



Creating A World Where Health Equity Is A Reality For All

PUBLIC MEETING Strategies to Improve Health Equity Amidst the Opioid Crisis

Thursday, November 21, 2019

9a.m. - 4p.m.

Hilton Washington DC/Rockville Hotel & Executive Meeting Center 1750 Rockville Pike, Roosevelt/Madison Rooms, Rockville, MD 20852

AGENDA

8:00am-9:00am Registration

9:00am-9:30am Welcome and Opening Remarks

CAPT Richardae Araojo, PharmD, MS

Associate Commissioner for Minority Health

Food and Drug Administration

Office of Minority Health and Health Equity

Douglas Throckmorton, MD

Deputy Director for Regulatory Programs

Food and Drug Administration

Center for Drug Evaluation and Research

VADM Jerome M. Adams, MD, MPH

Surgeon General

Department of Health and Human Services

Office of the Surgeon General

9:30am-10:30am Session 1: The Voice of the Patient - Diverse Patient Perspectives on Opioid Use Disorders

Purpose: To share perspectives from individuals with opioid use disorder (OUD) on health effects and daily impacts of OUD, as well as individuals' and families' perspectives on current approaches to treating chronic pain and/or OUD.

Moderator: Meghana Chalasani, MHA

Food and Drug Administration

Center for Drug Evaluation and Research

Speakers:

Amanda Sabino

Baltimore County Department of Health REACH Team

Adrienne Shapiro

Axis Advocacy Foundation

Adrian Williams

afwcreative

Q&A

10:30am-10:40am

Break

10:40am-11:45am

Session 2: Impact of Opioids on Diverse Communities - What does the data show?

Purpose: To discuss the impact of opioids on diverse communities and present data on use and abuse of prescription opioids, opioid overdose and overdose deaths, and access to Naloxone.

Moderator: Judy Staffa, PhD, RPh Food and Drug Administration Center for Drug Evaluation and Research

Speakers:

Jan Losby, PhD, MSW

Centers for Disease Control and Prevention

Jean Bennett, PhD

Substance Abuse and Mental Health Services Administration

Elisabeth Kato, MD

Agency for Healthcare Research and Quality

Suzanne Tamang, PhD

Department of Veterans Affairs

Q&A

11:45am-12:45pm

Lunch

12:45pm-2:00pm

Session 3: Innovative Initiatives and Research to Address the Opioid Crisis (Part I)

Purpose: To discuss innovative strategies such as community-based programs, national initiatives, research programs, guidelines, and guidance documents to prevent opioid use disorder.

Moderator (Part I): Mitra Ahadpour, MD, DABAM Food and Drug Administration
Center for Drug Evaluation and Research

Speakers:

Mitra Ahadpour, MD, DABAM
Food and Drug Administration
Center for Drug Evaluation and Research

Jonathan Nebeker, MD, MS
Department of Veterans Affairs

Jade Perdue, MPA
Centers for Medicare and Medicaid Services

CAPT Cynthia Gunderson, PharmD *Indian Health Service*

Alexander Ross, ScD *Health Resources and Services Administration*

Q&A

2:00pm-2:15pm

Break

2:15pm-3:50pm

Session 3: Innovative Initiatives and Research to Address the Opioid Crisis (Part II)

Moderator (Part II): Cariny Nuñez, MPH, CHRM Food and Drug Administration
Office of Minority Health and Health Equity

Speakers:

Kimberly Brown Smith, MD, PhD Food and Drug Administration Center for Devices and Radiological Health

Judith Racoosin, MD, MPH Food and Drug Administration Center for Drug Evaluation and Research

Jay Ruais, MPA Addiction Policy Forum

David Knight, JD *Department of Justice*

Q&A

Plenary Presentation: Helping to End Addiction Long Term (HEAL) Initiative

Rebecca Baker, PhD and Jack Stein, PhD National Institutes of Health

Q&A

3:50pm-4:00pm

Closing Remarks

RADM Denise Hinton
FDA Chief Scientist
Food and Drug Administration
Office of the Chief Scientist

SPEAKER BIOGRAPHIES



VADM Jerome M. Adams, MD, MPH Surgeon General Department of Health and Human Services Office of the Surgeon General

Jerome M. Adams, MD, MPH, is the 20th Surgeon General of the United States. Dr. Adams, a board-certified anesthesiologist, served as Indiana State Health Commissioner from 2014 to 2017.

