Opioid and Nicotine Use, Dependence, and Recovery: *Influences of Sex and Gender*

Health Policy, Research, Professional Education, and Clinical Care

September 27-28, 2018

FDA White Oak Campus, Bldg. 31, Great Room

INTRODUCTION

Sex differences may influence susceptibility to substance use disorders, which could have implications for optimal prevention and treatment. Gender influences also impact public health by influencing prescription rates, care, and treatment-seeking behaviors. To identify and treat at-risk women, researchers, educators, and clinicians must be able to recognize and consider sex and gender differences in substance use, misuse, and recovery.

The U.S. Food and Drug Administration's Office of Women's Health, in collaboration with the Center for Drug Evaluation and Research and Center for Tobacco Products, presents this 2-day meeting, ***Scientific Conference — Opioid and Nicotine Use, Dependence, and Recovery: Influences of Sex and Gender,*** to address this important issue. This conference will include presentations by experts in the fields of opioid and tobacco research, professional education, and clinical care on the biological (sex) and sociological (gender) influences on use, misuse, and recovery.

LEARNING OBJECTIVES

In relation to the sex and gender differences associated with opioid and nicotine use, dependence, and recovery, meeting participants will:

- Appreciate the sex and gender interactions in outcomes across the lifespan;
- understand the unique role of Health & Human Services (HHS) and other federal stakeholders;
- recognize research gaps and emerging therapeutic areas for drugs, devices, and behavioral approaches;
- recognize the necessity of a comprehensive, integrative approach to the treatment of addiction.

U.S. FOOD & DRUG ADMINISTRATION

Dear Esteemed Colleagues:

On behalf of the U.S. Food and Drug Administration (FDA), I am pleased to welcome you to today's conference, "Opioid and Nicotine Use, Dependence, and Recovery: Influences of Sex and Gender."

Our goal at FDA is to advance the Agency's vital mission to protect and promote the public health of millions of Americans. This is a responsibility that we take very seriously. Substance use disorders are one of the largest public health crises facing our country, and addressing addiction is one of my, and FDA's, highest priorities.

Currently, opioid misuse and smoking are the leading causes of preventable death and chronic disease in our country. The surge in opioid and nicotine-related deaths in women over the past decade has prompted an urgent need to reflect on sex- and gender-associated factors leading to increased substance use and misuse in women. I strongly believe that prevention and treatment strategies for substance use disorders should consider the individual needs of each patient. This is why I am so supportive of this meeting's unique and important focus on gender-specific challenges facing individuals struggling with addiction. The program highlights FDA's dedication to considering sex and gender in research and policy to ensure optimal outcomes and better health information for both men and women.

Through a collaborative effort, FDA's Office of Women's Health (OWH), the Center for Drug Evaluation and Research (CDER), and the Center for Tobacco Products (CTP), have brought together thought leaders including policy experts, world-renowned opioid and nicotine researchers, and patients affected by addiction for this 2-day public meeting. Our goal is to provide a platform to share current research and policies related to the causes, consequences, prevention, and treatment strategies of opioid and nicotine substance use disorders—all with a focus on sex and gender. I hope that discussing gender differences in relation to critical public health issues in a forum such as this will highlight opportunities to improve individualized care for more Americans. Addiction is a chronic illness. We must treat it as such, lessening the associated stigma and enhancing our focus on treatment.

I believe the success of this meeting will be determined not only by the quality of the information presented today, but also on the high level of collective commitment toward battling the opioid and nicotine public health crises across government, academic and nonprofit stakeholders that I believe will be sustained following this meeting. I pledge my continued support to address the devastation of substance misuse in our country and I am pleased that you are joining me in this endeavor.

Sincerely,

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

U.S. FOOD & DRUG ADMINISTRATION

Dear Friends and Colleagues,

On behalf of FDA's Office of Women's Health (OWH), Center for Drug Evaluation and Research (CDER), and Center for Tobacco Products (CTP) we enthusiastically welcome you to this collaborative two-day scientific conference on *Opioid and Nicotine Use, Dependence and Recovery: Influences of Sex and Gender*. At FDA, we are responsible for protecting the public health by ensuring that drugs, medical devices, vaccines, and other biological products are safe and effective. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

In addition, our Centers and Offices advance the public health by facilitating product innovations; innovations that can only be informed through rigorous scientific discovery. Innovation and advancement in medicine have never been so crucial, as our country faces an addiction epidemic touching hundreds of thousands of lives. This is precisely why today's meeting is imperative – by bringing together top scientists and policy experts on opioid and nicotine addiction and treatment, science informs the regulatory space. This meeting therefore represents a step toward advancing the Agency's priority of addressing the opioid overdose crisis effecting over 40,000 Americans each year and quelling the devastating public health impact of tobacco use tied to addiction, which costs the lives of over 400,000 Americans annually.

This meeting also highlights the Agency's investment in understanding and addressing addiction through the lens of sex and gender differences, as both biological and social factors lead women and men to use and recover from substances differently. Since its inception in 1994, OWH has played a key role in advising FDA and external stakeholders on scientific, ethical, and policy issues related to sex and gender differences and women's health. OWH works across the Agency on collaborative efforts, such as today's meeting, to bring awareness to public health issues that differentially affect women and men. CDER has been advancing inclusive science and medicine since the 1990s by implementing regulations and guidances that require data reporting and analysis by sex, race, ethnicity, and age for new drug applications. Within CDER, numerous researchers have ongoing scientific initiatives advancing regulatory science related to sex and gender differences to improve the country's access to safe and effective drugs. CTP's goal is to change the future of tobacco use and nicotine addiction in the U.S. through the use of regulatory policy, pre- and post-market controls, compliance and enforcement, and public education. Armed with a comprehensive knowledge of sex and gender, age, race, ethnicity and socio-economic data on tobacco product usage, CTP strives to continue to reduce tobacco-related death and diseases in our country for generations to come.

Importantly, this meeting's collective effort extends outside of FDA, with help from collaborators and colleagues across federal agencies, academia, and the nonprofit space. We thank all the members of our Executive Planning and Scientific Steering Committees and their collaborating institutions for their dedication to this important topic. Finally, we thank the experts who have generously given their time to travel to this meeting to share their knowledge. We are confident that the world-class scientific research and innovative ideas presented at this two-day meeting will continue to inform work in policy and the regulatory space to improve the lives of women and men struggling with substance use disorders.

