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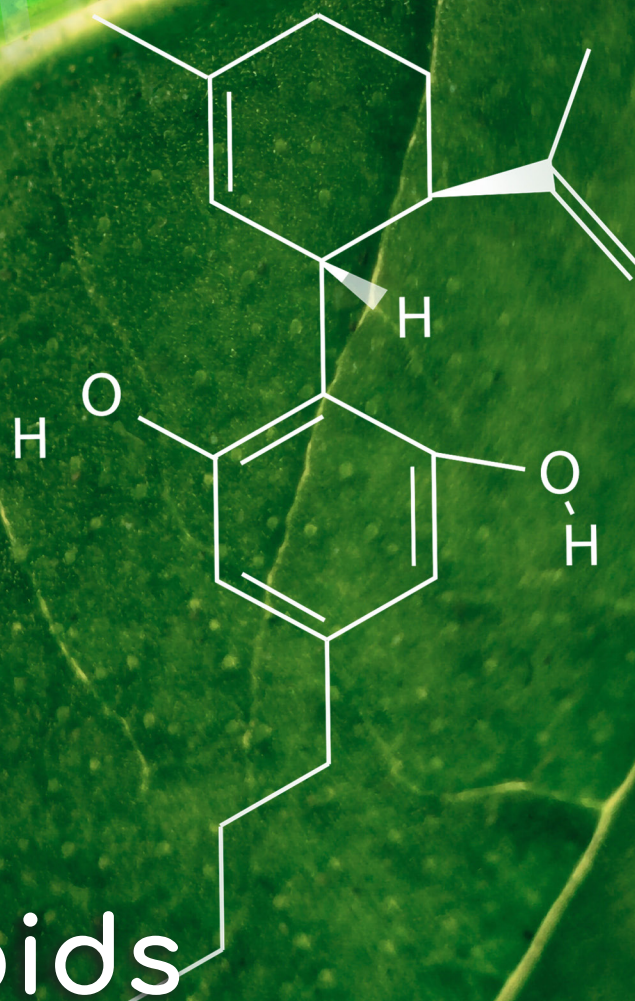
FDA OFFICE OF WOMEN'S HEALTH
SCIENTIFIC CONFERENCE



CBD & Other Cannabinoids

Sex and Gender Differences
in Use and Responses

Thursday, November 19, 2020 | 9:00 AM–4:00 PM EST
Virtual Meeting





FDA U.S. FOOD & DRUG
ADMINISTRATION

Dear Colleagues,

On behalf of the U.S. Food and Drug Administration's (FDA) Office of Women's Health (OWH), I am pleased to welcome you to today's conference, "CBD and Other Cannabinoids: Sex and Gender Differences in Use and Responses." The mission of FDA is to protect and promote public health. A top priority for OWH is to identify and monitor emerging areas of interest and potential concern for the health of women.

Cannabidiol (CBD) products are appearing everywhere – from medical cannabis dispensaries, to pharmacies, to gas stations. Many of these products are illegally marketed and purport to target a myriad of health concerns, including conditions more commonly experienced by women than men, such as chronic pain, sleep disturbances, anxiety and depression. Given that little is known about how and if many cannabis-derived products work, how and why women are using them, and their potential associated risks, there is a mounting need to consolidate and communicate what we know about these products and to identify knowledge gaps. Further, the use of these products during pregnancy and lactation raises additional questions and concerns.

The purpose of today's meeting is to highlight the needed and existing research to address the many "who", "what", and "why" questions surrounding products containing CBD and other cannabinoids. This program underscores FDA's dedication to considering sex and gender in emerging public health issues to promote improved health and safety for both women and men. As women are generally the principal healthcare consumers in the U.S., considering biological (sex) and psychosocial (gender) differences between women and men must be at the forefront of our minds as we consider the potential benefits and risks of products, such as those derived from cannabis.

Our hope is that this meeting, which brings together scientists, federal partners, and patient advocates, will result in a collective commitment to better understand consumer interests, concerns, and potential risks related to the use of CBD and other cannabinoids in order to better protect the health of all Americans.

Sincerely,

Kaveeta P Vasisht

Kaveeta P. Vasisht, MD, PharmD
Associate Commissioner for Women's Health
Director, FDA Office of Women's Health
US Food and Drug Administration

BACKGROUND

Introduction

Cannabidiol (CBD) has become increasingly available to consumers, marketed in a variety of products including food, cosmetics, and animal health products. Other than one prescription drug product to treat two rare and severe forms of epilepsy and seizures associated with tuberous sclerosis complex, to date, FDA has not approved any other CBD products. There is very limited available scientific information and data about CBD, including its effects on the body.

