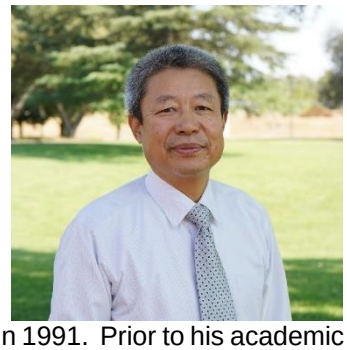
Defining "Candy-Like" Nonprescription Drug Products

Food and Drug Administration
University of Maryland Center of Excellence in Regulatory Science and Innovation

Public In-Person and Virtual Workshop
October 30, 2023 | 8:30 AM – 4:00 PM Eastern Time

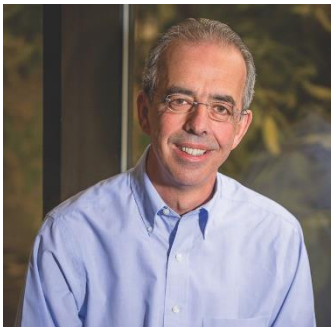
Biographies

Xiaoling Li, PhD, FAAPS, FAIMBE
Professor of Pharmaceutics, Thomas J Long School of Pharmacy
University of the Pacific



Dr. Xiaoling Li is a Professor of Pharmaceutics in Thomas J. Long School of Pharmacy at the University of the Pacific. Dr. Li is a Fellow of American Association of Pharmaceutical Scientists and a Fellow of American Institute for Medical and Biological Engineering. He received his BS in Pharmacy and MS in Nuclear Pharmacy from Shanghai Medical University in 1982 and 1985, respectively. Under the guidance of Dr. Sung Wan Kim, Dr. Li obtained his PhD in Pharmaceutics from the University of Utah in 1991. Prior to his academic career, he was a postdoctoral research fellow at Ciba-Geigy Corp (now Novartis). He served as department chair, graduate program director and Associate Dean of Graduate Education and Research during his tenure at University of the Pacific. Dr. Li's research interest areas include oral mucosal drug delivery, novel polymers for pharmaceutical and medical application, targeting drug delivery, antibody mimics, drug transport across biological membranes, and application of physicochemical concepts to novel dosage form design. His research projects are funded by both NIH and pharmaceutical industry. He holds 57 patents with 41 patent applications pending and has published 104 papers/book chapters, over 180 abstracts/presentations, and two books entitled "Design of Controlled Release Drug Delivery Systems" and "Oral Bioavailability". Dr. Li received CRS Outstanding Paper Award for the *Journal of Controlled Release in* 1992. He is a Thomas J. Long Fellow, recognized as a Distinguished Faculty Research Lecturer (2003), received Distinguished Faculty Award (2012) and Eberhardt Teacher/Scholar Award (2019) at the University of the Pacific. Dr. Li is the recipient of AAPS Outstanding Educator Award in 2015. He is a member of the Association of American Pharmaceutical Scientists, Controlled Release Society, and a convention member of USP. Dr. Li has mentored and trained 27 PhD, 4 MS, 16 post doctoral research fellows, and 18 visiting scientists. He co-founded two companies, Formurex, Inc., a formulation development company in 2006 and Triastek, a 3D printing pharmaceutical company in 2015. Dr. Li works closely with the pharmaceutical industry and provides consultation for product development to various pharmaceutical companies.

Jeffrey H. Worthington, BS, MBA
President and Founder
Senopsys LLC



Jeff Worthington is President and Founder of Senopsys LLC, a specialty services firm dedicated to the development of palatable pharmaceuticals. He has more than twenty-five years' experience applying analytical sensory analysis methods to help global pharma, biotech and drug delivery companies develop new products and solve complex taste and odor problems. He has directed development programs for dozens of investigational drugs, new dosage forms of approved drugs, and numerous over-the-counter medications.