Sincerely,

Marsha B. Henderson, MCRP
Associate Commissioner
for Women's Health

Janet Woodcock, MD
Director,
Center for Drug Evaluation and Research

Mitch Zeller, JD
Director,
Center for Tobacco Products

PROGRAM AT A GLANCE

THURSDAY, SEPTEMBER 27, 2018

8:30 AM - 8:40 AM
Welcome

8:40 AM - 8:55 AM
Keynote

8:55 AM - 9:25 AM
Discussing Sex as A Biological Variable: Terminology and Policy

9:25 AM - 10:25 AM
Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders

10:25 AM - 10:40 AM
Break

10:40 AM - 12:10 PM
Landscape of Federal Research Policy and Regulation of Opioids and Nicotine

12:10 PM - 1:10 PM
Lunch

1:10 PM - 1:40 PM
Pain, Sex, and Death

1:40 PM - 2:40 PM
Sex and Gender Influences within Integrative Approaches to Treatment of Addiction

2:40 PM - 2:55 PM
Break

2:55 PM - 3:15 PM
Innovative Program and Research Initiatives: Thinking Outside the Box

3:15 PM - 3:35 PM
Conversations with Patients Overcoming Opioid and Nicotine Dependency

3:35 PM - 4:00 PM
Capstone: Sex as a Biological Variable in the Opioid Crisis

FRIDAY, SEPTEMBER 28, 2018

8:30 AM - 8:40 AM
Welcome

8:40 AM - 9:00 AM
Keynote: Opioid and Nicotine Use: A Conversation with the U.S. Surgeon General

9:00 AM - 9:30 AM
Adverse Childhood Events and Trauma Across the Lifespan: Sex and Gender Contributions to Development of Substance Use Disorders

9:30 AM - 11:00 AM
SABV: Brain, Pain, and Addiction

11:00 AM - 11:15 AM
Break

11:15 AM - 12:15 PM
Hormones: From Basic Research to Addiction Medication

12:15 PM - 1:15 PM
Lunch

1:15 PM - 2:15 PM
Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period

2:15 PM - 2:30 PM
Break

2:30 PM - 3:15 PM
Sex and Gender Contributions in the Trajectory of Opioid and Nicotine Use and Addiction

3:15 PM - 3:55 PM
Recognizing the Benefits of Health Communications Research in Substance Abuse

3:55 PM - 4:00 PM
Wrap-up

THURSDAY, SEPTEMBER 27, 2018

8:30 AM - 8:40 AM — **Welcome**

Marsha B. Henderson, MCRP. Associate Commissioner for Women's Health, FDA OWH

Mitch Zeller, JD. Director, FDA CTP

8:40 AM - 8:55 AM — **Keynote**

Scott Gottlieb, MD. Commissioner of Food and Drugs

8:55 AM - 9:25 AM — **Discussing Sex as A Biological Variable: Terminology and Policy**

Speakers will discuss the importance of including sex as a biological variable (SABV) in clinical and preclinical studies, provide a basic background on biological sex differences, and introduce opioid and nicotine addiction and its growing influence on women's health.

Janine Clayton, MD. Associate Director for Research on Women's Health; Director, NIH ORWH

Marjorie Jenkins, MD, MEdHP, FACP. Director, Medical Initiatives and Scientific Engagement, FDA OWH

9:25 AM - 10:25 AM — **Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders**

This panel will discuss the data and databases available to inform the epidemiology of opioid and nicotine use, dependence, and recovery highlighting opportunities to determine sex differences and gender influences in this space and across demographic groups.

Moderator: **Wilson Compton, MD, MPE.** Deputy Director, NIH NIDA

Maciej Goniewicz, PharmD, PhD. Associate Professor of Oncology, Department of Health Behavior, Roswell Park Comprehensive Cancer Center

Tamra Meyer, PhD, MPH. Lead Epidemiologist, Office of Surveillance and Epidemiology, FDA CDER

Brenna VanFrank, MD, MSPH. Senior Medical Officer, CDC OSH

Shelly Greenfield, MD, MPH. Professor and Chair, Department of Psychiatry, Harvard Medical School; Chief Academic Officer, Director of Clinical and Health Services Research and Education, Division of Alcohol and Drug Abuse, McLean Hospital

10:25 AM - 10:40 AM — **Break**

10:40 AM - 12:10 PM — **Landscape of Federal Research Policy and Regulation of Opioids and Nicotine**

For this panel, federal representatives will present a regulatory review of NRTs, MAT and nicotine cessation drug indications and approval processes and will discuss the policies and processes in place to evaluate and consider population data in relation to opioids and nicotine use and treatment.

Moderator: **Mitch Zeller, JD.** Director, FDA CTP

Wilson Compton, MD, MPE. Deputy Director, NIH NIDA

Mitch Zeller, JD. Director, FDA CTP

Brian King, PhD, MPH. Deputy Director for Research Translation, Office on Smoking Health, CDC NCCDPHP

Scott Winiecki, MD. Supervisory Physician, Professional Affairs and Stakeholder Engagement, FDA CDER

Tony Campbell, RPH, DO, FACP, CDR USPHS. Medical Officer, SAMHSA CSAT

12:10 PM - 1:10 PM **Lunch**

1:10 PM - 1:40 PM **Pain, Sex, and Death**

This talk will detail nervous system mechanisms mediating the perception and inhibition of pain, address sex differences in pain research, implications for treatment, and the link between addiction and treatment for pain.

Jeffrey Mogil, PhD. Professor, Department of Psychology, McGill University

1:40 PM - 2:40 PM **Sex and Gender Influences within Integrative Approaches to Treatment of Addiction**

This panel will discuss the current research landscape related to sex and gender differences associated with NRTs, MAT and nicotine cessation drug use and effectiveness.

Moderator: **Cora Lee Wetherington, PhD.** Women & Sex/Gender Differences Research Coordinator, NIH NIDA

Sherry McKee, PhD. Professor, Psychiatry; Director, Yale Behavioral Pharmacology Laboratory, Yale University School of Medicine

Hendrée Jones, PhD. Professor, Department of Obstetrics and Gynecology; Executive Director, UNC Horizons, University of North Carolina, Chapel Hill

Kelly Barth, DO. Associate Professor, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina

2:40 PM - 2:55 PM **Break**

2:55 PM - 3:15 PM **Innovative Program and Research Initiatives: Thinking Outside the Box**

Speakers will discuss groundbreaking research and its potential impacts on policy for battling addiction epidemics.

Mitra Ahadpour, MD, DABAM. Principal Deputy Director, Office of Translational Sciences, FDA CDER

Jack Stein, PhD. Director, Office of Science Policy and Communications, NIH NIDA

Michelle Tarver, MD, PhD. Director, Patient Science & Engagement Program, FDA CDRH

3:15 PM - 3:35 PM **Conversations with Patients Overcoming Opioid and Nicotine Dependency**

Patients will highlight their experiences, the challenges associated with substance initiation and dependence, and the victories and adversities accompanying recovery.

Moderator: **Marsha B. Henderson, MCRP.** Associate Commissioner for Women's Health, FDA

3:35 PM - 4:00 PM **Capstone: Sex as a Biological Variable in the Opioid Crisis**

Nora Volkow, MD. Director, NIH NIDA

FRIDAY, SEPTEMBER 28, 2018

8:30 AM - 8:40 AM **Welcome**

RADM Denise Hinton, MS. Chief Scientist, FDA

8:40 AM - 9:00 AM **Keynote: Opioid and Nicotine Use: A Conversation with the U.S. Surgeon General**

VADM Jerome Adams, MD, MPH. Twentieth Surgeon General of the United States

9:00 AM - 9:30 AM **Adverse Childhood Events and Trauma Across the Lifespan: Sex and Gender Contributions to Development of Substance Use Disorders**

This presentation will highlight the links between early life physical, sexual, and emotional maltreatment and bullying, and adult depression, anxiety, post-traumatic stress, and substance use disorders.

Martin Teicher, MD, PhD. Director, Developmental Biopsychiatry Research Program, McLean Hospital; Associate Professor of Psychiatry, Harvard Medical School

9:30 AM - 11:00 AM **SABV: Brain, Pain, and Addiction**

In this panel, speakers will share foundational scientific research on the brain, pain, and addiction. Discussion will focus on sex differences in the addicted brain, the opioid system and pain mechanisms, and the development of behavioral and pharmacological methods of reducing and preventing substance use disorders.

