FDA Broad Agency Announcement Day

December 6, 2022

Speaker Bios

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Presenters List:

(in order of appearance)

- Dr. Tina Morrison, Director, ORSI
- Mr. Leonard D Grant, Director, OAGS
- Ms. Shaila Shaheed, ORSI
- Mr. Ian Weiss, OAGS
- Ms. Jessika Alfaro, ORSI
- Dr. Sammersingh Raney, OGD
- Dr. Neil Stiber, OPQ
- Dr. Thomas O'Connor, OPQ
- Dr. Emily Braunstein, CBER
- Dr. Christina Webber, CDRH
- Mr. Robert Orr, OCET
- Dr. Julie Schneider, OCE
- Dr. Christine Lee, OMHHE
- Dr. Susan Bersoff-Matcha, OWH
- Dr. Alice Welch, TTP
- Ms. Bridget Foltz, HSPPMS
- Ms. Domini Bean, PRA

Tina Morrison, PhD

OC/OCS/Office of Regulatory Science and Innovation (ORSI)

Tina Morrison is currently the Director of the Office of Regulatory Science and Innovation in the Office of the Chief Scientist at the FDA.

She joined the FDA in 2008 through the Medical Device Fellowship Program. For the first 7 years, Tina was a regulatory reviewer of cardiovascular devices, where she participated in several initiatives as part of CDRH's Innovation Pathway: early feasibility studies program, streamlining clinical trials, the medical device development tools program, and the Medical Device Innovation Consortium. Alongside the regulatory review work, she was also worked to advance the role of computer modeling and simulation in medical device design and product evaluation. She joined the Office of Science and Engineering Laboratories as a Deputy Division Director in 2015, to continue her regulatory science efforts on computational modeling, and to gain experience as a manager and supervisor, which allowed her to further develop her leadership skills. She founded and chaired two working groups: the Regulatory Review of Computational Modeling working group for CDRH, and the Modeling and Simulation working group for FDA. Additionally, Tina led the development of guidance and standards for enhancing modeling credibility and acceptance. For instance, she led the development a verification and validation standard for ASME, which culminated in 2018 with the first-ever set of evaluating procedures for computational modeling of medical devices, the ASME V&V 40 standard. This framework is currently being adapted for the review of computational modeling for drug development in CDER. Because of these efforts, Tina was selected as the 2019 Federal Engineer of the Year for the FDA, received ASME's Dedicated Service Award in 2020, and she was inducted into the University of Connecticut's Academy of Distinguished Engineers.

She is a mechanical engineer who completed a postdoctoral fellowship at Stanford University in Cardiovascular Biomechanics, earned her Ph.D. in Theoretical & Applied Mechanics from Cornell University, and her M.S. and B.S. in Mechanical Engineering from the University of Connecticut.

On a personal note, Tina is a wife and mother of a 7-year-old. Movement, music, and poetry are essential to her health and happiness, and ideally those happen outdoors. She also takes great pleasure in cooking and making chocolate (for others).

Leonard D Grant

Office of Finance, Budget, Acquisitions, and Planning/Office of Acquisitions and Grants Services

Leonard Grant serves as FDA's Head of Contracting Activity (HCA) and Director, Office of Acquisitions and Grants Services. In this capacity, he has the overall management and oversight of an office responsible for awarding approximately 7,400 contracts, grants, interagency agreements, and purchase card actions totaling approximately $2.52B annually. He also has oversight of the Acquisition Career Manager and the Federal Acquisition Certification in Contracting (FAC-C), FAC-COR, and FAC-P/PM programs. He began his Civil Service Career in 1991, as a Contract Specialist at the Office of Acquisitions and Grants Services. During his 30 years of federal service, he has held various positions including Contracting Officer, Team Leader, Branch Chief, Division Director, Associate Director, and is now a member of the Senior Executive Service (SES).

Leonard is a Federal Acquisition Certification-Contracting (FAC-C) level III Certified Contracting Officer with an Unlimited Warrant. Leonard serves on the Federal Acquisition Regulation (FAR) Technology Team, a workgroup under the Civilian Agency Acquisition Council (CAAC), responsible for assisting with updates or revisions to the FAR. He was also selected to serve on the National Contract Management Association (NCMA) Board of Advisors.

Leonard also served as a Commissioned Officer in the United States Army Reserves retiring at the rank of Lieutenant Colonel after 30 years of service. He served in various leadership positions during his military career and has been deployed twice serving as a Battalion Military Transition Team Leader in Iraq in 2005 and the G-3 Advisor to the Afghanistan National Civil Order Police in 2011.