Prior to founding Senopsys in 2006, Mr. Worthington was Vice President of Pharmaceutical Technology at Arthur D. Little, Inc. where he built an international reputation as a thought leader in taste masking, directing programs for pharma, biotech, and drug delivery companies. He is a frequent author and speaker on developing palatable products.

Mr. Worthington earned his BS in Chemistry from Northeastern University and MBA from Babson College. He holds several patents related to sensory technology.

David Tisi, MS
Technical Director
Senopsys LLC

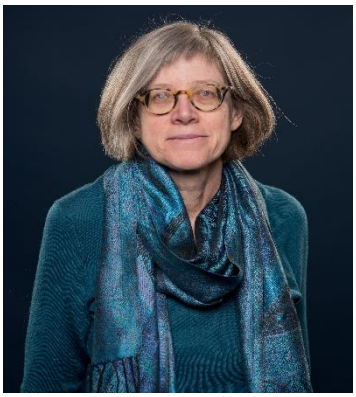
David Tisi is the Technical Director at Senopsys LLC, a specialty services firm dedicated to the development of palatable drug products. He has over 15 years of experience in analytical taste assessment and formulating drug products for improved palatability and taste masking. Mr. Tisi has worked on dozens of OTC, investigational and approved drugs for children and adults, leveraging his background in sensory science and food chemistry.

Mr. Tisi received his Masters in Food Science from Cornell University and began his career in product innovation for PepsiCo and Nestle. Mr. Tisi's work focuses on the modification of drug product formulations for improved flavor quality and has several applications and granted patents relating to drug palatability.

Christopher Hoyte, MD, MBA FAACT FACMT
Medical Director, Rocky Mountain Poison Center
Fellowship Director, Rocky Mountain Poison Center
Professor & Associate Vice Chair, Academic Affairs, Dept of Emergency Medicine, Univ of Colorado SOM

Dr. Christopher Hoyte is the Medical Director of the Rocky Mountain Poison Center and Professor of Emergency Medicine, Medical Toxicology, and Pharmacology at the University of Colorado School of Medicine. Dr Hoyte is also the Fellowship Director of the Rocky Mountain Poison and Drug Safety Medical Toxicology Fellowship Program. He is the current President of the American Academy of Clinical Toxicology, serves on the editorial board of Clinical Toxicology, and the Medical Toxicology Sub-Board of the American Board of Emergency Medicine. He is also the Associate Vice Chair for Academic Affairs for the Department of Emergency Medicine at the University of Colorado Hospital. His research interest is in discovering better ways to deliver care to poisoned patients. He completed his emergency medicine residency at the Cook County Hospital in Chicago, Illinois, his medical toxicology fellowship at the Rocky Mountain Poison and Drug Center in Denver, Colorado, and his Masters in Business Administration (MBA) at the University of Colorado.

Cynthia (Cindy) Connolly, PhD, RN
Rosemarie B. Greco Term Chair
University of Pennsylvania, School of Nursing



Historian and pediatric nurse practitioner Dr. Cynthia Connolly https://www.nursing.upenn.edu/details/profiles.php?id=43 is the Rosemarie B. Greco Term Endowed Professor in Advocacy at the University of Pennsylvania School of Nursing. At Penn, she is also Co-Faculty Director at the Field Center for Children's Policy, Practice, and Research. She received her BSN from the University of Pennsylvania, MSN from the University of Rochester, and PhD from the University of Pennsylvania. She also completed a postdoctoral fellowship at the Center for the History and Ethics of Public Health at Columbia University's Mailman School of Public Health and a legislative fellowship in the office of Paul Wellstone in the US Senate. Connolly's research analyzes the historical forces that have shaped children's health care delivery and family policy in the United States. Her 2018 book, *Children and Drug Safety: Balancing Risk and Protection in Twentieth Century America*, published by Rutgers University Press received the American Public Health Association's Viseltear Award. It was funded through a Robert Wood Johnson Foundation Investigator Award in Health Policy Research grant and a fellowship from the National Endowment for the Humanities. An earlier book, *Saving Sickly Children: The Tuberculosis Preventorium in American Life, 1909–1970* received the Lavinia Dock Award from the American Association for the History of Nursing.