Cannabis is a plant known to produce over 80 different compounds in a biologically active group of chemicals known as cannabinoids. Two of the most abundant cannabinoids in cannabis are delta-9 tetrahydrocannabinol (THC) and CBD. Some varieties of cannabis are grown for their high THC content, as THC is psychoactive and produces a “high.” Other types of cannabis, referred to as “hemp,” have higher CBD content and lower THC content. CBD does not produce a “high” like THC, but it has been associated with safety risks, including the potential for liver injury, drug interactions, and male reproductive toxicity. There are many unanswered questions about the science and safety of CBD. Aside from THC, other cannabinoids in cannabis are even less well understood.

In December 2018, the Agricultural Improvement Act (also known as the Farm Bill) removed “hemp” from controls under the Controlled Substances Act. According to the Farm Bill, “hemp” means *Cannabis sativa L.*, and any part of the plant or derivatives of the plant, with a THC concentration of not more than 0.3 percent on a dry weight basis.

FDA recognizes the significant public interest in cannabis and cannabis-derived compounds, particularly CBD. However, there are many unanswered questions about the science, safety, and quality of products containing CBD. The Agency is working on answering these questions through ongoing efforts, including feedback from an FDA hearing and information and data gathering through a public docket.

FDA’s Office of Women’s Health is hosting this multidisciplinary scientific conference to discuss potential sex and gender differences in the use and response to CBD and other cannabinoids. Presentations will reflect patient and healthcare provider perspectives on CBD and other cannabinoid use, sex differences in the effects of CBD and other cannabinoids, use of CBD and other cannabinoids in pregnancy, and government agency perspectives on CBD research and evaluation.

Defining Sex and Gender

“Sex” refers to an individual’s biological characteristics, stemming from chromosome complement, which produce male and female anatomy and physiology. Alternatively, “gender” refers to the social construct by which we define ourselves as masculine, feminine, neither, both, or other. Our understanding of one’s gender is highly influenced by our experiences, environment, and societal views of ourselves and others, as well as our prescribed gender roles. Influences of both sex and gender may be important in understanding male and female differences in use of CBD and other cannabinoids.

Potential Sex and Gender Differences Regarding CBD and Other Cannabinoids

Compared to research examining the sex-dependent effects of THC, there is less research focusing specifically on sex-dependent effects of CBD [1-3]. However, some conditions for which CBD is often marketed, such as chronic pain, anxiety, depression, and sleep disturbances, are more prevalent in women than men [4-7].

Additionally, use of CBD and other cannabinoids during pregnancy and lactation is an important public health concern [8-9]. We lack comprehensive research on the effects of CBD on the developing fetus, pregnant individuals, and breastfed baby. FDA is continuing to collect and analyze data on the possible harmful effects of CBD during pregnancy and while breastfeeding. However, based on what we do know, there is cause for concern. In preclinical studies, high doses of CBD in pregnancy have caused problems with the development of the male reproductive system [10]. In addition, based on what we already know about CBD, we expect that some amount of CBD will be transferred to babies through breast milk.

Symposium Objectives

In relation to the sex and gender differences associated with use and effects of CBD and other cannabinoids, meeting participants will:

- Recognize data gaps and real-world challenges as identified by scientists, clinicians, and patients.
- Appreciate potential sex and gender interactions in outcomes, including during pregnancy and lactation.
- Understand the role of federal stakeholders in CBD research.

DISCUSSION GUIDE

Panel 1: Use of CBD and Other Cannabinoids: Perspectives from Patients and Healthcare Professionals

This panel will discuss issues arising from public interest in, and use of, CBD and other cannabinoids. How can healthcare professionals help patients make informed choices about CBD, cannabis, and cannabis-derived compounds, and what is the patient experience of seeking input from providers on CBD, cannabis, and cannabis-derived compound use?

Learning objectives:

- Understand the relationship between cannabis, CBD, THC, and other cannabinoids.
- Describe public health concerns about CBD and gender-based differences in use or health effects.
- Highlight patient and healthcare professional views on use of and interest in CBD.

Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

This panel will discuss the biological plausibility for differential effects of CBD and other cannabinoids in women and men. Do women and men who use CBD and other cannabis-derived products for pain, addiction, and psychosis experience differences in symptom relief or adverse responses? Recent preclinical studies addressing the safety of CBD will also be discussed.

