

FDA RURAL HEALTH SYMPOSIUM



EVENT BACKGROUND & SPEAKERS BIOS

I. Background

The U.S. Food and Drug Administration (FDA) is conducting its inaugural Rural Health Symposium. The symposium will provide a forum for the FDA and key stakeholders in rural and tribal communities to discuss ways we can work together to address the critical and unique health challenges these communities face relative to the opioids crisis; tobacco use among youth; and telemedicine.

The symposium is a cross-center effort between the Office of Minority Health, the Office of Health and Constituent Affairs and the Center for Tobacco Products. There will be an opportunity to hear from senior leadership with the FDA Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Tobacco Products. In addition, leadership from other government agencies (HRSA, VAMC, FCC, IHS) will participate on the panel discussions.

Topics include Advancing Telemedicine: A Federal Perspective; Rural Tobacco Use: Research and Interventions; and The Opioid Crisis in Rural America and Tribal Communities.

Invitees to this symposium include government and state agencies; organizations with a rural health focus, (e.g. hospitals, health professional organizations, academic institutions); and tribal communities.

II. FDA Officials

CAPT Richardae Araojo, PharmD, is the Assistant Commissioner for Minority Health and Director of the Office of Minority Health in the Office of the Chief Scientist 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 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 continually 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.

Jack Kalavritinos, JD, is the Associate Commissioner for External Affairs and advises the Commissioner and other high-ranking officials on communications related to FDA policies and activities and oversee the agency's media, social media, and stakeholder outreach. Prior to this appointment, Mr. Kalavritinos joined the Administration in the Office of the Secretary at the Department of Health and Human Services (HHS). Before his HHS appointment, he served on the Domestic Agency Appointments team on the Presidential Transition.

Mr. Kalavritinos has worked in the public affairs arena for over 20 years, developing a strong health care background both at HHS and in the private sector. As Director of Intergovernmental Affairs at HHS under Secretary Mike Leavitt, he served as the liaison to the nation's governors, state, local and tribal leaders where he led a team of national and regional policy experts, liaisons and public affairs staff during the roll-out of Medicare Part D. He was also instrumental in organizing and implementing the department's pandemic flu emergency preparedness summits with the Governors of all states, territories and tribal leaders and helped to support Secretary Leavitt's efforts post-Hurricane Katrina to establish rapid response efforts with Gulf state governors and other state, local and tribal leaders.

For over 7 years, Mr. Kalavritinos worked for a medical device company on domestic and international policy issues and collaborated closely with that industry's association, AdvaMed. From 2001-2005, Mr. Kalavritinos served as the White House Liaison at the Department of Labor and as the Associate Administrator in the Office of Procurement Policy at OMB. He has also represented the engineering industry and promoted workforce development and building opportunities for high school students. Mr. Kalavritinos received his undergraduate degree from Wake Forest University and his law degree from Catholic University of America.

Heidi C. Marchand, Pharm.D., is the Assistant Commissioner, Office of Special Health Issues (OSHI), Office of External Affairs in the Office of Commissioner. Heidi has ten plus years of experience at FDA. Heidi began her FDA career as a Review Officer in Division of Drug Marketing and Communications (DDMAC) in FDA's Center for Drug Evaluation and Research (CDER) before coming to OSHI in the mid-1990's. She returned to FDA in 2008 after a 12-year departure to pursue positions within the pharmaceutical industry. From October 2010 to July 2011, she served as the Director of the Healthcare Professional Liaison Program within the Office of Special Health Issues. While in the pharmaceutical industry she held some increasingly responsible positions including Director of International Planning and Administration at Novartis, Pharmaceuticals; Director of Regulatory Affairs, Regulatory Policy and Intelligence at Pfizer, Inc.; and Executive Director of Global Regulatory Intelligence and Policy at Amgen, Inc. Heidi began her career at Suburban Hospital, Bethesda, Maryland as a clinical pharmacy practitioner and Director of Hospital Pharmacy and Materials Services. She holds Bachelors and Doctor of Pharmacy degrees from the Medical College of Virginia at Virginia Commonwealth University. She also is a graduate of the Executive Management Fellowship Program at the Leonard Davis Institute at the University of Pennsylvania and a graduate of the Leadership Development Program at the Harvard Business School in Boston.