Gilbert Burckart, PharmD
Associate Director for Pediatrics
OCP | OTS | CDER | FDA

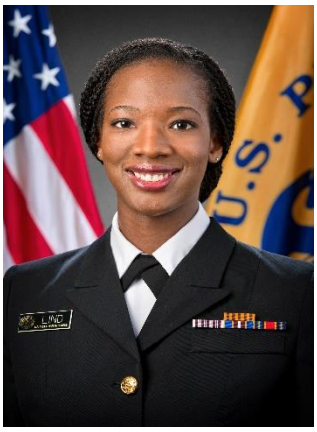
Dr. Gilbert Burckart is presently Associate Director for Pediatrics, Office of Clinical Pharmacology, U.S. Food and Drug Administration. Dr. Burckart received his BS in Pharmacy from the University of Pittsburgh in 1972, his PharmD from the University of Kentucky in 1975, and did his pediatric residency at the UK Medical Center 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. He joined the University of Pittsburgh and the Pittsburgh Children's Hospital in 1982 where his research focused on drug therapy in organ transplant patients. He has been Principal 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 Chairman of the Department of Pharmacy, Director of the Clinical Pharmacogenomics Laboratory, Professor of Pharmacy and Professor of Pediatrics. Dr. Burckart was 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. He is a member of the Pediatric Pharmacy Advocacy Group, and received their Sumner J. Yaffe Lifetime Achievement Award in Pediatric Pharmacology and Therapeutics in 2014.

Dr. Burckart moved to the US FDA in 2008. His duties include the direction of the Pediatric Clinical Pharmacology program within the Office of Clinical Pharmacology, and participation in the FDA's Pediatric Review Committee. His present research program includes analyses of pediatric drug development studies from 1997 to present.

Jennifer N. Lind, PharmD, MPH, MBA
CAPT, United States Public Health Service
Partnerships & Prevention Lead, Medication Safety Program
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention (CDC)



Jennifer N. Lind, PharmD, MPH, MBA, is a Pharmacist and Epidemiologist in CDC's Medication Safety Program and a Captain in the United States Public Health Service Commissioned Corps. CAPT Lind received her Doctor of Pharmacy degree from Florida A&M University in 2007, Master of Public Health from Georgia State University in 2012, and Master of Business Administration from Emory University in May 2022. After receiving her MPH, she completed a two-year fellowship as an Epidemic Intelligence Service (EIS) officer in CDC's National Center for Chronic Disease Prevention and Health Promotion, conducting research and surveillance related to infant and young child feeding practices. Following EIS, she worked in CDC's Birth Defects Branch and eventually became the Lead Scientist for CDC's Treating for Two initiative, focused on safer medication use in pregnancy. CAPT Lind's current work in CDC's Medication Safety Program focuses on reducing harms from the use of medications and she serves as Lead Pharmacist for the PROTECT initiative, an innovative public-private partnership that uses a collaborative, data-driven approach to reduce harms from unintentional medication overdoses in children. CAPT Lind has also been a leader in multiple emergency responses, including COVID-19.

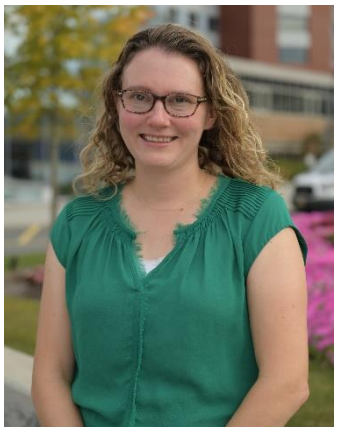
During her 16 years of experience, CAPT Lind has authored/co-authored 36 publications, presented at national and international conferences, and has been interviewed/featured by numerous media outlets, including the national radio show "Top of Mind with Julie Rose," USA Today, Consumer Reports, CNN, The Doctors Channel, and HealthDay News.