Moderator: **Jill Becker, PhD.** Biopsychology Area Chair; Patricia Y. Gurin Collegiate Professor of Psychology; Research Professor, Molecular & Behavioral Neuroscience Institute, University of Michigan

Anne Murphy, PhD. Professor, Neuroscience Institute, Georgia State University

Rita Valentino, PhD. Director, Division of Neuroscience and Behavior, NIH NIDA

George Koob, PhD. Director, NIH NIAAA

Marilyn Carroll, PhD. Professor of Psychiatry and Neuroscience, University of Minnesota

11:00 AM - 11:15 AM **Break**

11:15 AM - 12:15 PM **Hormones: From Basic Research to Addiction Medication**

Panelists will address the role of gonadal steroid hormones in addiction, behavioral and brain outcomes in substance use disorders, and studies of progesterone as a potential treatment for nicotine addiction.

Moderator: **Gioia Guerrieri DO, FAPA.** Medical Officer, Division of Anesthesia, Analgesia, and Addiction Products, FDA CDER

Jill Becker, PhD. Biopsychology Area Chair; Patricia Y. Gurin Collegiate Professor of Psychology; Research Professor, Molecular & Behavioral Neuroscience Institute, University of Michigan

Teresa Franklin, PhD. Research Associate Professor of Neuroscience, University of Pennsylvania

Mehmet Sofuoglu, MD, PhD. Professor of Psychiatry, Yale University School of Medicine

FRIDAY CONTINUED

12:15 PM - 1:15 PM **Lunch**

1:15 PM - 2:15 PM **Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period**

Panelists will address current guidance recommending how and when to include pregnant women in clinical trials, prenatal exposure to nicotine and opioids, and addiction treatments specific to pregnant and postpartum women.

Moderator: **Terri Cornelison, MD, PhD, FACOG.** Assistant Director for Health of Women, FDA CDRH

Mishka Terplan, MD, MPH. Professor, Virginia Commonwealth University School of Medicine

Hendrée Jones, PhD. Professor, Department of Obstetrics and Gynecology, UNC Chapel Hill School of Medicine; Executive Director, UNC Horizons, University of North Carolina, Chapel Hill

Cheryl A. Oncken, MD, MPH. Professor and Chair, Department of Medicine, UConn Health

Christine Pham Nguyen, MD. Deputy Director for Safety, Division of Bone, Reproductive and Urologic Products, Office of New Drugs, Center for Drug Evaluation and Research, FDA CDER

2:15 PM - 2:30 PM **Break**

2:30 PM - 3:15 PM **Sex and Gender Contributions in the Trajectory of Opioid and Nicotine Use and Addiction**

Presenters will tell the behavioral and biological story of addiction, from initiation to addiction and the development of addiction treatments, discussing factors that differentially affect initiation of opioid and nicotine use in men and women, and the differential effectiveness of addiction treatments.

Kenneth Perkins, PhD. Professor of Psychiatry, University of Pittsburgh

Kathleen Brady, MD, PhD. Distinguished University Professor; Vice President for Research; Director, South Carolina Clinical & Translational Research Institute, Medical University of South Carolina

3:15 PM - 3:55 PM **Recognizing the Benefits of Health Communications Research in Substance Abuse**

Speakers will discuss gendered communications and health communications outcomes, social media mining research, and other outreach initiatives associated with tobacco and opioid communication and cessation resources.

Christine Lee, PharmD, PhD. General Health Scientist, Professional Affairs and Stakeholder Engagement, FDA CDER

Erik Augustson, PhD, MPH. Behavioral Scientist and Program Director, Tobacco Control Research Branch (TCRB), Division of Cancer Control and Population Sciences (DCCPS), NIH NCI

3:55 PM - 4:00 PM **Wrap-up**

Marjorie Jenkins, MD, MEdHP, FACP. Director, Medical Initiatives and Scientific Engagement, FDA OWH

KEYNOTE SPEAKERS

SCOTT GOTTLIEB, MD
COMMISSIONER OF FOOD AND DRUGS

Dr. Scott Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner. He also worked on implementation of the Medicare drug benefit as a senior advisor to the Administrator of the Centers for Medicare and Medicaid Services, where he supported policy work on quality improvement and the agency's coverage process, particularly as it related to new medical technologies. In 2013 Dr. Gottlieb was appointed by the Senate to serve on the Federal Health Information Technology Policy Committee, which advises the Department of Health and Human Services on healthcare information technology. He completed a residency in internal medicine at the Mount Sinai Medical Center in New York, and is a graduate of the Mount Sinai School of Medicine and Wesleyan University in Middletown, Connecticut, where he studied Economics.

VADM JEROME M. ADAMS, MD, MPH
U.S. SURGEON GENERAL

Dr. Jerome M. Adams, the 20th Surgeon General of the United States, was sworn into office by Vice President Mike Pence on September 5, 2017. Dr. Adams, a board-certified anesthesiologist, served as Indiana State Health Commissioner from 2014 to 2017. Dr. Adams has bachelor's degrees in both biochemistry and psychology from the University of Maryland Baltimore County, a master of public health degree from the University of California at Berkeley, and a medical degree from Indiana University School of Medicine. Dr. Adams was also an associate professor of clinical anesthesia at Indiana University School of Medicine and a staff anesthesiologist at Eskenazi Health, where he was Chair of the Pharmacy and Therapeutics Committee. He has served in leadership positions at a number of professional organizations, including the American Medical Association, the Indiana State Medical Association and the Indiana Society of Anesthesiologists.

CAPSTONE SPEAKER

NORA D. VOLKOW, MD
DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Dr. Nora D. Volkow became Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health in May 2003. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. Dr. Volkow's work has been instrumental in demonstrating that drug addiction is a disease of the human brain. As a research psychiatrist and scientist, Dr. Volkow pioneered the use of brain imaging to investigate the toxic effects and addictive properties of abusable drugs. Her studies have documented changes in the dopamine system affecting, among others, the functions of frontal brain regions involved with motivation, drive, and pleasure in addiction. She has also made important contributions to the neurobiology of obesity, ADHD, and aging.

CONFERENCE SPEAKERS AND MODERATORS

Mitra Ahadpour, MD, DABAM

Principal Deputy Director, Office of Translational Sciences, FDA CDER

Innovative Program and Research Initiatives: Thinking Outside the Box

Mitra Ahadpour is a board-certified addiction medicine physician and the Principal Deputy Director of the Office of Translational Sciences (OTS) at the U.S. Food and Drug Administration. Dr. Ahadpour previously was the Director of the Division of Pharmacologic Therapies at the Substance Abuse and Mental Health Services Administration. She led the accreditation and certification of more than 1,500 opioid treatment programs and health professionals on safe opioid prescribing and medication assisted treatment. In private practice, she contributed to legislation making Maryland smoke-free. She is the recipient of multiple awards for her novel program development, including the U.S. Department of Health and Human Services 2015 Hubert H. Humphrey Award for Service to America and 2016 HHS Ignite competition for creating and fully implementing the nationwide Rapid Opioid Alert and Response (ROAR). Dr. Ahadpour earned her medical degree from the University of Maryland and completed residency at George Washington University.