Leonard's dedication to service has garnered many awards over his career to include the Commissioner's Special Citation award and many Leadership Excellence awards and military decorations.

Leonard is married and has three children. They reside in Derwood, Maryland.

Shaila Shaheed, MS, PM, FAC-COR

OC/OCS/Office of Regulatory Science and Innovation (ORSI)

Shaila Shaheed joined ORSI in 2013, and serves as the leader for a regulatory science program focused on extramural research and development with an annual investment portfolio of 70+M. She is responsible for the scientific, administrative, and/or technical aspects of the program, including developing annual solicitation announcement, coordinating, and leading technical panel evaluation and signing off on panel recommendations and correspondences. Shaila provides programmatic technical assistance to various FDA subject matter experts (SMEs) interested in regulatory science research to fulfill an unmet area of need. She provides coordination and guidance for the centers, offices, and related programs agency wide. She is well versed in FDA's Focus Area of Regulatory Science (FARS) report 2021, 2022 and the FDA Strategic Science Plan 2011. She supervises a team of project managers and coordinators in ORSI. Shaila and her team manages the BAA SharePoint solution with data repositories and business process workflows.

Before joining ORSI, Shaila worked as a Business Program Manager at Office of Regulatory Affairs (ORA) FDA for three years. In this role, she led and managed the Laboratory Information Management System (LIMS), a large and complex scientific IT system related project for 13 field ORA labs, HQ and 2 mobile labs.

Before entering the regulatory agency, Shaila worked at Covance (currently known as Labcorp Drug Development), a Contract Research Organization (CRO), for more than seven years. As an IT Quality Control, she assisted in implementing and validating 30+ local, global web and client-server computer applications in compliance with GLP, GCP, GMP, 21 CFR part 11. As a Research Assistant, Shaila performed various non-clinical genetic toxicology lab assays.

Shaila has been a Contracting Officer's Representative (COR) Level II for over ten years and holds a Project Management Master Certificate from George Washington University. She has a M.S. in Biotechnology with a concentration in Regulatory Affairs from Johns Hopkins University and a Bachelor of Science in Biology degree from George Mason University.

Shaila is married with two kids and lives in Ellicott City, Maryland. She enjoys traveling, reading, music and spending time outdoors.

Ian Weiss

Office of Finance, Budget, Acquisitions, and Planning/OAGS/DAO/ Scientific Support Branch

Ian Weiss is the Branch Chief for the Scientific Support Branch (SSB) under the Division of Acquisition Operations (DAO).

Ian has contributed to OAGS serving as the Team Lead for the Service Contract Branch (SCB) for the last 7 months. In his role as Team Leader, he used his extensive experience in contracting, management, and administration in solving acquisition challenges faced by OAGS and FDA Centers. Ian used his passion for Federal contracting and assisted in closing out FY2022, helping to award major contracts, and ensured that his customers met their acquisition objectives. During his time as Team Lead, Ian displayed a lot of confidence and maturity in the acquisition field and has been committed to building relationships across the branch, division and with the program office. Ian prefers to lead and teach by example. This has been demonstrated through his participation in “Ask OAGS Day”. He is customer focused and believes in engaging with staff every day.

Prior to coming to OAGS, Ian Weiss held a Branch Chief (equivalent to Division Director position) at the United States Coast Guard’s (USCG) Surface Forces Logistics Center for three years. Here he managed approximately 50 contracting professionals with a portfolio of over 90 contracts for both goods and services, FAR parts 8, 12, 13 and 15, with a total value of over $180M. He served as the “Level above review” for 8 contracting officers with warrant authority ranging from $250K - $25M. Ian also served for 2 years with the Army Corps of Engineers. Ian has several awards from the Army Corps and the Coast Guard for teamwork and contracting excellence. Ian proudly served in the USCG as an active-duty Chief Warrant Officer.

When Ian is not awarding contracts and mentoring his team members, he enjoys beekeeping, crafting charcuterie to share with friends and family and tending to his garden.