Maribeth L. Sivilus, MPH
Epidemiologist, Medication Safety Program, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention (CDC)

Maribeth L. Sivilus is lead epidemiologist in CDC's Medication Safety Program in the Division of Healthcare Quality Promotion. Ms. Sivilus received her Master of Public Health from Columbia University and joined CDC's Medication Safety Program in 2009. Her work focuses on using national public health surveillance data to characterize adverse drug events and to target safety interventions. Over the past decade, Ms. Sivilus has focused her attention on developing innovative approaches to preventing medication overdoses in young children and fostering implementation and adoption of these approaches through CDC's public-private PRevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) Initiative. She has authored over 35 scientific publications, including articles focused on pediatric overdose prevention, in *JAMA*, *Pediatrics*, and *American Journal of Preventive Medicine*.

Rachel Meyers, PharmD, BCPS, BCPPS, FPPA
Clinical Professor
Ernest Mario School of Pharmacy, Rutgers University

Pediatric Clinical Pharmacist
Cooperman Barnabas Medical Center



Dr. Rachel Meyers is a Clinical Professor at the Ernest Mario School of Pharmacy at Rutgers University, and the Pediatric Clinical Pharmacist at Cooperman Barnabas Medical Center in Livingston, New Jersey. Dr. Meyers completed her undergraduate degree at the University of Mary Washington and her Doctor of Pharmacy degree at the University of Connecticut. After graduation she completed a PGY-1 residency at the University of Wisconsin Hospital and Clinics in Madison, Wisconsin, and a PGY-2 residency in Pediatric Pharmacotherapy at the University of North Carolina Children's Hospital in Chapel Hill, North Carolina. In her current position, Dr. Meyers provides both didactic and experiential education in pediatric pharmacotherapy for pharmacy students and residents. She practices in both the Pediatric Intensive Care Unit and General Pediatric Unit at Cooperman Barnabas Medical Center. Dr. Meyers has been a participant in two clinical trials. Her research interests are focused on dosage forms for pediatric patients.

Natalia Davydova, PhD
Principal Scientist, Dietary Supplements and Herbal Medicines Department
United States Pharmacopeia (USP)

Dr. Natalia Davydova is a Principal Scientist at the Dietary Supplements and Herbal Medicines Department at USP. She has over twenty years of experience in development and validation of analytical methods for analysis of drugs and vitamins in solutions, formulations, and biological fluids. She has extensive experience with drug pharmacokinetics, quality assurance of medicines, and post-marketing surveillance.
Dr. Davydova joined USP in 2001, working first for the Reference Standards Laboratory as Chemist III-IV, then at the USP International Technical Alliances Program (ITAP) as Program Manager, and, starting from June 2008, at the Dietary Supplements and Herbal Medicines Department as the scientific liaison with the responsibility of development of dietary supplement ingredients and dosage forms monographs and standards related to performance tests (Disintegration and Dissolution) for dietary supplements.
Before joining USP, Dr. Davydova worked for 3.5 years at the Bioanalytical Laboratory at Department of Pharmacology of Georgetown University, Washington DC, where she was responsible for development and validation of analytical methods for analysis of drugs in formulations and biological fluids. Prior to her career at Georgetown University, Dr. Davydova worked as a post-doctoral research associate at the Department of Medicine of University of Florida, Gainesville, FL on vitamins stability and drugs pharmacokinetics and metabolism.