Erik Augustson, PhD, MPH

Behavioral Scientist and Program Director in the Tobacco Control Research Branch (TCRB), Division of Cancer Control and Population Sciences (DCCPS), NIH NCI

Recognizing the Benefits of Health Communications Research in Substance Abuse

Dr. Augustson's current primary lines of research involve studies considering the use of psychological principles and functionality of emerging technologies to improve reach and engagement of interventions for health behaviors and ultimately improved treatment outcomes. He has also performed research in the areas of the epidemiology of tobacco use and nicotine dependence, tobacco use among individuals with comorbid mental health and substance abuse, perceived risk, chronic pain, cancer screening, sun safety, obesity, and health communication topics. He has more than 90 scientific publications and has made more than190 scientific presentations.

Kelly Barth, DO

Associate Professor, Medical University of South Carolina College of Medicine, Department of Psychiatry and Behavioral Sciences

Sex and Gender Influences within Integrative Approaches to Treatment of Addiction

Dr. Barth is an Associate Professor in the Departments of Psychiatry and Internal Medicine at Medical University of South Carolina, where she is actively engaged in research, clinical care, and education at the local and national level. Her area of focus is in chronic pain and in the identification and management of opioid use disorders across different medical settings. She is the PI of a K23 Award investigating the use of buprenorphine-assisted opioid discontinuation in patients with chronic pain, and a previous recipient of a BIRCWH award evaluating gender differences in the effects of sleep deprivation on pain.

Jill B. Becker, PhD

Biopsychology Area Chair, Patricia Y. Gurin Collegiate Professor of Psychology, and Research Professor, Molecular & Behavioral Neuroscience Institute, University of Michigan

Hormones: From Basic Research to Addiction Medication

Moderator: SABV: Brain, Pain, and Addiction

Professor Becker completed her PhD in Neuroscience at the University of Illinois. She joined the faculty at the University of Michigan in 1987. Professor Becker is one of the pioneers in the field of sex differences in brain and behavior. She discovered sex differences in and hormonal modulation of the dorsal striatum during her dissertation research. Professor Becker's research elegantly demonstrates that there are sex differences in the neural systems mediating motivation and addiction. Current experiments in the laboratory investigate the effects of psychomotor stimulants on behavior in rats, how ovarian hormones act in the brain to influence motivated behaviors, as well as the impact of oxytocin on drug taking behavior. Professor Becker's research program seeks to relate behavioral measures to underlying neurobiological mechanisms and translate these findings to more effective treatments for both females and males.

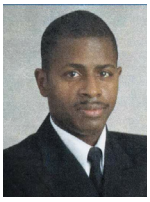
Kathleen T. Brady, MD, PhD

Distinguished University Professor, Vice President for Research, Director, South Carolina Clinical & Translational Research (SCTR) Institute

Sex and Gender Contributions in the Trajectory of Opioid and Nicotine Use and Addiction

Dr. Brady is an experienced clinical and translational researcher and has been conducting scientific investigations and clinical work in the field of addictions and psychiatric disorders for over 30 years. Her research focuses on pharmacotherapy of substance use disorders, comorbidity of psychiatric disorders and addictions (e.g., posttraumatic stress disorder and bipolar disorder), gender differences and women's issues in addictions, and the neurobiologic connections between stress and addictions. She has received numerous federal research grants and has published over 300 peer-reviewed journal articles and co-edited 10 books. She is the principal Investigator of MUSC's Clinical and Translational Science Award (CTSA), Principal Investigator of the Southern Consortium Node of the NIDA- funded Clinical Trials Network and Director of MUSC's Women's Research Center. She has been the Co- Director of MUSC's NIH- funded post-doctoral fellowship program focused on translational research training in addictions for 15 years.

CONFERENCE SPEAKERS AND MODERATORS



Tony Campbell, RPH, DO, FACP, CDR USPHS

Medical Officer, Substance Abuse and Mental Health Service Administration

Landscape of Federal Research Policy and Regulation of Opioids and Nicotine

Dr. Anthony Campbell is a Clinical Specialty Consultant with the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment in the Division of Pharmacologic Therapies (SAMHSA/CSAT/DPT) and serves as a Commander in the United States Public Health Service. In his role at SAMHSA, he is responsible for planning, directing and evaluating the development of pharmacotherapy-based treatment standards and guidelines that require specialized DPT medical review. In addition he is an adjunct professor at both Howard University Colleges of Pharmacy and Medicine in Washington DC. Dr. Campbell earned two bachelor's degrees from Howard University; Chemistry (85) and Pharmacy (88). He earned his Doctorate of Osteopathic Medicine from Ohio University (94). Additional training followed including a residency in Internal Medicine, with Board certification and specific training in Clinical Pharmacology.

Marilyn E. Carroll, PhD

Professor of Psychiatry and Neuroscience, University of Minnesota

SABV: Brain, Pain, and Addiction

Dr. Marilyn Carroll received her Bachelors degrees in Psychology and Pre-Law from Penn State and her PhD from Florida State University in Psychobiology and Neuroscience in 1975. Her Postdoctoral training was at the University of Minnesota in Psychology and Neuroscience under an NRSA award with Dr. Richard Meisch. Dr. Carroll's research career has focused on causes and treatments for addiction. She has developed models for studying all stages of drug addiction, from initiation, maintenance, escalation of drug seeking, cessation of drug use /withdrawal to incubation of craving leading to relapse. Her recent focus has been on developing long-term self-maintained behavioral strategies to prevent or reduce addiction, such as healthy, competing nondrug rewards (e.g., aerobic exercise) to allow the animal to choose a healthy behavior vs. taking an addictive drug.

Janine Clayton, MD

NIH Associate Director for Research on Women's Health; Director, NIH ORWH

Discussing Sex as A Biological Variable: Terminology and Policy

Janine Austin Clayton, M.D., is Associate Director for Research on Women's Health and Director of the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH). Since assuming this role in 2012, Dr. Clayton has strengthened NIH support for research on diseases, disorders, and conditions that affect women. She is the architect of a trans-NIH initiative to require scientists to consider sex as a biological variable across the research spectrum. As co-chair of the NIH Working Group on Women in Biomedical Careers with NIH Director Dr. Francis Collins, Dr. Clayton also leads NIH's efforts to advance women in science careers. Prior to joining ORWH, Dr. Clayton was the Deputy Clinical Director of the National Eye Institute (NEI), and has been an attending physician and clinical investigator in cornea and uveitis at the NEI since 1996. In the course of her research on ocular surface disease, she discovered a novel form of disease associated with premature ovarian insufficiency in young women, which set the stage for her commitment to rigorous, thoughtful exploration of the role of sex and gender in health and disease.

Wilson Compton, MD, MPE

Deputy Director, NIH NIDA

Moderator: Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders

Wilson M. Compton, M.D., M.P.E. is Deputy Director of the National Institute on Drug Abuse (NIDA) of the National Institutes of Health. Prior to his current appointment, Dr. Compton served as the Director of NIDA's Division of Epidemiology, Services and Prevention Research from 2002 until 2013. In this leadership role, he oversaw the scientific direction of a complex public health research program of national and international scope addressing: 1) the extent and spread of drug abuse, 2) how to prevent drug abuse, and 3) how to implement drug abuse prevention and treatment services as effectively as possible. Of note, he led the development of the Population Assessment of Tobacco and Health (PATH), a large scale longitudinal population study with 45,971 study subjects ages 12 and older to assess the impact of new tobacco regulations in the United States. This project, jointly sponsored by NIDA and the U.S. Food and Drug Administration, includes prospective data collection, using both surveys and biological assessments of tobacco exposures, risk factors and health outcomes. Before joining NIDA, Dr. Compton was a tenured faculty member in psychiatry and Director of the Master in Psychiatric Epidemiology Program at Washington University in Saint Louis as well as Medical Director of Addiction Services at the Barnes-Jewish Hospital in Saint Louis. Dr. Compton received his undergraduate education from Amherst College. He attended medical school and completed his residency training in psychiatry at Washington University.