Dr. Adams has bachelor's degrees in 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.

As Health Commissioner, Dr. Adams presided over Indiana's efforts to deal with the state's unprecedented HIV outbreak, caused by the sharing of needles among people

who inject drugs. In this capacity, he worked directly with the CDC, as well as with state and local health officials and community leaders, and brought the widest range of resources, policies and care available to stem the epidemic affecting that community.

Dr. Adams' motto as Surgeon General is "better health through better partnerships." As Surgeon General, he is committed to maintaining strong relationships with the public health community and forging new partnerships with non-traditional partners.

As Surgeon General, Dr. Adams oversees the operations of the U.S. Public Health Service Commissioned Corps, which has approximately 6,700 uniformed health officers who serve to promote, protect and advance the health and safety of our nation.

Mitra Ahadpour, MD, DABAM
Food and Drug Administration
Center for Drug Evaluation and Research

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. OTS is comprised of the Office of Biostatistics, Office of Clinical Pharmacology, Office of Computational Science, Office of Study Integrity and Surveillance and Immediate Office. Dr. Ahadpour helps oversee translational medicine efforts across the Center for Drug Evaluation and Research (CDER) and leads the areas of health informatics; data mining; technology transfer; training and career development; and regulatory and policy development.



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 training of physicians, nurse practitioners and physician assistants on safe opioid prescribing and medication assisted treatment. In private practice, she contributed to legislation making Montgomery County and Maryland smoke-free and, as chair of Montgomery County Medical Society's Community Service Programs, created and launched a tobacco awareness education program in middle schools.

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, 2016 HHS Ignite competition for creating and fully implementing the nationwide Rapid Opioid Alert and Response (ROAR) project, and the 2017 Federal Health IT Innovation Award for the Medication Assisted Treatment (MATx) mobile app. Dr. Ahadpour earned her medical degree from the University of Maryland and completed residency at George Washington University Hospital.



CAPT Richardae Araojo, PharmD, MS
Associate Commissioner for Minority Health
Food and Drug Administration
Office of Minority Health and Health Equity

CAPT Richardae Araojo serves as the Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity (OMHHE) in the Office of the Commissioner at the U.S. Food and Drug Administration (FDA). In this role, CAPT Araojo provides leadership, oversight, and direction on minority health and health disparity matters for the Agency. The Office of Minority Health and Health Equity aims to promote and protect the health of diverse populations through research and communication of regulatory science that addresses health disparities.

CAPT Araojo previously served as the Director of the Office of Medical Policy Initiatives (OMPI) in FDA's Center for Drug Evaluation and Research (CDER), where she managed

the OMPI immediate office and three divisions. She led a variety of broad-based medical and clinical policy initiatives to improve the science and efficiency of clinical trials and enhance professional and patient labeling. CAPT Araojo worked collaboratively with other FDA disciplines, program areas, and FDA centers to foster an interdisciplinary approach to policy development and to enhance the integration of the continuingly evolving science and policy into FDA's drug development and regulatory review processes. She provided oversight and direction for cross-cutting center and Agency working groups, as well as collaborations with external constituents, to advance medical policy development.

CAPT Araojo joined FDA in 2003, where she held a number of positions in CDER's Office of New Drugs, first serving in the Division of Psychiatry Drug Products (formerly the Division of Neuropharmacological Drug Products) and then with the Pediatric and Maternal Health Staff (currently the Division of Pediatric and Maternal Health). She then transitioned to the Office of Medical Policy in 2010, where she served as Acting Director of the Division of Medical Policy Programs, Deputy Director of OMPI, and finally Director of OMPI.

CAPT Araojo received her Doctor of Pharmacy Degree from Virginia Commonwealth University, completed a Pharmacy Practice Residency with Emphasis in Community Ambulatory Care at the University of Maryland, and later earned a Master's degree in Pharmacy Regulation and Policy from the University of Florida.