Suzanne Doyson, MD, MPH, FACMT, ASAM
Director Connecticut Poison Control Center, UConn Health
Associate Professor Department Emergency Medicine, UConn Health

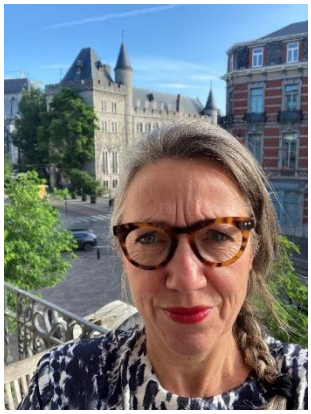
Dr. Suzanne Doyon has over 25 years of poison center directorship experience. She is currently the Director of the Connecticut Poison Control Center and Associate Professor in the Department of Emergency Medicine both at UConn Health. She completed medical school and emergency medicine residency at McGill University in Montreal, Canada (1991). She completed her medical toxicology fellowship at the Medical College of Pennsylvania (1993) and completed a Master of Public Health in Epidemiology at University of Maryland (2018). Her research interests include acetaminophen toxicity, opioid use disorder, naloxone distribution, and public policy regarding prevention of unintentional pediatric exposures to pharmaceuticals.

Judith R. Chin, DDS, MS
Resident Program Director and Professor, Department of Pediatric Dentistry
Nova Southeastern College of Dental Medicine

Dr. Judith Chin is the Pediatric Dental Resident Program Director at Nova Southeastern University located in Ft. Lauderdale, Florida. She is Board Certified in Pediatric Dentistry. She has been involved with pediatric dentistry for over 35 years. She obtained a BS degree in Chemistry from Indiana University. She obtained her first dental degree at the Indiana University School of Dentistry and practiced for several years as a general dentist. She then started a residency in Pediatric Dentistry at the University of Illinois at Chicago where she received both a Certificate of Specialty in Pediatric and Master's Degree in Oral Science. She then completed a National Institute of Health Fellowship in Craniofacial Anomalies at the University of California, San Francisco.

Dr. Chin has published over 88 articles, four book chapters and research abstracts in peer-reviewed dental, medical and educational literature. She has been active in over 100 clinical research trials. She has been involved with over $10 million dollars in educational, service, training, and research grants. She serves as a Reviewer for four highly respected peer-reviewed international dental journals. She is active on a national level as a Council Member of the Council for Scientific Affairs for the American Academy of Pediatric Dentistry (AAPD). She has presented lectures throughout the United State, Europe, and Asia on a variety of topics related to prevention of dental caries, infection control and pediatric dentistry.

Catherine TULEU, Docteur en Pharmacie, PhD
Professor in Paediatric Pharmaceutics
Equality, Diversity, and Inclusion Committee co-Chair
Postgraduate Research Tutor
UCL School of Pharmacy, London, United Kingdom



Catherine TULEU, Docteur en Pharmacie, PhD, is Professor in Paediatric Pharmaceutics at UCL School of Pharmacy, UK. (https://orcid.org/0000-0001-8384-357X ; H-index 27) Her research, inherently translational, ranges from formulation, methodology development to clinical implementation, integrating the following themes: children centric excipient research; repurposing by reformulating for better medicines for children; development of innovative age appropriate dosage forms (especially for under 5s); administration issues and devices and sensory pharmaceutics™ (dosage form acceptability and in vitro/in vivo taste assessment). https://www.ucl.ac.uk/pharmacy/people/professor-catherine-tuleu

Her spin out company senCeuTics Ltd. specializes in pharmaceutical sensory evaluation and offers a full spectrum of preclinical, clinical and paediatric formulation services under one roof. https://senceutics.com/

She is the founder and chairperson of the European Paediatric Formulation Initiative (EuPFI), a consortium working in a pre-competitive way on paediatric drug formulations. http://www.eupfi.org/
https://www.linkedin.com/in/catherine-tuleu-9b842214/

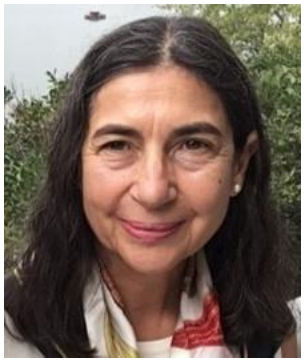
Theresa Michele, PhD
Director
ONPD | OND | CDER | FDA

Dr. Theresa Michele is currently the Director of the Office of Nonprescription Drugs (ONPD) in the Office of New Drugs, Center of Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). Prior to joining FDA in the Division of Pulmonary and Allergy Drug Products, she spent 10 years in industry, with clinical research experience across a variety of therapeutic areas in both commercial and development stage companies. She is board certified in internal medicine, pulmonary medicine, and critical care medicine, completing her training at Johns Hopkins University, where she currently serves on the faculty.