CONFERENCE SPEAKERS AND MODERATORS

Terri Cornelison, MD, PhD, FACOG

Assistant Director for Health of Women, FDA CDRH

Moderator: Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period

Dr. Terri Cornelison is the first Director of the Health of Women Program, Assistant Director for the Health of Women, Office of the Center Director, Center for Devices and Radiologic Health (CDRH), U.S. Food and Drug Administration (FDA), U.S. Department of Health and Human Services, a Board Certified Gynecologic Oncologist, and a Fellow of The American Congress of Obstetricians and Gynecologists. As the Director of the Health of Women Program, Dr. Cornelison is building a program with an overarching mission to improve the health of all women. Before joining the FDA, Dr. Cornelison was the first Associate Director for Clinical Research, Office of Research on Women's Health (ORWH), Office of the Director, National Institutes of Health, where she was responsible for the clinical oversight of a complex biomedical national research program involving basic and pre-clinical studies, clinical trials, and epidemiologic studies. Dr. Cornelison received her medical degree from Yale University, and her Ph.D. from George Washington University. She completed her internship and residency in Obstetrics and Gynecology at the Beth Israel Hospital and her clinical fellowship in Gynecologic Oncology at Roswell Park Cancer Institute. Dr. Cornelison has completed research fellowships at the National Cancer Institute and at the Uniformed Services University of the Health Sciences. She has held academic appointments at Harvard University, State University of New York, and currently holds an appointment as Associate Professor at the Johns Hopkins University and School of Medicine, where she has her clinical and academic practice. Dr. Cornelison has an extensive broad-based background in molecular and cellular oncology, laboratory science, clinical care, academia, public health, program and policy development, and executive leadership.

Teresa R. Franklin, PhD

Research Associate Professor of Neuroscience, University of Pennsylvania

Hormones: From Basic Research to Addiction Medication

Dr. Franklin is a Research Associate Professor of Neuroscience in Psychiatry. One aim of her research is to characterize inter-individual differences (i.e., protections and vulnerabilities) within individuals who smoke cigarettes to aid them in achieving successful smoking cessation. There are two major factors that motivate relapse to smoking: craving induced by pharmacological withdrawal from nicotine and craving elicited by exposure to smoking reminders (smoking cues). One hypothesis that guides her work is that inter-individual variability exists in the relative contribution of withdrawal- and smoking cue-induced craving to relapse. Further, she hypothesizes that biological sex and fluctuating gonadal sex hormones in naturally cycling females moderate these two major motivators of relapse. Her team uses pharmacological, behavioral, genetic and neuroimaging probes to query relapse vulnerabilities and protections. Ultimately, the goal for contemporary medicine is to establish endophenotypes, so that treatment strategies can be tailored to manage individual vulnerabilities to aid in conquering this devastating and difficult to treat addiction.

Maciej Goniewicz, PharmD, PhD

Associate Professor of Oncology, Department of Health Behavior, Roswell Park Comprehensive Cancer Center

Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders

Dr. Maciej L. Goniewicz is an Associate Professor of Oncology at the Department of Health Behavior, Roswell Park Comprehensive Cancer Center in Buffalo, NY. He earned a Pharm.D. degree (2002) and a Ph.D. in Toxicology and Pharmacology (2007) from the Medical University of Silesia, Poland. He completed his postdoctoral fellowships in Clinical Pharmacology and Tobacco Control at the University of California San Francisco and in Smoking Cessation Treatment in Queen Mary University of London, UK. Dr. Goniewicz's primary research area is in nicotine pharmacology, with a focus on nicotine dependence and smoking cessation. He has research experience in smoking cessation behavioral treatment, pharmacotherapy, and pharmacokinetics in both clinical and community-based settings. Dr. Goniewicz's current research is focused on new nicotine-containing products and alternative forms of tobacco. He examines safety and efficacy of electronic nicotine delivery devices, commonly called e-cigarettes. These studies include the laboratory evaluation of the products, pharmacological and toxicological assessment, surveys among their users, and their potential application in harm reduction and smoking cessation.

Shelly Greenfield, MD, MPH

Professor and Chair, Department of Psychiatry, Harvard Medical School; Chief Academic Officer, Director of Clinical and Health Services Research and Education, Division of Alcohol and Drug Abuse, McLean Hospital

Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders

Shelly F. Greenfield, MD, MPH, is an addiction psychiatrist, clinician, and researcher. She serves as principal and co-investigator on federally funded research focusing on substance use disorders treatment, gender differences, and substance health services. She received a National Institute on Drug Abuse (NIDA)-funded career award in substance use disorder patient oriented research and NIDA-funded grants to develop and test a new manual-based group therapy for women with substance use disorders, the Women's Recovery Group. Dr. Greenfield is President of the Board of Directors of the American Academy of Addiction Psychiatry, is past-chair and a member of the American Psychiatric Association's Council on Addiction Psychiatry, and chair of the NIDA Clinical Trial Network's Gender Special Interest Group. She served as editor in chief of the Harvard Review of Psychiatry for sixteen years, is a distinguished fellow of the American Psychiatric Association, and is the recipient of numerous awards including McLean's Jack H. Mendelson Memorial Award for Research and the R. Brinkley Smithers Distinguished Scientist Award from the American Society of Addiction Medicine.

CONFERENCE SPEAKERS AND MODERATORS

Gioia M. Guerrieri, DO, FAPA

Medical Officer, Division of Anesthesia, Analgesia, and Addiction Products, FDA CDER

Moderator: Hormones: From Basic Research to Addiction Medication

Dr. Guerrieri is board-certified in the specialty of psychiatry with a fellowship subspecialty in reproductive psychiatry and is a full-time medical officer at FDA. She transferred to the Washington, D.C. area from the Mayo Clinic in 2011 to study the effect of gonadal hormones (sex steroids) on mood and behavior in women at the NIH/NIMH in the Section of Behavioral Endocrinology. In 2015, Dr. Guerrieri transferred to FDA, where she reviews drug applications in the Division of Anesthesia, Analgesia, and Addiction Products.

Marsha B. Henderson, MCRP

Associate Commissioner for Women's Health, FDA

Moderator: Conversations with Patients Overcoming Opioid and Nicotine Dependency

Marsha B. Henderson is the Associate Commissioner for Women's Health at FDA and is responsible for leading policy, science, and outreach initiatives conducted by FDA's Office of Women's Health. Associate Commissioner Henderson is a nationally recognized leader, innovator, and change agent for the health of women and their families. Prior to coming to FDA in 1996, Associate Commissioner Henderson served as the Director of Evaluation for the Interagency Council on the Homeless; Director of Placement for the National Health Service Corps, Chief of Analysis and Information, Bureau of Maternal and Child Health. Under her leadership OWH has received awards from more than 97 national associations.