Jessika Alfaro

OC/OCS/Office of Regulatory Science and Innovation (ORSI)

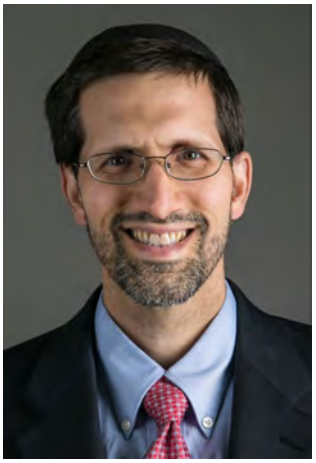
Jessika Alfaro joined the Office of Regulatory Science and Innovation (ORSI) in July of 2018 and serves as a program coordinator to the FDA Broad Agency Announcement (BAA) program. She provides critical support to the BAA program manager and is responsible for cross-agency communication and coordination to facilitate the BAA review process. In addition, she has provided support for the Center of Excellence (CERSI) program and OCS Challenge grant. Her dedication contributes toward a highly effective program with sustained growth that is critical to the FDA's ability to stay at the forefront of regulating emerging technologies.

She started at FDA in 2012 as a student and worked in CDER's Office of Surveillance and Epidemiology. In 2015, she joined the Office of Generic Drugs in the Office of Research Standards as an ORISE fellow and worked on the Generic Drug User Fee Amendments (GDUFA) regulatory science research program. In 2017, she moved to the Office of New Drugs in the Office of Antimicrobial Products as an ORISE fellow where she supported the regulatory research science program.

Jessika is a COR-Level I and holds an M.S. in Regulatory Science from the University of Maryland Baltimore Pharmacy School, and a B.S. in Public Health Science from The University of Maryland, College Park.

Sammersingh Raney, PhD

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 30 years of experience in skin research, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, and serves on multiple expert committees and panels for the U.S. Pharmacopeia. He is the Associate Director for Science in the FDA's Office of Research and Standards and serves as the Chief Scientific Advisor for topical product bioequivalence issues in FDA's Office of Generic Drugs. Dr. Raney holds a Bachelor's Degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.



Neil Stiber, PhD

Neil Stiber is the Associate Director for Science and Communication in CDER/OPQ/Office of Quality Surveillance. During nine years at CDER, he has innovated risk-based approaches, provided collaborative program leadership, and engaged stakeholders to advance pharmaceutical quality. Previously, he was the director of ORA's Risk Management Staff and for eight years was an environmental scientist at the U.S. EPA. Prior to joining the federal government, he specialized in environmental risk assessment. Neil earned BSE and MS degrees in civil engineering. He received a PhD in Engineering and Public Policy from Carnegie Mellon University.

Thomas O'Connor, PhD

Thomas O'Connor, PhD is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is the vice-chair of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches.

Emily Braunstein, PhD

Dr. Braunstein is the CBER Regulatory Science Program Manager at the Center for Biologics Evaluation and Research (CBER) at the FDA. In this position, Emily serves as an advisor to the CBER Associate Director for Science supporting CBER's regulatory science research program. She represents CBER and the research program on various agency and center initiatives and develops policies and procedures supporting CBER's research laboratories. Dr. Braunstein leads a broad range of activities including research program reporting and evaluation and the CBER Select Agent Program. Emily joined CBER/FDA in 2012. Prior to her position in CBER, she was a research scientist at Pfizer working on vaccine research and development. In 2005, Dr. Braunstein received her Ph.D. in microbiology and immunology from Albert Einstein College of Medicine.

Christina Webber, PhD

Dr. Christina Webber is a Regulatory Science Program Manager on the Partnerships to Advance Innovation and Regulatory Science (PAIRS) team in the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration. She coordinates CDRH's regulatory science research intramural and extramural funding programs, manages CDRH's public-private partnerships, and develops regulatory science fellowship programs. Dr. Webber also leads the Collaboration and Partnership Workstream for CDRH's Advance Health Equity Strategic Priority. Her other work at the Agency is with the Digital Health Center of Excellence to advance the appropriate use of digital health technologies, or DHTs, in the regulatory space. Dr. Webber began her time at the FDA as an American Institute for Medical and Biological Engineering (AIMBE) Scholar. Prior to joining the FDA, she completed her Ph.D. in Biomedical Engineering and Physiology at the Mayo Clinic Graduate School of Biomedical Sciences. Her doctoral research focused on upper extremity biomechanics, characterizing the independent function in adults with traumatic brachial plexus injuries. Dr. Webber also holds an M.S. degree in Biomedical Engineering, specializing in biomechanics, from the University of Akron where she conducted lower extremity prosthetics research. She earned her B.S. in Bioengineering at the Pennsylvania State University.