Learning objectives:

- Recognize the potential impact of biological sex on cannabinoid actions and effects.
- Highlight data gaps wherein sex may influence cannabinoid safety.

Panel 3: Use of CBD and Other Cannabinoids During Pregnancy

Recent data suggest that the use of products containing cannabis or cannabis-derived compounds is becoming more common in pregnant women. However, there are knowledge gaps regarding the health impacts of CBD, THC, and other cannabinoid use in pregnancy. In this panel, speakers will discuss our current understanding of the risks associated with cannabis and CBD use during pregnancy and lactation and highlight critical knowledge gaps.

Learning objectives:

- Understand the safety concerns of cannabis or cannabis-derived compound use during pregnancy.
- Identify the data gaps regarding cannabis or cannabis-derived compound use during pregnancy and lactation.

Panel 4: Government Agency Perspectives on CBD Research and Evaluation

This panel will discuss topics related to government efforts regarding CBD, ranging from CBD grant portfolios and research findings to ethical considerations for CBD research and evaluation.

Learning objectives:

- Identify current federal efforts to address scientific data gaps, including extramural grants, intramural research, and consumer updates.
- Recognize the scientific and ethical considerations affecting CBD research and evaluation.

AGENDA

9:00 am **Welcome**

Kaveeta Vasisht, MD, PharmD. Associate Commissioner for Women's Health and Director, Office of Women's Health, FDA

9:05 am **Opening Remarks**

Amy Abernethy, MD, PhD. Principal Deputy Commissioner of Food and Drugs, Office of the Commissioner, FDA

9:15 am **Keynote**

Douglas Throckmorton, MD. Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, FDA

9:30 am **Panel 1: Use of CBD and Other Cannabinoids: Perspectives from Patients and Healthcare Professionals**

Moderator: **Susan Bersoff-Matcha, MD.** Deputy Director, Office of Women's Health, FDA

Cinnamon Bidwell, PhD. Assistant Professor, Institute of Cognitive Science and Department of Psychology and Neuroscience; Director, Center for Research and Education Addressing Cannabis and Health (REACH), University of Colorado, Boulder

Daniel Clauw, MD. Professor of Anesthesiology, Medicine and Psychiatry, University of Michigan

Shari Berman. Patient Leader and Educator

10:30 am **Break**

10:45 am Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

Moderator: **Inna Belfer, MD, PhD.** Program Director, Basic and Mechanistic Research Branch, Division of Extramural Research, National Center for Complementary and Integrative Health, NIH

Igor Koturbash, MD, PhD. Associate Professor and Chair, Department of Environmental Health Sciences; Founder and Co-Director, Center for Dietary Supplements Research, Fay W. Boozman College of Public Health, University of Arkansas for Medical Sciences

Ryan Vandrey, PhD. Professor, Behavioral Pharmacology Research Unit, Johns Hopkins University School of Medicine

Ziva Cooper, PhD. Director, UCLA Cannabis Research Initiative, Jane and Terry Semel Institute for Neuroscience and Human Behavior; Associate Professor, Department of Psychiatry and Biobehavioral Sciences

Yasmin Hurd, PhD. Ward Coleman Chair of Translational Neuroscience and Professor of Psychiatry and Neuroscience, Icahn School of Medicine at Mount Sinai; Director of the Addiction Institute, Mount Sinai Behavioral Health System

12:15 pm Lunch Break

1:00 pm Panel 3: Use of CBD and Other Cannabinoids in Pregnancy

Moderator: **Leyla Sahin, MD.** Senior Medical Officer, Division of Pediatric and Maternal Health, Office of New Drugs, Center for Drug Evaluation and Research, FDA

Scott Parnell, PhD. Assistant Professor, Cell Biology and Physiology, University of North Carolina, Chapel Hill

Mark Zakowski, MD, FASA. Professor of Anesthesiology, Cedars-Sinai Medical Center

Nathaniel DeNicola, MD, MSHP, FACOG. Environmental Health Expert, American College of Obstetricians and Gynecologists

Katrina Mark, MD, FACOG. Associate Professor, Department of Obstetrics, Gynecology & Reproductive Sciences, University of Maryland School of Medicine

2:15 pm Break

2:30 pm Panel 4: Government Agency Perspectives on CBD Research and Evaluation

Moderator: **Cassandra Taylor, PhD.** Chemist, Office of Pharmaceutical Quality, Office of New Drug Products, Botanical Review Team, Center for Drug Evaluation and Research, FDA