Rebecca Baker, PhD *National Institutes of Health*

Rebecca G. Baker, Ph.D., is the director of the Helping to End Addiction Long-termSM Initiative, or NIH HEAL InitiativeSM, in the Office of the Director, NIH. Dr. Baker leads coordination of NIH HEAL Initiative programmatic activities between the Office of the Director and relevant Institutes and Centers (ICs). She manages the Office of the NIH HEAL Initiative, including NIH HEAL Initiative staff, and oversees management of NIH HEAL Initiative governance committees. Dr. Baker helped develop the NIH HEAL Initiative, working closely with NIH and IC leadership. She also provides expert advice to and represents the NIH Director on initiative-related activities, including interagency efforts in pain and opioid research and policy.



Prior to holding this position, Dr. Baker was special assistant to the NIH Director and the Principal Deputy Director working directly with NIH leadership to analyze complex biomedical research policy issues and assist in the development of new science and policy initiatives. Before that, she worked in the NIH Office of Science, Outreach, and Policy, where she worked on legislative, communications, and policy issues. Dr. Baker also worked in the NIH Office of Science Policy, where she contributed to the development and implementation of the NIH Genomic Data Sharing Policy. Previously, she worked as a postdoctoral scientist using next-generation DNA sequencing to identify novel disease-causing genes in patients with rare immunological diseases. She earned her Ph.D. from the University of Pennsylvania and her bachelor's degree from Cornell University.



Jan Bennett, PhD
Substance Abuse and Mental Health Services Administration

Since 2011, Dr. Jean Bennett has served as the Philadelphia-based Regional Administrator for the Substance Abuse and Mental Health Services Administration, responsible for federal Region III, which includes Pennsylvania, Delaware, DC, Maryland, Virginia and West Virginia. Dr. Bennett chairs the HHS Region III Opioid Task Force, convenes regional stakeholders focused on interprofessional addiction education, expanding access to medication assisted treatment, suicide prevention, Naloxone, Harm Reduction, Philanthropy and Peers and as a result is overseeing the implementation of dozens of opioid-related project ideas developed during in person regional summits on stakeholder-recommended topics. Jean served in the Navy where she retired at the rank of Captain after serving in clinical, administrative and leadership positions. She spent 10 years after 9/11 serving in emergency preparedness and response roles for Children's

Hospital Boston, the Veterans Integrated Service Network in San Francisco, and for HHS Region 6 impacted directly by Hurricane Katrina. Dr. Bennett has four academic degrees including a BS and MS in nursing, a MS in Management and a PhD in Organization and Management. Jean grew up in Boston but currently resides in Nutley, New Jersey with her husband Michael and their two kitties Beanie and Snaggy.



Kimberly Brown Smith, MD, PhD
Food and Drug Administration
Center for Devices and Radiological Health

Kimberly Brown Smith, M.D., Ph.D., is an ophthalmologist, glaucoma expert, and biomedical engineer. Currently, she is on the Clinical and Scientific Policy Staff in the Office of Product Evaluation and Quality in FDA's Center for Devices and Radiological Health. In addition, for over ten years she has cared for patients at the Walter Reed National Military Medical Center Ophthalmology Clinic. Previously, she was on faculty at the University of Maryland, College Park in the Biological Resources Engineering Department. She started her career as a Corporate Research Fellow with AT&T Bell Laboratories.

Meghana Chalasani, MHA
Food and Drug Administration
Center for Drug Evaluation and Research

Meghana Chalasani currently serves as a senior research analyst for the Patient-Focused Drug Development (PFDD) Program in FDA's Center for Drug Evaluation and Research (CDER). She works closely on CDER's various PFDD initiatives and provides strategic, regulatory, program, and policy assistance to facilitate the incorporation of patient input into decision-making. Prior to joining the FDA in July 2015, Meghana worked on Capitol Hill and for FasterCures. She also has a strong biomedical research and clinical experience background in genomic medicine and infectious diseases. Meghana holds a master's degree in Health Policy and Management from Columbia University and a bachelor's in Medicine, Health and Society from Vanderbilt University.