Robert Orr

Robert "Bobby" Orr is a biologist and project manager for the extramural component of the MCMi Regulatory Science Program He serves as a contracting officer representative (COR) and technical point of contact for both OCET and OCS contract and grant programs, and also provides technical support for the OCET Monitoring and Assessment (M&A) portfolio. Bobby joined OCET in 2016, and FDA in 2012 as a contract specialist and has expertise in both biological sciences and in acquisition, including contracts, grants, and the FDA's Broad Agency Announcement. Before joining FDA, Bobby consulted on the Agricultural Defense portfolio in the Department of Homeland Security, Chemical & Biological Defense Division. Bobby earned a BS in biology from James Madison University and an MS in biodefense from George Mason University.

Julie Schneider, PhD

Julie Schneider, Ph.D. is Associate Director for Research Strategy and Partnerships at the FDA Oncology Center of Excellence (OCE). In this role, she oversees the OCE Scientific Collaborative which supports applied research activities addressing topics identified during regulatory review of oncology products. She previously ran the HHS Entrepreneurs-in-Residence Program within the HHS IDEA Lab and worked in several roles at the National Cancer Institute (NCI) focused on developing new research funding opportunities. Julie initially joined the NCI as an AAAS Science and Technology Policy Fellow and obtained her doctoral degree in genetics from the University of Oxford and her bachelor's degree in biology from Yale.

Christine Lee, PhD

Dr. Christine Lee serves as the Lead for Strategic Research Engagement for the Office of Minority Health and Health Equity (OMHHE) in the Office of the Commissioner at the U.S. Food and Drug Administration. She leads minority health and health disparity focused research and develops strategic partnerships to advance the health of diverse populations. Prior to joining OMHHE, Dr. Lee's work included structuring unstructured FDA materials as well as social media data to inform regulatory decision making. Christine Lee received her PharmD from the University of Buffalo and her PHD in Pharmaceutical Outcomes and Policy from the University of Florida. Dr. Lee aims to develop research and strategic innovations that advance the health for all populations.

Alice Welch, PhD

As Director of the FDA Technology Transfer Program, Dr. Welch leads a team responsible for enhancing FDA's regulatory science programs by establishing collaborations for FDA research programs and partnerships for FDA initiatives. The Technology Transfer Program also promotes the full use of and access to inventions that come out of FDA's research investment, encompassing a wide range of technology areas including pathogen detection and reduction, substandard and falsified drug detection, and phantoms for performance evaluation of medical imaging devices. The Technology Transfer Program provides FDA with over 60 years of combined partnership, intellectual property management, and technology transfer expertise. The Program leads and coordinates technology transfer efforts across FDA by engaging with researchers and technology transfer staff in FDA's seven product Centers, the Office of Regulatory Affairs, and the Oncology Center of Excellence. Dr. Welch has directed the Program since 2008, driving expansion of the Program to its present scope of responsibilities, collaborative networks, and impact. Dr. Welch previously managed invention and collaboration portfolios at the National Institute of Diabetes, Digestive, and kidney diseases and at the National Institute of Allergy and Infectious Diseases at NIH. She holds a B.S. in Life Sciences from MIT and a Ph.D. in Cellular and Molecular Physiology from Tufts University School of Medicine.

Bridget Foltz, MS, MT(ASCP)

Bridget serves as FDA's HSP Executive Officer and provides overall leadership, direction, expert technical advice, and support for human subject protection program activities coordinated by the Office of the Chief Scientist (OCS) for human subjects research conducted or supported by the FDA. She works closely and collaboratively with the Offices and Centers to support and advise FDA staff involved in human subjects research and facilitates OCS coordinating activities to promote and respect the rights, welfare, and wellbeing of human subjects in research conducted or supported by FDA. Bridget previously worked in the Office of Clinical Policy (OCLiP) where she supported the development and revision of regulations and guidance and served as a resource to a variety of internal and external stakeholders on good clinical practice (GCP) and HSP issues relating to FDA-regulated clinical trials. Prior to joining FDA in 2003, Bridget worked in both the medical device and pharmaceutical industries, specifically in the areas of clinical diagnostics and vaccine development and production. Her background is in both biology and medical technology. She has earned a Master of Science in Biotechnology from Johns Hopkins University and a Master's Certificate in Project Management from the George Washington University.

Domini Bean

Domini Bean is a desk officer in FDA's Office of Operations. Domini joined FDA's Office of the Chief Counsel in 1991 as legal assistant to the Deputy Chief Counsel for Litigation. As a paralegal specialist, Domini subsequently went on to serve as Regulatory Counsel in the Center for Devices and Radiological Health. Domini also holds a master's certificate in Project Management from the George Washington University School of Business and currently serves as the Agency's lead analyst regarding implementation of the Paperwork Reduction Act.