RADM Denise Hinton, MS

Chief Scientist, FDA

RADM Denise Hinton is the Chief Scientist for the U.S. Food and Drug Administration (FDA). In this capacity, she provides strategic leadership and support for cross-cutting scientific research programs, polices, and initiatives, overseeing a diverse portfolio of activities that advance regulatory science. RADM Hinton facilitates scientific cooperation among FDA's centers as well as with the external scientific community, working to leverage FDA's expertise and resources to fill scientific gaps that are critical to fulfilling FDA's regulatory mission to protect and promote public health. As Chief Scientist, she also oversees FDA's Senior Science Council and its scientific working groups, bringing together the Agency's subject matter experts to solve scientific problems and provide technical advice to the Commissioner in areas such as modeling and simulation, toxicology, global health security, counterterrorism, and emerging threats. Before leading OCS, RADM Hinton was the Deputy Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER). RADM Hinton joined FDA in 2002 in CDER's Division of Cardiovascular and Renal Products and, later, served in the Center's former Division of Training and Development. Before joining FDA, RADM Hinton served as an officer in the U.S. Air Force. She received her Bachelor of Science in Nursing from Florida State University and her Master of Science degree from Boston University.

Marjorie Jenkins, MD, MEdHP, FACP

Director, Medical Initiatives and Scientific Engagement, FDA OWH

Discussing Sex as A Biological Variable: Terminology and Policy

Dr. Jenkins serves as a tenured Professor of Medicine, Associate Dean for Women in Science, Founding Director and Chief Scientific Officer for the Laura W. Bush Institute for Women's Health at Texas Tech University Health Sciences Center (TTUHSC). She joined the FDA Office of Women's Health (OWH) in 2015 via an interprofessional agreement. In her role as OWH Director of Medical Initiatives and Scientific Engagement, Dr. Jenkins provides sex and gender scientific expertise within research, educational, and health policy initiatives. A national thought leader in sex and gender health science, Dr. Jenkins founded the TTUHSC Laura W. Bush Institute for Women's Health, whose focus is sex and gender- specific women's health. She subsequently led its expansion across six campuses and to national prominence. She has served in a variety of roles such as Program Chair of the 2015 and 2018 National Sex and Gender Health Professional Education Summits, co-Chair of the Reproduction Workgroup of NASA's Decadal Review of Sex and Gender Research, a member of the Women's Health Writing Group of the National Board of Medical Examiners, HRSA and NIH expert panel advisories, and the International Gender Medicine Scientific Advisory Committee.

Hendree Jones, PhD

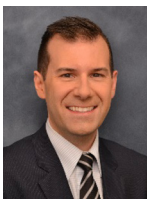
Professor, Department of Obstetrics and Gynecology & Executive Director of Horizons, The University of North Carolina at Chapel Hill

Sex and Gender Influences within Integrative Approaches to Treatment of Addiction

Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period

Dr. Jones is an internationally recognized expert in the development and examination of both behavioral and pharmacologic treatments for pregnant women and their children in risky life situations. She has received continuous NIH funding since 1994 and has written more than 195 peer-reviewed publications. Dr. Jones authored two books, one on treating patients for substance use disorders and the other on comprehensive care for women who are pregnant and have substance use disorders. She also has written multiple textbook chapters on the topic of pregnancy and addiction, as well as other non-peer-reviewed articles for clinicians. In 2012, Dr. Jones won the Betty Ford Award from the Association for Medical Education and Research in Substance Abuse for her scientific contributions in advancing women's addiction treatment.

CONFERENCE SPEAKERS AND MODERATORS



Brian King, PhD, MPH

Deputy Director for Research Translation, Office on Smoking Health, National Center for Chronic Disease Prevention and Health Promotion, CDC

Landscape of Federal Research Policy and Regulation of Opioids and Nicotine

Dr. Brian King is the Deputy Director for Research Translation in the Office on Smoking and Health (OSH) within the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention (CDC). In this capacity, he is responsible for providing scientific leadership and technical expertise to CDC/OSH, the lead federal agency for comprehensive tobacco prevention and control. Dr. King joined the CDC in 2010 as an Epidemic Intelligence Service Officer, before which he worked as a Research Affiliate in the Division of Cancer Prevention and Population Sciences at Roswell Park Cancer Institute in Buffalo, New York. During his time at Roswell Park, his primary research focus related to tobacco prevention and control. Dr. King has worked for over a decade to provide sound scientific evidence to inform tobacco control policy and to effectively communicate this information to key stakeholders, including decision makers, the media, and the general public. He has authored or co-authored over 125 peer-reviewed scientific articles pertaining to tobacco prevention and control, was a contributing author to the 50th Anniversary Surgeon General's Report on Smoking and Health, was the lead author of CDC's 2014 update to the evidence-based state guide, "Best Practices for Comprehensive Tobacco Control Programs," and was the senior associate editor of the 2016 Surgeon General's Report, "E-cigarette Use Among Youth and Young Adults." Dr. King holds a PhD and MPH in Epidemiology from the State University of New York at Buffalo.

George Koob, PhD

Director, NIH NIAAA

SABV: Brain, Pain, and Addiction

George F. Koob, Ph.D., is an internationally-recognized expert on alcohol and stress, and the neurobiology of alcohol and drug addiction. He is the Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), where he provides leadership in the national effort to reduce the public health burden associated with alcohol misuse. As NIAAA Director, Dr. Koob oversees a broad portfolio of alcohol research ranging from basic science to epidemiology, diagnostics, prevention, and treatment. He is a Senior Investigator at the National Institute on Drug Abuse where his laboratory is exploring the neurobiology of drug and alcohol transition to dependence.

Christine Lee, PharmD, PhD

General Health Scientist, FDA CDER

Recognizing the Benefits of Health Communications Research in Substance Abuse

Dr. Christine Lee received her PhD from the University of Florida Pharmaceutical Outcomes and Policy department and PharmD from the University at Buffalo. Her role at CDER FDA includes research and collaborations with the private and public sector to reduce preventable drug harm. She is an expert in social and behavioral sciences, decision analysis, and human behavioral theories. She is currently spearheading research and innovation in linking real-world, real-time data to dissemination communications strategies, implementation and supports regulatory decision making and public health. Her work includes structuring unstructured FDA materials, as well as social media data, to inform regulatory decision making, harnessing new technologies in data mining and applying novel, scientifically rigorous, real-world data methodologies to gather timely and relevant information from patients and health care professionals and improve information dissemination strategies.

Sherry McKee, PhD

Professor, Psychiatry; Director, Yale Behavioral Pharmacology Laboratory

Sex and Gender Influences within Integrative Approaches to Treatment of Addiction

Dr. Sherry McKee is a Professor of Psychiatry, Director of the Yale Behavioral Pharmacology Laboratory, Director of the Forensic Drug Diversion Clinic, and Director of the Yale-SCOR Translational Center for Develop Gender-Sensitive Therapeutics for Tobacco Dependence, at the Yale School of Medicine. Over the past 20 years, Dr. McKee's federally-funded work in addiction has spanned human laboratory paradigms, clinical trials, survey, and epidemiological research to uncover the mechanisms underlying poor treatment outcomes and to translate these findings into improved interventions for women and men. Dr. McKee has held national leadership positions within the Research Society on Alcoholism (RSA) and the American Psychological Association (APA), has published over 180 peer- reviewed papers, and has received awards for her research contributions from the Society for Research on Nicotine and Tobacco, the NIH NIDA, RSA, and APA.

