryonic and fetal hemoglobins**".** *Gene. (261), 277-87.*
16. **Ikonomi P**, Rivera C.E, Riordan M, Washington G, Schechter A N, Noguchi C T (2000) "Overexpression of GATA-2 inhibits erythroid and promotes megakaryocyte differentiation"**.** *Exp Hematol. (28), 1423-31.*
17. Shen T J, **Ikonomi P**, Smith R D, Noguchi C T, Ho C "Multi-ribozyme targeting of human alpha-globin gene expression". (2000) *Blood Cells Mol Dis (25), 361-73.*
18. Boy-Marcotte, E, **Ikonomi, P**, and Jacquet, M (1996) "*SDC25*, A Dispensable RAS Guanine Nucleotide exchange factor of *Sacharomyces cerevisiae* differs from CDC25 by its regulation". *Molecular Biology of the Cell: 7, 529-539.*

Selected Presentations:

1. "Highlights of Over-the-Counter Drug Monograph Reform"; CDER Scientific Rounds, January 2021.
2. "Over the Counter Drugs; Monograph Reform"; Division of Diabetes, Lipid Disorders and Obesity, May 2021; Division of General Endocrinology: May 2021; Division of Anti-Infectives March 2021; Division of Antiviral Products January 2021; Division of Ophthalmology; October 2020; Division of Pulmonology, Allergy and Critical Care Sept 2020.
3. "Food Handler Antiseptics; an FDA Perspective" Annual meeting of International Association for Food Protection, July 2017, Tampa, Florida.