David Shurtleff, PhD. Deputy Director, National Center for Complementary and Integrative Health, NIH

Betty Jo Salmeron, MD, MA. Staff Clinician, Intramural Research Program, Neuroimaging Research Branch, National Institute on Drug Abuse, NIH

Andrew Shen, PhD. Neuroscientist, National Center for Toxicological Research, FDA

David Carbone, PhD. Toxicologist, Division of Neurology Products, Center for Drug Evaluation and Research, FDA

3:50 pm Closing Remarks

Kaveeta Vasisht, MD, PharmD. Associate Commissioner for Women's Health and Director, Office of Women's Health, FDA

CONFERENCE SPEAKERS AND MODERATORS



AMY ABERNETHY, MD, PhD

Principal Deputy Commissioner of Food and Drugs, Office of the Commissioner, FDA

Opening Remarks

Dr. Abernethy is an oncologist and internationally recognized clinical data expert and clinical researcher. As the Principal Deputy Commissioner of Food and Drugs, Dr. Abernethy helps oversee FDA's day-to-day functioning and directs special and high-priority cross-cutting initiatives that impact the regulation of drugs, medical devices, tobacco, and food. As Acting Chief Information Officer, she oversees FDA's data and technical vision and its execution. She has held multiple executive roles at Flatiron Health and was Professor of Medicine at Duke University School of Medicine, where she ran the Center for Learning Health Care and the Duke Cancer Care Research Program. Dr. Abernethy received her MD at Duke University, where she did her internal medicine residency, served as Chief Resident, and completed her hematology/oncology fellowship. She received her PhD from Flinders University and her BA from the University of Pennsylvania, and she is board certified in palliative medicine.



INNA BELFER, MD, PhD

Program Director, Basic and Mechanistic Research Branch, Division of Extramural Research, National Center for Complementary and Integrative Health, NIH

Moderator, Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

Dr. Belfer is a world-recognized expert in human pain genetics and phenomics. She began her career as a neurologist, then received extensive training in neurobiology and genetics. For over 15 years, her primary research interest has been the relationship between gene polymorphisms and complex phenotypes such as pain, psychiatric disorders, and addictions. Her research focused on biobehavioral aspects of acute and chronic pain, sex influence on pain and analgesia, and genomic predictors of the transformation of acute pain into a chronic condition. After serving as a Staff Scientist in the NIH Intramural Pain Program, she joined the University of Pittsburgh as Associate Professor of Anesthesiology and Human Genetics and the Director of the Molecular Epidemiology of Pain Program. In 2015, Dr. Belfer joined FDA as a Medical Officer for novel analgesics, evaluating clinical trends including sex-specific factors controlling pain. Recently, Dr. Belfer returned to NIH to direct the extramural pain research portfolio at NCCIH.



SHARON (SHARI) BERMAN

Patient Leader and Educator

Speaker, Panel 1: Use of CBD and Other Cannabinoids: Perspectives from Patients and Healthcare Professionals

Shari Berman lends her patient voice as a two-time cancer survivor. She graduated from Cornell University; worked as a Vice President, Human Resources Manager in the financial services industry for 15 years; and moved into patient advocacy after the death of her mother from lung cancer. She most recently authored an article about medical marijuana published in STAT/The Boston Globe and started a consulting practice to educate people on how to navigate and use cannabis responsibly. Shari is a former Co-Chair of the Dana Farber Adult Patient Family Advisory Council, served on Dana Farber's Quality Improvement and Risk Management Committee, and serves as Co-Chair of the Beryl Institute's Patient Experience Policy Forum. Shari has also been asked to consult on a variety of projects with organizations such as the National Academy of Medicine's American Society of Clinical Oncology (ASCO), the Journal of the American Medical Association (JAMA), and Livestrong.



SUSAN BERSOFF-MATCHA, MD

Deputy Director, Office of Women's Health, FDA

Moderator, Panel 1: Use of CBD and Other Cannabinoids: Perspectives from Patients and Healthcare Professionals

Dr. Matcha is the Deputy Director in the Office of Women's Health at FDA, where she oversees the Office's scientific programs. Since coming to FDA in 2016, Dr. Matcha has worked in the Office of Medical Policy and the Office of Surveillance and Epidemiology. She has a longstanding interest in women's health and has published several peer-reviewed articles on this topic. Dr. Matcha attended Georgetown University School of Medicine, completed her internship and residency training at Emory University, and pursued subspecialty fellowship training at Washington University School of Medicine, Division of Infectious Diseases in St. Louis, Missouri. Dr. Matcha is board certified in both internal medicine and infectious diseases.