Tamra Meyer, PhD, MPH

Lead Epidemiologist, Office of Surveillance and Epidemiology, FDA CDER

Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders

Dr. Tamra Meyer currently leads the prescription drug abuse team in the Division of Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research at the FDA. Her team is responsible for evaluating the postmarket safety of drugs with respect to risks of misuse, abuse, addiction, and overdose. Dr. Meyer has served at FDA since January of 2013 as both an epidemiology reviewer and team lead across several therapeutic areas. She previously served as an epidemiologist with the Army Pharmacovigilance Center where she conducted drug safety studies using the Military Health System electronic health data. Prior to her work in pharmacoepidemiology, Dr. Meyer studied genetic and cancer epidemiology while earning an MPH and PhD at the University of Texas Health Science Center and later as a postdoctoral fellow at the National Cancer Institute.

CONFERENCE SPEAKERS AND MODERATORS

Jeffrey Mogil, PhD
Professor, Department of Psychology, McGill University
Pain, Sex, and Death

Prof. Mogil is interested in nervous system mechanisms mediating the perception and inhibition of pain. Pain is a complex, subjective experience that displays considerable variability compared to other sensory modalities. In some instances, and in some people, intensely noxious stimuli are not reported as causing pain, whereas others can experience excruciating pain from light touching of the skin. Some people are highly sensitive to pain relief from placebo administration, while others are insensitive to even high doses of morphine. Research is focused on uncovering and explaining sources of variability in these phenomena. Dr. Mogil and his team use a multidisciplinary approach ranging from molecular gene mapping to the development of new behavioral models. Recent experiments have uncovered surprising and intriguing social effects on pain behaviors in mice, and much current work in the laboratory is aimed at understanding these.

Anne Z. Murphy, PhD
Professor, Neuroscience Institute, Georgia State University
SABV: Brain, Pain, and Addiction

Dr. Anne Z. Murphy is a neuroscientist with special interests in sex differences in pain and stress. She joined the faculty of Georgia State University in 2003 and is currently a Full Professor in the Neuroscience Institute. Dr. Murphy studies the molecular, cellular and neurobiological mechanisms underlying opioidergic signaling in the brain and spinal cord. Her NIH funded research focuses heavily on the impact of organismic factors, including sex and age, on opioid modulation of chronic pain using rodent models. Dr. Murphy reviews grants regularly for NIH and currently serves on the Editorial Boards of the journals Hormones & Behavior and Journal of Pain. She is a member of the Executive Board of the Organization for the Study of Sex Differences.

Christine Pham Nguyen, MD
Deputy Director for Safety, Division of Bone, Reproductive and Urologic Products, FDA CDER
Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period

Dr. Christine Nguyen is the deputy director for safety in the Division of Bone, Reproductive, and Urologic Products in the Office of New Drugs at FDA's Center for Drug Evaluation and Research. In this capacity, she oversees a diverse group of drugs for men's and women's health. Her interests include content and policy issues related to the Pregnancy and Lactation Labeling Rule, and Agency efforts to obtaining clinical evidence to guide the use of prescription drugs in pregnancy. Board-certified in Obstetrics and Gynecology, Dr. Nguyen has had extensive clinical experience in obstetrics, reproductive health, and other areas of women's health. She received her Doctor of Medicine degree from the University of California at San Francisco, and completed her residency in obstetrics and gynecology at the Johns Hopkins Hospital.

Cheryl A. Oncken, MD, MPH
Professor & Chair, Department of Medicine, UConn Health
Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period

Dr. Cheryl A. Oncken is Professor of Medicine, and Obstetrics and Gynecology at the UConn School of Medicine. Dr. Oncken has international recognition for her work on the treatment of smoking in women. She has conducted numerous smoking cessation trials in pregnant women including behavioral interventions, short-term studies of the safety of nicotine replacement therapy during pregnancy, and randomized controlled trials of nicotine gum and inhaler for smoking cessation during pregnancy. She is also interested in interventions to reduce tobacco exposure during pregnancy in low and middle-income countries. She has been a member of the World Health Organization (WHO) Committee developing guidelines for the treatment of tobacco use and second hand exposure during pregnancy. Dr. Oncken has contributed to over 80 peer reviewed articles on smoking related research. She has authored five book chapters, and has been an invited speaker at more than 50 Advisory Board Meetings, Symposia, and Conferences.

Kenneth Perkins, PhD
Professor of Psychiatry, University of Pittsburgh
Sex and Gender Contributions in the Trajectory of Opioid and Nicotine Use and Addiction

Dr. Perkins' research focuses largely on two broad themes. One emphasizes translational studies drawing on preclinical findings to examine acute effects of nicotine (and cigarette smoking) that may explain the persistence of tobacco dependence in humans, and the second is aimed at improving clinical treatments for smoking cessation. Several of these projects address both themes, as basic research findings are then often followed by evaluation of their implications for clinical treatment. These include the first programmatic lab-based research in humans, to our knowledge, on: 1) nicotine and energy balance, to partly determine why smoking lowers body weight, which may help maintain smoking in those with weight concerns; 2) chronic tolerance to nicotine (tolerance being a classic hallmark of abused drugs) and examination of associations of tolerance with dependence; 3) discriminative stimulus effects of nicotine, believed related to nicotine reinforcement; and 4) sex differences in reinforcing and rewarding effects of nicotine vs. non-nicotine stimuli of smoking. The initial key to all these projects was our development of a novel nasal spray method to administer measured doses of nicotine per se in rapid fashion, to mimic the speed of intake via cigarette smoking, but in isolation from all the other constituents in tobacco smoke. More recent projects continue these themes, as one (translational) evaluates nicotine's reinforcement enhancing effects in humans, and a second (clinical) involves developing and validating an efficient and innovative procedure for initial screening of novel medications for evidence of smoking cessation efficacy. A third project extends testing of nicotine discrimination (#3 above) to cigarette smoking, for the first time.

CONFERENCE SPEAKERS AND MODERATORS

Mehmet Sofuoglu, MD, PhD
Professor of Psychiatry, Yale University School of Medicine
Hormones: From Basic Research to Addiction Medication

Dr. Sofuoglu is a Professor of Psychiatry at Yale University School of Medicine and the Director of the VA New England Mental Illness Research, Education and Clinical Center (MIRECC). Dr. Sofuoglu's research interests include development of pharmacotherapies for addictive and co-morbid psychiatric disorders. He is particularly interested in understanding the impact of sex and cycle phase effects on addictive disorders and how these differences can guide new treatment development. His early work demonstrated the potential therapeutic effects of progesterone for addictive disorders. These findings led to a series of ongoing systematic human studies ranging from human laboratory to clinical trials examining the potential utility of progesterone as a treatment for cocaine and tobacco addiction and other co-morbid psychiatric disorders.

Jack Stein, PhD
Director, Office of Science Policy and Communications, NIDA
Innovative Program and Research Initiatives: Thinking Outside the Box

Jack B. Stein, Ph.D., became Director of the Office of Science Policy and Communications (OSPC) within the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, in August 2012. OSPC leads science policy, strategic planning, program evaluation, communications, and public liaison activities for NIDA. Dr. Stein has over two decades of professional experience in leading national drug and HIV-related research, practice, and policy. Stein first joined NIDA as the OSPC Deputy Director, and later as the Deputy Director for the Division of Epidemiology, Services and Prevention Research. He then left NIDA to become Director of the Division of Services Improvement, Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration. Immediately prior to rejoining NIDA, Stein served as the Chief of the Prevention Branch, Office of Demand Reduction, at the White House Office of National Drug Control Policy.