CAPT Cynthia Gunderson, PharmD *Indian Health Service*

CAPT Cynthia (Cindy) Gunderson is a United States Public Health Service (PHS) Pharmacist stationed with the Indian Health Service (IHS). She graduated from the University of Nebraska Medical Center College of Pharmacy in 2004 with her doctorate in pharmacy. CAPT Gunderson is currently serving as the Chair of the IHS National Committee on Heroin, Opioids, and Pain Efforts (HOPE). The IHS HOPE Committee was established in April 2017 and exists to promote appropriate and effective pain management, reduce overdose deaths from heroin and prescription opioid misuse, and improve access to culturally appropriate treatment. CAPT Gunderson is also the IHS Federal Lead for Prescription Drug Monitoring Program response activities. She has a demonstrated passion for working with tribal communities to augment local responses

to the opioid crisis. She currently serves concurrently as the Acting Chief Operating Officer at the Red Lake Hospital, in Red Lake, MN.

She lives in rural MN with her husband and three small children.



RADM Denise Hinton
FDA Chief Scientist
Food and Drug Administration
Office of the Chief Scientist

RADM Denise Hinton is FDA's Chief Scientist. In this capacity, she is responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts.

The Office of the Chief Scientist works closely with FDA's product centers, providing strategic leadership and support for FDA's regulatory science and innovation initiatives, including the Advancing Regulatory Science Initiative, the Critical Path Initiative, health informatics, scientific professional development, scientific integrity, and the Medical Countermeasures Initiative (MCMi).

RADM Hinton previously served as Deputy Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER), where she concurrently served as Acting OMP Director from 2014 to 2016. There, she led the development, coordination, and implementation of medical policy programs and strategic initiatives, including the efficient integration of rapidly evolving science and new technologies into the drug development and regulatory review processes. RADM Hinton's work involved close collaboration with other CDER program areas, FDA product centers, and a broad variety of stakeholders.

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 coming to FDA, she was an officer in the U.S. Air Force. RADM Hinton earned her Bachelor of Science in Nursing from Florida State University and her Master of Science degree from Boston University.

Elisabeth Kato, MDAgency for Healthcare Research and Quality

Elisabeth Kato is a medical officer at the Agency for Healthcare Research and Quality in the Center for Evidence and Practice Improvement, where she coordinates AHRQ activities related to opioids and supports the National Center for Excellence in Primary Care. She previously served as medical officer to the Evidence-based Practice Center Program and the US Preventive Services Task Force at AHRQ. Prior to joining the federal government, she worked as a Senior Medical Research Analyst with Hayes Inc. Dr. Kato received medical training at the University of Maryland and has Master's and Bachelor's degrees from Cornell University.





David Knight, JD *Department of Justice*

David Knight has been an attorney with the Disability Rights Section of the Civil Rights Division at the U.S. Department of Justice for eleven years and practiced civil rights for sixteen years. In that role he works on a wide range of disability discrimination matters, including combating discrimination against individuals with a history of opioid use disorder. He received his undergraduate degree from the University of Maryland, and his Juris Doctorate from Fordham Law School.

Jan Losby, PhD, MSW Centers for Disease Control and Prevention

Jan L. Losby, PhD, MSW is the Branch Chief for the Health Systems and Research Branch in the Division of Overdose Prevention at the Centers for Disease Control and Prevention. Dr. Losby is responsible for evaluating and advancing the implementation of CDC's Guideline for Prescribing Opioids for Chronic Pain, conducting applied health systems research, and building scientific evidence to support state, community, and tribal efforts to address the opioid overdose epidemic. To support uptake and use of the guideline, Dr. Losby works with healthcare systems on quality improvement, electronic clinical decision support tools, and data system integration with electronic health records.





Jonathan Nebeker, MD, MS
Department of Veterans Affairs

Dr. Nebeker is Acting Chief Medical Informatics Officer at Veterans Health Administration and Professor of Medicine at the University of Utah. His degrees and training took place at Harvard and the University of Pennsylvania.

He has been the clinical and/or informatics lead of all EHR-related programs at VA from 2014 through 2017. He works with other federal agencies and industry associations on standards and best practices to help VHA participate in markets of health IT and content.