CINNAMON BIDWELL, PhD

Assistant Professor, Institute of Cognitive Science and Department of Psychology and Neuroscience; Director, Center for Research and Education Addressing Cannabis and Health (REACH), University of Colorado, Boulder

Speaker, Panel 1: Use of CBD and Other Cannabinoids: Perspectives from Patients and Healthcare Professionals

Dr. Bidwell's primary research focus is on the impact of cannabinoids and other drugs on psychological and physical health, acutely and chronically. For over a decade, she has been building on her training in studies of drug dependence, neurobehavior, behavioral genetics, and co-occurring psychiatric disorders. She has expertise in human laboratory studies on cannabis, cannabinoids, alcohol, and nicotine and maintains research projects on the underlying factors that contribute to successful clinical treatment of psychiatric and substance use conditions. Her current research investigates the direct neurobiological, physiological, and behavioral effects of cannabinoids in psychiatric and medical populations as they pertain to both their abuse potential and potential therapeutic effects. Dr. Bidwell has published over 55 scientific publications and two book chapters on the neurobiology of substance abuse and its overlap with psychiatric disorders.



DAVID L. CARBONE, PhD

Toxicologist, Division of Neurology Products, Center for Drug Evaluation and Research, FDA

Speaker, Panel 4: Government Agency Perspectives on CBD Research and Evaluation

Dr. Carbone has a PhD in Toxicology from the University of Colorado and completed postdoctoral fellowships at Colorado State University and the University of Arizona before joining FDA in 2014. Dr. Carbone is currently a nonclinical reviewer in CDER's Office of New Drugs, Office of Neuroscience.



DANIEL J. CLAUW, MD

Professor of Anesthesiology, Medicine and Psychiatry, University of Michigan

Speaker, Panel 1: Use of CBD and Other Cannabinoids: Perspectives from Patients and Healthcare Professionals

Dr. Clauw is a Professor of Anesthesiology, Medicine and Psychiatry at the University of Michigan, where he also attended undergraduate and medical school. He completed an internal medicine residency and rheumatology fellowship at Georgetown University, where he held roles including Chief of Rheumatology and Vice Chair of Medicine. In 2002, he and his research team moved to the University of Michigan, where Dr. Clauw helped grow the clinical and translational research infrastructure, becoming the first Assistant and then Associate Dean for Clinical Research, and the first Principal Investigator (PI) of the University of Michigan Clinical and Translational Sciences Award. This group has identified the critical phenotypic features of individuals whose central nervous system is amplifying or magnifying their pain, and as such has been critical in helping elucidate the importance of the central nervous system in all chronic pain conditions. He currently is co-PI of three NIH center grants studying the mechanisms underlying chronic pain in urological and musculoskeletal disorders and is an active mentor of clinical and pain researchers.



ZIVA D. COOPER, PhD

Director, UCLA Cannabis Research Initiative, Jane and Terry Semel Institute for Neuroscience and Human Behavior; Associate Professor, Department of Psychiatry and Biobehavioral Sciences

Speaker, Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

Dr. Cooper is the Research Director of the UCLA Cannabis Research Initiative in the Jane and Terry Semel Institute for Neuroscience and Human Behavior and Associate Professor in the Department of Psychiatry. Her research involves understanding variables that influence both the therapeutic potential and adverse effects of cannabis and cannabinoids through double-blind, placebo-controlled studies. Dr. Cooper served on the National Academies of Sciences Committee on the Health Effects of Cannabis that recently published a comprehensive report of the health effects of cannabis and cannabinoids. She is a board director for the College on Problems of Drug Dependence, an associate editor of The American Journal of Drug and Alcohol Abuse, and an editorial board member of several journals including Cannabis and Cannabinoid Research and Neuropsychopharmacology.



NATHANIEL DENICOLA, MD, MSHP, FACOG

Environmental Health Expert, American College of Obstetricians and Gynecologists

Speaker, Panel 3: Use of CBD and Other Cannabinoids in Pregnancy

Dr. DeNicola is an obstetrician and gynecologist at Johns Hopkins Health System. He is the American College of Obstetricians and Gynecologists (ACOG) environmental health expert and liaison to the American Academy of Pediatrics Executive Council on Environmental Health. In this role, he has lectured nationally and internationally on the health impacts of cannabis use during pregnancy and on longitudinal developmental outcomes. He represents ACOG on the Medical Society Consortium on Climate and Health, and he is the ACOG international liaison to the International Federation of Gynecology and Obstetrics (FIGO) and the World Health Organization “Pollution-Free Generation” initiative. He has published peer-reviewed articles on environmental exposures on reproductive health and is an international speaker on this topic. He completed the Robert Wood Johnson Clinical Scholars Program at the University of Pennsylvania and did residency training in obstetrics and gynecology at Tulane University.