Kristine A. Parbuoni, PharmD, BCPPS
Associate Professor, Department of Practice, Sciences, and Health Outcomes Research
Director of Postgraduate Training
Pediatric Clinical Pharmacy Specialist
University of Maryland, School of Pharmacy

Dr. Kristine Parbuoni is an Associate Professor at the University of Maryland School of Pharmacy in the Department of Practice, Sciences and Health Outcomes Research. Dr. Parbuoni serves as the PGY2 Pediatric Residency Program Director at the University of Maryland. She is also the Director of Postgraduate Training, where she oversees all of the pharmacy residents and fellows at the University of Maryland. Kristine obtained her Doctor of Pharmacy from the University of Maryland School of Pharmacy in Baltimore, Maryland. She then completed a PGY-1 Pharmacy Residency and PGY-2 Pediatric Residency at The Johns Hopkins Hospital. Dr. Parbuoni is a Board Certified Pediatric Pharmacotherapy Specialist (BCPPS) and she maintains a clinical practice site in the Pediatric Intensive Care Unit at the University of Maryland Children's Hospital where she precepts pharmacy students and residents. Her research interests include pediatric pharmacokinetics, sedation in critically ill children, and pediatric infectious diseases.

Danae Christodoulou, PhD
Branch Chief
ONDP | OPQ | CDER | FDA



Dr. Danae Christodoulou is a Branch Chief with the Office of New Drug Products, Office of Pharmaceutical Quality, CDER/FDA currently supporting Non-Prescription Drug Products. Danae has been with FDA since 1998 and served as a CMC reviewer, CMC Lead, and Branch Chief. She has a PhD in Inorganic Chemistry from the University of Michigan and worked previously as a senior research chemist in R&D at Johnson Matthey Inc. and the National Cancer Institute.

Swapan K De, PhD
Senior Chemist
ONDP | OPQ | CDER | FDA

Currently, Dr. Swapan K. De is a Senior Chemist and serving as a 'Senior Product Quality Assessor" for the Office of New Drug Products (ONDP). He is working with the Division of Non-Prescription Drug Products (DNPD) as a Team Lead (TL) since 2012. He started his career at FDA in 1998 as a review chemist and since then he has worked in various capacities with multiple Clinical Divisions. He has participated in the revision and updating of policies, guidelines, and guidance's. In his role as Application Team Lead (ATL), he directs, manages, and coordinates the work of the professional CMC reviewing team to finalize approval or non-approval of the New Drug Applications (NDAs). He serves in multiple guidelines working committees related to non-prescription application as well as Over-The-Counter Monograph Drug User Fee Program (OMUFA). He serves as a "labeling expert" for ONDP and resolves complex labeling issues for multiple offices within CDER. He is also serving as a USP-Member on the Committee of Experts from 2015. He helped organized a USP-India workshop at Hyderabad, India on "Quality of Chemical Medicines-Impact of Impurities and strategies for Control" in 2016 and represented FDA.

Before joining FDA, he was a laboratory Scientist at the University of Kansas Medical Center and later at the National Institute of Health (NIH). He has more than 35 publications in book chapters and reputed journals. He started his career as a protein biochemist, but later gained experience as a peptide chemist and molecular biologist. He performed his graduation work at Indian Institute of Chemical Biology and received his Ph.D. in Biochemistry from the University of Kolkata, India.