His research has three areas of focus: adverse drug events, human interface design, and scientific computing. His work concerning the characterization, epidemiology, and

prevention of adverse drug events is widely cited. Much of this work concerns how EHRs help or don't help prevent these events. More recently, he has focused on translating basic science of cognitive and social psychology to medical informatics and EHR design. Randomized controlled trials of his novel user-interface designs have demonstrated increased accuracy of and decreased time to diagnosis of medical conditions. He is helping incorporate these lessons into the design of VA's EHR systems. Previously, he led the establishment of VA's scientific computing center and led architectural work for technologies to support epidemiology and natural language processing. He practices geriatrics in Salt Lake City.

Cariny Nuñez, MPH
Food and Drug Administration
Office of Minority Health and Health Equity

Cariny Nuñez is a Senior Public Health Advisor for the Office of Minority Health and Health Equity (OMHHE) within the Office of the Commissioner. She also serves as the colead for the Outreach and Communications Program within FDA OMHHE and the agency's lead for the Language Access Program.

Cariny started her career with FDA in 2010 as a Public Affairs Specialist in Florida. She has a Bachelor's Degree in Science, a Master's Degree in public health with a specialization in Health Policy and Management, and two Post-Graduate Degrees in Health Disease Prevention and Promotion and Healthcare Risk Management from Florida International University. She is currently a Doctoral Candidate in Public Health at Walden University.





Jade Perdue, MPA
Centers for Medicare and Medicaid Services

Jade has spent the past nineteen years serving as a catalyst for healthcare transformation in those areas with the most vulnerable populations. Her government career began in the field of Organ Donation and Transplantation at the Health Resources and Services Administration (HRSA) where she, as part of a dynamic team of dedicated professionals saved 15,000 additional lives by culling and spreading best practices of high performing organ procurement organizations and transplant centers. Using that knowledge, she joined the Centers for Medicare & Medicaid Services, Quality Improvement Innovation Group where she has worked to improve healthcare quality in nursing homes, hospitals and vulnerable populations.

Currently, Jade serves as the Director for the Division of Quality Improvement Innovations Model Testing at CMS which is focused on working with hospitals and populations in the

greatest need of quality technical assistance as it pertains to opioid stewardship, harm reduction, healthcare access and capacity building in rural hospitals.

Jade holds a Master's in Public Administration from the University of Baltimore and resides in Catonsville, MD with her husband Bala, and seven year old twins Benjamin and Indira.

Judy Racoosin, MD, MPHFood and Drug Administration
Center for Drug Evaluation and Research

Judith A. Racoosin, MD, MPH is the Deputy Director for Safety in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) in FDA's Center for Drug Evaluation and Research (CDER).

During 23 years in CDER, Dr. Racoosin's responsibilities have encompassed the breadth of drug safety investigation including reviewing premarket New Drug Application (NDA) safety data; planning drug safety-related policy initiatives that stemmed from the postmarket drug safety authorities included in the FDA Amendments Act of 2007; collaborating on new tools for assessing the safety of marketed drugs; leading the evaluation of postmarket safety for an Office of New Drugs review division; and publishing original scientific studies and commentaries on postmarket safety issues.



Over that time Dr. Racoosin led the evaluation of several high-profile drug safety issues including agranulocytosis with clozapine; sudden unexplained death in epilepsy patients; cardiovascular thrombotic risk with the NSAIDs; serious neurological sequelae in patients receiving epidural steroid injections; and respiratory depression in children treated with codeine post-adenotonsillectomy.

During her eight-year tenure in DAAP, Dr. Racoosin has been deeply involved in several initiatives related to opioid safety encompassing safety labeling changes to improve the communication of safety concerns, risk evaluation and mitigation strategies (REMS) to optimize the safe use of opioids, and postmarket required studies to better understand safety concerns with opioids.

Dr. Racoosin graduated magna cum laude from the University of Maryland School of Medicine and completed a residency in Internal Medicine at the University of Chicago Hospitals. Following her residency, she earned a Master's in Public Health from the University of Illinois at Chicago School of Public Health, and is board-certified in Clinical Pharmacology.