YASMIN HURD, PhD

Ward Coleman Chair of Translational Neuroscience and Professor of Psychiatry and Neuroscience, Icahn School of Medicine at Mount Sinai. Director of the Addiction Institute, Mount Sinai Behavioral Health System

Speaker, Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

Dr. Hurd is the Ward Coleman Chair of Translational Neuroscience and Professor of Psychiatry and Neuroscience at the Icahn School of Medicine at Mount Sinai in New York, as well as the Director of the Addiction Institute within the Mount Sinai Behavioral Health System. Dr. Hurd is an internationally renowned neuroscientist whose translational research examines the neurobiology of drug abuse and related psychiatric disorders. Her research exploring the neurobiological effects of cannabis and heroin has significantly shaped the field. Using multidisciplinary research approaches, her research has provided novel insights into the impact of developmental cannabis exposure and epigenetic mechanisms underlying the drug’s protracted effects into adulthood and even across generations. Dr. Hurd’s basic science research is complemented by clinical studies evaluating the therapeutic potential of novel strategies including phytocannabinoids (such as cannabidiol) for the treatment of addiction disorders, with a focus on opioid abuse.

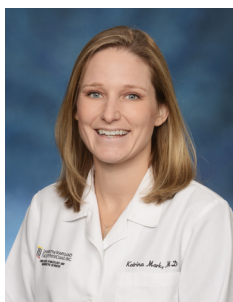


IGOR KOTURBASH, MD, PhD

Associate Professor and Chair, Department of Environmental Health Sciences; Founder and Co-Director, Center for Dietary Supplements Research, Fay W. Boozman College of Public Health, University of Arkansas for Medical Sciences

Speaker, Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

Dr. Koturbash received his MD from the State Medical University in Ivano-Frankivsk, Ukraine (2001), and his PhD in Biomolecular Sciences from the University of Lethbridge, Canada (2008). Being both MD and PhD, Igor has a long-lasting interest in diet and dietary supplements and their impact on human health. The major focus of his research is the safety, efficacy, and mechanisms of action of dietary supplements and understanding how diet and dietary supplements can modulate tissue response to cancer therapy. Igor has published over 90 peer-reviewed articles and book chapters, and his research has received uninterrupted extramural funding since the beginning of his independent career. In 2018, he founded the Center for Dietary Supplements Research, the mission of which is to provide regulatory agencies, industry, and the public with credible information, assessments, expert opinions, and risk communications, as well as professional and educational services relating to the efficacy and safety of dietary supplements.



KATRINA MARK, MD, FACOG

Associate Professor, Department of Obstetrics, Gynecology & Reproductive Sciences, University of Maryland School of Medicine

Speaker, Panel 3: Use of CBD and Other Cannabinoids in Pregnancy

Dr. Mark is an Associate Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of Maryland School of Medicine. She is a Board Certified, practicing OBGYN whose clinical and research interests focus on cannabis use in pregnancy. Her particular interest is in screening, testing, ethical and legal concerns and women's decision-making surrounding use and continued use of cannabis during pregnancy and barriers to abstinence.



BRIDGET NUGENT, PhD

Biologist and Research Program Lead, Office of Women's Health, FDA

Conference Chairperson

Dr. Nugent received her PhD in Neuroscience from the University of Maryland School of Medicine (UM SOM), where she studied the molecular mechanisms of sexual differentiation of the developing brain. She continued her research on sex differences during her postdoctoral fellowships at Yale University and the University of Pennsylvania. Prior to joining FDA in 2018, she was an Assistant Professor in the Department of Pharmacology at UM SOM and the Associate Director for Research Analyses in the Center for Epigenetic Research in Child Health and Brain Development. In her role as the Research Program Lead, Dr. Nugent oversees OWH's research funding initiatives and serves on several FDA committees and working groups.