Michelle Tarver, MD, PhD
Director, Patient Science & Engagement Program, FDA CDRH
Innovative Program and Research Initiatives: Thinking Outside the Box

As a board-certified ophthalmologist and epidemiologist, Dr. Tarver has worked on developing patient-reported outcome measures and surveys to capture patient preferences with medical devices. She currently directs the patient engagement efforts and leads the Patient Engagement Advisory Committee meetings. In addition to facilitating patient engagement opportunities across CDRH, she helps foster research in patient-reported outcomes and patient preference information to inform medical device evaluation. She is a co-leader of the FDA Innovation Challenge on devices to prevent and treat opioid use disorder.

Martin Teicher, MD, PhD
Director, Developmental Biopsychiatry Research Program at Mclean Hospital,
Associate Professor of Psychiatry, Harvard Medical School
Adverse Childhood Events and Trauma Across the Lifespan: Sex and Gender Contributions to Development of Substance Use Disorders

Martin Teicher, MD, PhD, has been director of the Developmental Biopsychiatry Research Program at McLean Hospital since 1988. He was director of the former Developmental Psychopharmacology Laboratory (now the Laboratory of Developmental Neuropharmacology), and is currently an associate professor of psychiatry at Harvard Medical School. Dr. Teicher is a member of the editorial board of the Journal of Child and Adolescent Psychopharmacology, Current Pediatric Reviews, and Current Psychosomatic Medicine. He is a member of the Scientific Advisory Council of the Juvenile Bipolar Research Foundation, and has been part of Harvard University's Brain Development Working Group. He has served on or chaired numerous review committees for the National Institutes of Health, published more than 150 articles, and has received numerous honors.

Mishka Terplan, MD, MPH
Professor, Virginia Commonwealth University School of Medicine
Opioid and Nicotine Use, Dependence, and Recovery: Challenges of Pregnancy and the Postpartum Period

Mishka Terplan is board certified in both obstetrics and gynecology and in addiction medicine. His clinical, research and advocacy interests lie along the intersection of reproductive and behavioral health. He is currently Professor in both Obstetrics and Gynecology and Psychiatry and the Associate Director of Addiction Medicine at Virginia Commonwealth University. He is the Medical Director of MOTIVATE – an outpatient Office Based Opioid Treatment clinic, Addiction Medicine Consultant for DMAS (Department of Medicaid Services, VA) and provides consultative services for the National Center on Substance Abuse and Child Welfare. Dr. Terplan has active grant funding and has published over 80 peer-reviewed articles with recent emphasis on health disparities, stigma, and women's access to treatment. He has spoken before the United States Congress and has participated in expert panels at CDC, SAMHSA, ONDCP and NIH.

CONFERENCE SPEAKERS AND MODERATORS

Rita Valentino, PhD

Director, Division of Neuroscience and Behavior, National Institute on Drug Abuse

SABV: Brain, Pain, and Addiction

Dr. Valentino is the Director of the Division of Neuroscience and Behavior at NIDA. She received her PhD in Pharmacology from the University of Michigan and did postdoctoral fellowships at the University of North Carolina and The Salk Institute. Her career spans 30 years of academic, research, and leadership experience in neuropsychopharmacology and stress neurobiology. She held faculty positions at George Washington University, Hahnemann University and was a Professor at the University of Pennsylvania School of Medicine prior to joining NIDA. Dr. Valentino is recognized for her research on the effects of stress and the impact of sex, age and coping style on behavioral and cognitive health, and how this can determine vulnerability to substance use. She is a Fellow of the American College of Neuropsychopharmacology and a member of the Scientific Advisory Board of the Brain Behavior Foundation. She is also the Editor-in-Chief of Neurobiology of Stress.

Brenna VanFrank, MD, MSPH

Senior Medical Officer, Office on Smoking and Health, CDC

Resources and Opportunities to Explore Sex and Gender: Epidemiology of Opioid and Tobacco Use Disorders

Dr. Brenna VanFrank is the senior medical officer in the Office on Smoking and Health (OSH) at the Centers for Disease Control and Prevention (CDC). In this capacity, she is responsible for providing input on the medical aspects of OSH's scientific research and serves as a scientific and medical consultant for OSH programs and projects. She has particular interest in the integration of healthcare and public health and the use of epidemiologic data for public health action. Dr. VanFrank joined CDC in 2014 as an Epidemic Intelligence Service (EIS) officer, and has worked on a variety of public health topics including tobacco prevention and control, nutrition and obesity, and emergency preparedness and response. Dr. VanFrank is board certified in pediatrics, board eligible in preventive medicine, and is a member of the national Delta Omega Honorary Society in public health.

Cora Lee Wetherington, PhD

Women & Sex/Gender Differences Research Coordinator, NIH NIDA

Moderator: Sex and Gender Influences within Integrative Approaches to Treatment of Addiction

Since 1995, Dr. Cora Lee Wetherington has served as the Women and Gender Research Coordinator at the National Institute on Drug Abuse (NIDA), chair of NIDA's Women and Gender Research Group, and NIDA's representative to the NIH Coordinating Committee of the Office of Research on Women's Health. She is also a program officer in the Division of Neuroscience and Behavior, Behavior and Cognitive Science Research Branch. Prior to joining NIDA in 1987, Dr. Wetherington was a tenured faculty member in the Department of Psychology at the University of North Carolina at Charlotte where for 12 years she taught and conducted research in the field of animal learning and behavior and received grant support from NIH and NSF. She is a Fellow of Divisions 25 and 28 of the American Psychological Association (APA). She has received awards from APA and awards from the College on Problems of Drug Dependence.

Scott K. Winiecki, MD

Supervisory Physician, Professional Affairs and Stakeholder Engagement, FDA CDER

Landscape of Federal Research Policy and Regulation of Opioids and Nicotine

Dr. Scott Winiecki received his MD degree from the University of Maryland and completed his pediatric training at the Children's Hospital of Philadelphia. After 12 years in private pediatric practice, he joined the U.S. Food and Drug Administration in 2011. In 2012, he received the FDA's "Outstanding New Reviewer" Award for his work on thromboembolism after administration of immune globulin products. In 2014, he received a Public Health Achievement Award for leading the first project at FDA to use Sentinel electronic data combined with medical record review to rapidly refine a safety concern. After 5 ½ years working on biologics, he joined the CDER in September, 2016. He is currently Director of the Safe Use Initiative, a group whose goal is to reduce preventable harm from medications by collaborating with both public and private groups within the healthcare community.

Mitch Zeller, JD

Director, Center for Tobacco Products, FDA

Landscape of Federal Research Policy and Regulation of Opioids and Nicotine

As director of the Center for Tobacco Products, Mitch Zeller leads FDA's efforts to reduce disease and death from tobacco use and bring previously unavailable information about its dangers to light. Zeller is dedicated to carrying out CTP's charge to reduce the harm from all tobacco products across the entire population—with a focus on how and why people start, stop, or start using these products again. Mitch Zeller, J.D., became director of the FDA's Center for Tobacco Products in March 2013. The mission of CTP—established by enactment of the 2009 Family Smoking Prevention and Tobacco Control Act—is "to make tobacco-related death and disease part of America's past, not America's future, and, by doing so, ensure a healthier life for every American family." Zeller, a graduate of Dartmouth College and the American University Washington College of Law, has been working on FDA issues for more than 30 years.

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