III. Keynote Speaker

Lauren Silvis, JD, is the Chief of Staff for the Office of the Commissioner. Ms. Silvis provides leadership, coordination, and management of the Commissioner's priority policies and issues across the Office of the Commissioner and FDA-wide. She has been instrumental in implementing public health priorities and advises and provides integrated policy analysis and strategic consultation to the Commissioner and other Senior FDA officials on activities and issues that affect important agency programs, projects and initiatives.

Lauren joined FDA in 2015 as Deputy Center Director for Policy in the Center for Devices and Radiological Health. At CDRH, she provided executive leadership for the development and

implementation of all policies, regulations, and guidance. Lauren also supervised a wide range of Center functions and staff, involving legislation, communications, and regulatory operations. She has worked regularly with many of you across the agency, especially on critical cross-cutting issues. Before joining FDA, Ms. Silvis was a partner at Sidley Austin LLP, where she practiced FDA regulatory law. She also practiced at Covington & Burling LLP. Lauren graduated from Duke University and received her law degree from Georgetown University Law Center. She clerked for the Honorable James L. Ryan, U.S. Court of Appeals for the Sixth Circuit.

IV. Speakers

Advancing Telemedicine: A Federal Perspective

Marisa L. Cruz, MD is the Senior Medical Advisor for the Digital Health Unit at FDA's Center for Devices and Radiological Health. Marisa has previously served FDA as a medical advisor in other regulatory capacities, including food safety and tobacco control. Prior to joining FDA, Marisa worked in academia as an endocrinologist at the University of California, San Francisco. Her post-doctorate research interests have included the impact of asynchronous telehealth consultations on patient outcomes. She continues active clinical care as an Assistant Clinical Professor at George Washington University. She received her B.A. from Johns Hopkins University and her M.D. from the Johns Hopkins School of Medicine.

William L. England, PhD, JD, Director, Office for the Advancement of Telehealth, Federal Office of Rural Health Policy, HRSA

William England is director of the Office for the Advancement of Telehealth (OAT) in the Federal Office of Rural Health Policy at HRSA. Bill joined OAT in 2016. He started work in telehealth at CMS/Medicare, followed by 15 years as Director and Vice President of the FCC/USAC Rural Health Care Program. He is a Fellow and former Director of the American Telemedicine Association. Prior to telehealth, Bill was an assistant professor of Industrial Engineering at the University of Wisconsin-Madison, a Robert Wood Johnson Healthcare Financing Fellow at Johns Hopkins, and a biomedical engineer at Indiana University Health (Regenstrief Institute) in Indianapolis. He has a BS and MS in Electrical Engineering and a PhD in Industrial Engineering from Purdue University. His law degree is from the University of Maryland.

John Peters, Deputy Director, Office of Connected Care/Telehealth Services, Veterans Health Administration

John Peters is the Deputy Director for Telehealth Services within the Department of Veterans Affairs' Office of Connected Care. John has been with VA's Telehealth Services for the last 18 years, and has helped VA telehealth grow to current levels that served over 700,000 Veterans last year, which is about 12% of Veterans seeking VA quality health care. From VA's central office John collaborates with clinical, technical, and administrative leaders to create national VA guidelines, policies, and equipment contracts to help enhance and expand telehealth services across VA's network of 150 medical centers and 700 clinics, as well as telehealth services into Veterans' own homes. John received his Bachelor of Science degree in mechanical engineering from the University of Notre Dame in 1987, and continued his studies at the graduate level in biomedical engineering at Georgetown University, where he received his Master of Science degree in 1992.