SCOTT E. PARNELL, PhD

Assistant Professor, Cell Biology and Physiology, University of North Carolina, Chapel Hill

Speaker, Panel 3: Use of CBD and Other Cannabinoids in Pregnancy

Dr. Parnell is an Assistant Professor in the Department of Cell Biology and Physiology and Bowles Center for Alcohol Studies at the University of North Carolina at Chapel Hill. His developmental neurobiology laboratory studies fetal alcohol spectrum disorder (FASD) and the effects of other drugs on the developing brain and face. These studies include identifying the stage-dependent effects of early developmental drug exposure and the underlying mechanistic pathogenesis, as well as identifying genes that alter susceptibility to the effects of prenatal drug exposure.



LEYLA SAHIN, MD

Senior Medical Officer, Office of New Drugs, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, FDA

Moderator, Panel 3: Use of CBD and Other Cannabinoids in Pregnancy

Dr. Sahin's background is in obstetrics and gynecology, and she is a Senior Medical Officer in the FDA's Division of Pediatric and Maternal Health in the Office of New Drugs. She has led various scientific and regulatory/policy initiatives, including the 2018 Inclusion of Pregnant Women in Clinical Trials Guidance, the 2019 Post-Approval Pregnancy Safety Studies Guidance, and the 2014 publication of the Pregnancy and Lactation Labeling Rule. She was a working group member on the Task Force for Research Specific to Pregnant Women and Lactating Women. The focus of her work involves providing pregnancy and lactation scientific and regulatory expertise to the review divisions in the Office of New Drugs through all phases of drug development. Her principal area of interest is promoting the public health of pregnant and breastfeeding women through improved data collection of medications used in pregnant and lactating women.



BETTY JO SALMERON, MD, MA

Staff Clinician, Intramural Research Program, Neuroimaging Research Branch, National Institute on Drug Abuse, NIH

Speaker, Panel 4: Government Agency Perspectives on CBD Research and Evaluation

Dr. Salmeron is a board-certified psychiatrist who has been conducting research in substance abuse since 1997. Her work uses functional neuroimaging to elicit the neural underpinnings of responses to drugs of abuse and cues for drugs, as well as the network and functional differences that accompany drug use and prenatal exposure to drugs of abuse. She also earned a master's degree in bioethics in 2013 and has served on the NIDA Institutional Review Board and contributed to ethical discourse on the handling of incidental findings in imaging research and dealing with substance-using research participants in an ethical framework.

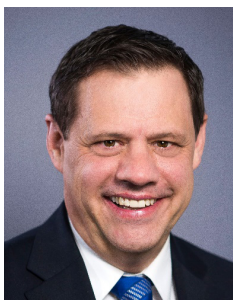


ANDREW N. SHEN, PhD

Neuroscientist, National Center for Toxicological Research, FDA

Speaker, Panel 4: Government Agency Perspectives on CBD Research and Evaluation

Dr. Shen is a neuroscientist in the Department of Neurotoxicology at the National Center for Toxicological Research (NCTR/FDA). Dr. Shen received a BA in Cognitive and Behavioral Psychology from Marquette University. He completed his MS and PhD in Experimental Psychology at Auburn University, where he focused on the neurobehavioral consequences of chronic exposure to environmental contaminants in adult and aging rodent models. Dr. Shen completed a postdoctoral scholar's program at University of Kentucky's Sanders-Brown Center on Aging that utilized transgenic rodent models of Alzheimer's disease to study the contribution of neurovascular dysfunction to neurodegeneration and cognitive impairment. In 2018, Dr. Shen began an Oak Ridge Institute for Science and Education-sponsored research fellowship at the NCTR investigating neurobehavioral consequences of developmental arsenite exposure. He is now continuing his work in developmental neurotoxicology at the NCTR as a Staff Fellow.



DAVID SHURTLEFF, PhD

Deputy Director, National Center for Complementary and Integrative Health, NIH

Speaker, Panel 4: Government Agency Perspectives on CBD Research and Evaluation

Dr. Shurtleff is Deputy Director of the National Center for Complementary and Integrative Health (NCCIH), performing activities aimed toward directing and implementing a program of research that builds a scientific evidence base about complementary and integrative health approaches that advances fundamental knowledge and informs clinical practice. Dr. Shurtleff began his NIH career in 1995 at the National Institute on Drug Abuse (NIDA). From 2001 to 2010, he was the Director of the Division of Basic Neuroscience and Behavioral Research at NIDA. From January 2011 to June 2013, he was the Acting Deputy Director of NIDA. Before coming to NIH, Dr. Shurtleff was a research psychologist at the Naval Medical Research Institute, where he conducted research related to cognitive performance and environmental stress. He has received various honors and awards, including one award that recognized his outstanding contributions to the 2014 President's BRAIN Initiative.