Alexander Ross, ScD

Health Resources and Services Administration

Alexander Ross is senior advisor on behavioral health in the Office of Planning, Analysis and Evaluation, at the Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Service. Alex supports HRSA Bureaus and Offices fostering the integration of behavioral health and primary care. Dr. Ross' work has included an emphasis on financing issues regarding behavioral health/primary care services and assuring that an appropriately trained health care workforce is available to meet the Nation's needs. In addition to his current work, Dr. Ross has held positions at HRSA in the Office of Planning and Evaluation, the Bureau of HIV/AIDS, and the Office of Public Health Practice. Alex has a Doctor of Science Degree in Health Policy from The Johns Hopkins University Bloomberg School of Hygiene and Public Health.



Jay Ruais, MPA
Addiction Policy Forum

Jay Ruais is the Chief of Staff at the Addiction Policy Forum, a national nonprofit committed to ending addiction as a major health condition. He oversees the organization's external stakeholder relationships, including its work with state chapters and Advisory Board while managing the Employer Initiative and federal affairs initiatives on Capitol Hill. Prior to working for the Addiction Policy Forum, Jay was the Chief of Staff and Campaign Manager for U.S. Congressman Frank Guinta of New Hampshire's First Congressional District. Jay graduated with a degree in political science from Gettysburg College in 2008, and received his Master's Degree in Public Administration from American University in 2013.

Amanda SabinoBaltimore County Department of Health REACH Team

I have been working in the substance use and mental health field since 2014. I have worked primarily with private nonprofits in high needs areas of Baltimore County, South East specifically. Beginning as the program director for the Adolescent delinquency and substance use prevention afterschool program, I quickly learned of the need for holistic wrap around services to prevent and break the cycle of substance use and generational poverty. In 2016 I began to work with adult populations in a Medication Assisted Treatment program as well as transition age youth through the MDBAY grant. This was an evidenced based practice model utilizing individual counseling, family counseling component and community support resources.

I currently work for the Baltimore County Department of Health REACH Team. This is a combination of Harm Reduction, access to treatment, community support connection as well as community education as it relates to substance use disorders. My focus has been with the partnership with first responders and law enforcement. Through these partnerships, we have been able to establish a Naloxone leave behind program for individuals who experience and overdose and do not wish to go to the hospital. With this program we are able to connect individuals and loved ones to supports, harm reduction and treatment if desired with little or no interaction with the Emergency Departments. In addition, I feel very strongly about working with these two groups to combat compassion fatigue and stigma that is connected with working with those in active addiction and recovery as they define it.

Adrienne Shapiro Axis Advocacy foundation

Adrienne Bell-Cors Shapiro is a Sickle Cell Disease and stem cell Patient Advocate, the Founder and Science Administrator of the Axis Advocacy foundation, and a fifth generation mother of a child with Sickle Cell Disease. She is a recipient of the highest honor in the regenerative medicine community, the 2018 Stem Cell and Regenerative Medicine Action Inspiration Award. She was one of the first supporters of the work done by UCLA'S Dr. Don Kohn in bone marrow and later stem cell transplants. As a firm believer that stem cell science will cure Sickle Cell Disease, she has dedicated a large portion of her life to improving the lives and overall healthcare of those living with the disease. In the past three years Ms. Shapiro has found her voice as a stem cell activist, speaking at multiple forums in support of the funding for clinical trails through the California Institute for Regenerative Medicine (CIRM) and her role as an ambassador for



the Americans for Cures Foundation. Adrienne is also on patient advisory panels for the FDA, ASH and the NIH Heart Lung & Blood. Her experience includes attending educational conferences and seminars, as well as meeting with lawmakers to promote support for the Sickle Cell Community.

She believes stem cell science will be the answer. However, until we have a cure for Sickle Cell Disease, pain is a fact of the illness and humane treatment and support is required. Thus, Adrienne and Axis Advocacy are dedicated to supporting scientists, researchers and care providers as well as patients, caregivers and their families.