Karen Edwards Onyeije, Associate General Counsel, Federal Communications Commission (FCC) and Chief of Staff of the Connect2HealthFCC Task Force

Karen Onyeije is an Associate General Counsel at the Federal Communications Commission (FCC) and serves as Chief of Staff of the Connect2Health^{FCC} Task Force, a senior-level, multi-disciplinary effort designed to explore the intersection of broadband, advanced technology and health. Connect2Health^{FCC} is

working to chart the broadband future of health and care, recognizing the critical role connectivity will play in the health care system of the future, and focusing on improving data-driven decision-making in the connected health space. Ms. Onyeije is a 17-year veteran of the FCC, where she has held a wide variety of leadership positions throughout the agency including overseeing the Enforcement Bureau's wireless enforcement portfolio and serving as an Assistant General Counsel focusing on administrative law, universal service, and transactional matters. In addition, Ms. Onyeije has over a decade of experience in broadcast and cable regulation, Internet and competition policy, previously serving as the media advisor to former FCC Chairman William Kennard. In her current role as Chief of Staff of the Task Force, she marries this extensive communications law and policy experience with a passion for exploring how technology can connect individuals to the people, services, and information they need to get well and stay healthy. Before joining the FCC, Ms. Onyeije was Senior Policy Advisor for Intergovernmental Affairs at the Commerce Department's National Telecommunications and Information Administration (NTIA). Her work at NTIA involved universal service, spectrum management, and policy efforts to bridge the digital divide. Ms. Onyeije received an LL.M. in Advocacy from Georgetown University, a J.D. from the University of Southern California, and a B.A. in Psychology from Loma Linda University

M. Chris Gibbons, MD, MPH, Senior Consultant, Connect2HealthFCC Task Force, Chief Executive Officer, Greystone Health IT Solution.

In this capacity, he helps to lead efforts to lay a robust broadband foundation for future advances in the health sector. Dr. Gibbons is also a physician entrepreneur, academic scientist and expert in Preventive Medicine, Minority Health, Health IT/Digital Health and Health Disparities. For over a decade Dr. Gibbons was an Associate Director of the Johns Hopkins Urban Health Institute, and an Assistant Professor of Medicine, Public Health and Health Informatics at Johns Hopkins University. He is a published author, advisor and expert consultant to state and federal agencies, private industry and legislators. Dr. Gibbons obtained his medical degree from the University of Alabama and then completed residency training in Preventive Medicine, and a General Surgery fellowship and molecular neuro-oncology basic research training at Johns Hopkins. Dr. Gibbons also earned a Master of Public Health degree from Johns Hopkins, focusing on health promotion among urban and disadvantaged populations.

Rural Tobacco Use: Research and Interventions

Janine Delahanty, PhD, is a Health Scientist in the Office of Health Communication and Education of the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products. Dr. Delahanty leads the Research and Evaluation team and supports the efforts for all of the CTP's public education campaigns: The Real Cost, The Real Cost Smokeless, This Free Life, Fresh Empire, Point of Sale. Janine has over 20 years of tobacco control experience.

Matthew W. Walker, DPH, is a Health Scientist in the Office of Health Communication and Education of the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products. Dr. Walker has led State and Federal public health intervention efforts targeting youth populations for more than a decade, with a primary focus on adolescent health and substance abuse prevention. Dr. Walker currently serves as the Formative Evaluation Team lead, managing the design, implementation, and analysis of foundational research that guide the creation of FDA's tobacco public education campaigns, including "The Real Cost," the agency's first national campaign designed to prevent teens from using tobacco.

Alexandria Smith, MSPH, is a Social Scientist in the Office of Health Communication and Education of the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products. Ms. Smith has worked on public education campaigns on tobacco, obesity prevention and HIV prevention. Ms. Smith currently works on the evaluation of The Real Cost Smokeless, the FDA's rural smokeless tobacco public education campaign.