CASSANDRA L. TAYLOR, PhD

Chemist, Office of Pharmaceutical Quality, Office of New Drug Products, Botanical Review Team, Center for Drug Evaluation and Research, FDA

Moderator, Panel 4: Government Agency Perspectives on CBD Research and Evaluation

Dr. Taylor is a chemist at FDA within the Center for Drug Evaluation and Research (CDER) and is a member of the Botanical Review Team (BRT), which resides within the Office of Pharmaceutical Quality (OPQ). BRT collectively serves as an expert resource for CDER on all botanical issues. Dr. Taylor joined FDA in December 2014 as a primary BRT reviewer and has evaluated many botanical drug submissions from all of CDER's clinical divisions, with a focus on reviewing cannabis submissions. She serves as a cannabis subject matter expert (SME) for CDER and across FDA, primarily concentrating on the botanical and quality aspects of cannabis. She received her BS in Chemistry with a minor in Forensics from St. Francis University in Loretto, PA (2005), and her PhD in Analytical Chemistry from the University of Maryland in College Park, MD (2014) under the guidance of Dr. Alice Mignerey.



DOUGLAS THROCKMORTON, MD

Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, FDA

Keynote Speaker

Dr. Throckmorton serves as Deputy Director for Regulatory Programs in the Center for Drug Evaluation and Research (CDER) at FDA, where he shares the responsibility for overseeing the regulation of research, development, manufacture, and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Among his responsibilities in CDER, Dr. Throckmorton works on issues related to controlled substances, including cannabis and cannabis-derived products.

Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.



RYAN VANDREY, PhD

Professor, Behavioral Pharmacology Research Unit, Johns Hopkins University School of Medicine

Speaker, Panel 2: Sex Differences in the Effects of CBD and Other Cannabinoids

Dr. Vandrey is an experimental psychologist with degrees from the University of Delaware (BA) and University of Vermont (PhD). He is currently a Professor at the Johns Hopkins University Behavioral Pharmacology Research Unit (BPRU).

Dr. Vandrey's research focuses primarily on the impact of route of administration, dose, and chemical composition of cannabis products on resultant drug effects and pharmacokinetics. In addition, Dr. Vandrey has been involved with a broad range of studies related to the risks and benefits of medicinal cannabis use, the effects of cannabis use on sleep, cannabis withdrawal and the treatment of Cannabis Use Disorder, cannabis product testing, and developing measures of cannabis use behavior.



KAVEETA P. VASISHT, MD, PharmD

Associate Commissioner for Women's Health and Director, Office of Women's Health, FDA

Welcome and Closing Remarks

Dr. Vasisht is Associate Commissioner for Women's Health and Director of the Office of Women's Health (OWH) in the Office of the Commissioner at FDA. OWH provides leadership and policy direction for the Agency and coordinates efforts to establish and advance a women's health agenda. Under her leadership, OWH works

to protect and advance the health of women through scientific programs, policy development, research, education, stakeholder collaboration, and outreach that incorporates an understanding of sex and gender differences to facilitate FDA regulatory decision making.

Dr. Vasisht is board certified in both internal medicine and adult endocrinology and holds a Doctor of Pharmacy degree. She completed her internal medicine internship and residency as well as fellowship training at the University of Chicago Hospitals, where she also served on the faculty.



MARK ZAKOWSKI, MD, FASA

Professor of Anesthesiology, Cedars-Sinai Medical Center

Speaker, Panel 3: Use of CBD and Other Cannabinoids in Pregnancy

Dr. Zakowski is Clinical Chief and Fellowship Director of Obstetrical Anesthesiology and Professor of Anesthesiology at Cedars-Sinai Medical Center in Los Angeles. He has also served as President of the California Society of Anesthesiologists and the Society for Obstetric Anesthesia and Perinatology. He loves hiking and the outdoors, and he remains an advocate for pregnant women and their newborns. Dr. Zakowski

lectures nationally and internationally and has authored many textbook chapters, scientific articles, and a book for pregnant women about cesarean sections.

APPENDIX

FDA Draft Guidance and Consumer Updates on Cannabis and Cannabis-Derived Products, Including CBD

What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD

- U.S. Food and Drug Administration. What you need to know (and what we're working to find out) about products containing cannabis or cannabis-derived compounds, including CBD. Updated March 5, 2020. Accessed September 10, 2020.
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Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments

- U.S. Food and Drug Administration. Scientific data and information about products containing cannabis or cannabis-derived compounds; public hearing; request for comments.
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What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding

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