Judy Staffa, PhD, RPh
Food and Drug Administration
Center for Drug Evaluation and Research

Judy Staffa, Ph.D., R.Ph., is the Associate Director for Public Health Initiatives at FDA, Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE), where she is responsible for setting strategic direction for complex, multidisciplinary reviews related to opioid abuse – from a planning, scientific, and policy point of view. Prior to this role, Judy was the Director, Division of Epidemiology II, directing the regulatory review and research work of epidemiologists in CDER. She has spent her FDA career serving in various roles as the office has evolved over the years. While in the role of the Associate Director for Regulatory Research she assisted in building OSE's epidemiologic research program, and prior to that she was an epidemiology reviewer and a drug utilization analyst team leader. Before joining FDA

in 1999, Judy was a researcher at The Degge Group for ten years, conducting numerous pharmacoepidemiologic studies using both administrative claims data and electronic medical records data to investigate drug safety issues. Judy is a registered pharmacist who received her bachelor's degree in pharmacy from the University of Connecticut. She practiced community pharmacy prior to receiving her training in public health. She holds a master's degree in behavioral sciences from the Harvard School of Public Health, and a doctoral degree in epidemiology from the Johns Hopkins Bloomberg School of Public Health.

Jack Stein, PhD
National Institutes of Health

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. In March 2019, Dr. Stein was appointed NIDA Chief of Staff

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.

Dr. Stein has authored numerous articles, book chapters, and reports on HIV prevention and substance use services. He is a graduate of Union College, where he earned a bachelor of science in biology. He holds a master's degree in social work from New York University and a doctoral degree in health services from Walden University.



Suzanne Tamang, PhD *Department of Veterans Affairs*

Dr. Tamang is the Assistant Faculty Director, Data Science, at the Stanford Center for Population Health Science and an Instructor at the Department of Biomedical Data Science, Stanford University School of Medicine. As a computer scientist with training in biology, health services research and biomedical informatics, Dr. Tamang works with interdisciplinary teams of experts on population health problems of public interest. Integral to her work, is the analysis of large and complex population-based datasets, using techniques from natural language processing, machine learning and deep learning. She brings extensive experience with US and Danish population-based registries, Electronic Medical Records from various vendors, administrative claims and other types of health and demographic data sources in the US and internationally; also, constructing, populating and applying knowledge-bases for automated reasoning. Dr. Tamang has

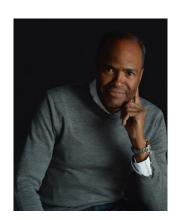
developed open source tools for the extraction of health information from unstructured free-text patient notes and licensed machine learning prediction models to Silicon Valley health analytics startups. She is also affiliated with the Department of Veterans Affairs, where she supports overdose and suicide prevention initiatives, for mental health operations.

Douglas Throckmorton, MDDeputy Director for Regulatory Programs
Food and Drug Administration
Center for Drug Evaluation and Research

As Deputy Director for Regulatory Programs, Dr. Throckmorton 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.

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 the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital. He is a board-certified physician.





Adrian Williams afwcreative

The native Washingtonian and resident who grew up in Ward 8 has a unique understanding of the challenging health issues that face underserved communities because of his life long battle with Sickle Cell Disease.

The unpredictable disease is known to take the lives of countless individuals each year and disrupt every aspect of child adolescent and adult life of survivors and can make it difficult if not impossible for survivors to live normal productive lives. And the disease can leave many patients broken by their inability to consistently participate in the lives of friends and family members and contribute to their communities.

However through sheer tenacity and determination Adrian embarked on an emotional physical and spiritual wellness journey that included a plant based diet, exercise and a

stress reduction program that has resulted in him becoming happier healthier and most importantly sickle cell crises free, hospital and emergency room free for more than 7 years.

As a result he has dedicated his life to advocating on the behalf of underserved communities by teaching individuals communities and health professionals about how to better understand each other and understand the seen and unseen barriers and challenges each face in attempting to improve individual and community health outcomes nationwide.

His company afwcreative the contemporary elevations of innovative ideas and Facebook wellness blog and upcoming book entitled The Wellness Revolution and work with the Children National Medical Center and the Rodham Institute are extensions of his creativity dedication passion and commitment to positive change and community service.

NOTES

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