Alexander Persoskie, PhD, is a Social Scientist in the Office of Science of the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products. Dr. Persoskie works on product application reviews and conducts research on tobacco product perceptions, packaging, and use behavior.

The Opioid Crisis in Rural America and Tribal Communities

Rea Blakey is the Communications Policy Strategist for the Professional Affairs and Stakeholder Engagement (PASE) at the Center for Drug Evaluation and Research's (CDER). She's responsible for the strategic planning and implementation of patient and public stakeholder engagement. Her team manages and strives to enhance two-way communication and collaboration with patient and advocacy groups, professional health care providers, medical associations and others regarding CDER issues related to drug development, drug review, and drug safety. Before serving at FDA, Rea was the Director of Communication at GW Medical Faculty Associates, a CNN Medical Correspondent, on-air host of a Discovery Channel CME program and an Emmy-winning Washington, DC news anchor and health reporter. She has more than 25 years of experience strategizing with and engaging thought-leaders in health professions and advocacy organizations to achieve effective national medical partnerships and educational messaging.

Scott Winiiecki, MD, is the Lead Medical Officer, Professional Affairs and Stakeholder Engagement (PASE) in the Center for Drugs and Evaluation Research. Dr. Winiiecki received his MD degree from the University of Maryland School of Medicine 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, Dr. Winiiecki received the FDA's "Outstanding New Reviewer" Award for his work on blood product safety. In 2014, he won the Public Health Achievement Award for leading the first project at FDA to use electronic healthcare data combined with medical record review to refine a safety concern rapidly. In September 2016 he moved from the Center for Biologics to the Center for Drugs. He is currently Team Lead of the Safe Use Initiative, a group whose goal is to reduce preventable harm from medications by collaborating with both public and private organizations within the healthcare community.

Dr. Beverly Cotton, DNP, RN, CPNP-PC, is the Director, Division of Behavioral Health in Indian Health Service Headquarters. Dr. Cotton has a Doctor of Nursing Practice degree from Vanderbilt University, Masters of Science in Nursing as a Primary Care Pediatric Nurse Practitioner from the University of Alabama at Birmingham, and a Bachelor of Science in Nursing from the University of Southern Mississippi. Dr. Cotton's career began with the Indian Health Service in 2011 as a Public Health Advisor in the Division of Behavioral Health where she launched the Tribal Forensic Healthcare Training Project and helped to revise the Indian Health Manual, Chapter 29, Sexual Assault Policy. In her role as the Director of the HIS Division of Behavioral Health, Dr. Cotton provides managerial leadership to continue the advancement of behavioral health priorities in Native American and Alaska Native Communities.

Michael Fallahkhair, MPH, is the Deputy Director of the Community-Based Division for the Federal Office of Rural Health Policy in the Health Resources and Services Administration of the U.S. Department of Health and Human Services (HHS). In this role, Mr. Fallahkhair helps to lead the work of the Federal Office of Rural Health Policy, which is charged with advising the Secretary of HHS on rural health issues and improving the delivery of rural health care. Through grant programs such as Outreach and Network Development, the Community-Based Division, which has an annual budget of \$76 million, administers a range of direct services and capacity building grant programs that serve rural communities. He has past work experience in the Office of Budget of the Assistant Secretary for Financial Resources at HHS as well as in the Office of Management and Budget. Mr. Fallahkhair has an undergraduate degree in Neurobiology and Physiology from the University of Maryland at College Park and a Master's in Public Health with a concentration in Health Policy from George Washington University.

Michael Blodgett is a Public Health Analyst in the Federal Office of Rural Health Policy at the Health Resources and Services Administration (HRSA). He is the Program Coordinator for the Rural Opioid Overdose Reversal grant program and the Rural Health Opioid Program. Before joining HRSA, Mr. Blodgett was a Peace Corps Volunteer in Cambodia and an Emergency Medical Technician in Henrico County, Virginia. He has an undergraduate degree in Leadership Studies from the University of Richmond.