



U.S. FOOD & DRUG
ADMINISTRATION

2021 FDA Science Forum

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Science as the Foundation for Protecting
and Promoting Public Health

May 26 & 27, 2021



2021 FDA Science Forum

FDA: Science as the Foundation for Protecting
and Promoting Public Health

Wednesday, May 26, 2021
& Thursday, May 27, 2021

Virtual Webcast

To access the 2021 FDA Science Forum main sessions
and topic areas, please use the webcast links

[2021 FDA Science Forum](#)





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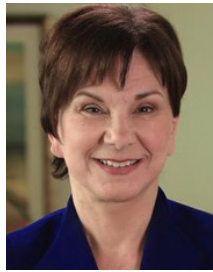
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A Message from FDA's Acting Commissioner



Janet Woodcock, MD
Acting Commissioner, FDA

It is a pleasure to welcome this year's participants to the FDA Science Forum, our biennial gathering that celebrates the many ways our agency applies groundbreaking science and emerging technologies in support of innovation and science-based regulation, which ultimately translates to a healthier and safer U.S. population.

It is thanks to the expertise, hard work, and creativity of our scientists that we can develop the tools and resources to support the many scientific and technological developments that are shaping our world and that can make such an enormous difference in the lives of Americans. Importantly, we are joined in this meeting by members of industry, academia, patient advocacy organizations, and government, with whom we often collaborate and support in our work.

The FDA's scientific activities are wide-ranging. They match the broad expanse of our regulatory responsibilities, which include: strengthening food safety; providing more and better information on the dangers of tobacco products; facilitating medical device innovation by advancing regulatory science; creating tools to better measure patient perspectives; and encouraging and promoting the development of new treatments and cures for disease, which also places an emphasis on engaging patients' voices.

During this Forum, you will have the opportunity to hear about a number of these applications and explorations. There may be no better example of how we embrace these scientific challenges, however, than FDA's response over the past year to the SARS-CoV-2 virus, a public health crisis that has had an overwhelming impact on our lives and, to some degree, scientific research.

Not only has the FDA's workforce demonstrated extraordinary commitment and resilience throughout this public health emergency, they have also brought to it the best scientific research and most rigorous examination of available data. They confirmed that the FDA is uniquely equipped to respond to this kind of crisis through our ability to provide the nation with science and data-based answers to these unparalleled medical challenges.

We've been working non-stop since the beginning of the pandemic to gain greater understanding of COVID-19, and to support the development and availability of medical products to respond to this unprecedented public health emergency.

From our efforts to strengthen the design and conduct of clinical trials, to expanding the data sources that can aid in our evaluation of medical products through the use of real-world evidence, to the analysis of new tests and treatments, the FDA has applied the

best in scientific innovation to quickly react to the crisis.

For example, our use of the Emergency Use Authorization has allowed the FDA to provide a speedy response to the nation's demand. We've authorized more than 350 EUAs, enabling access to more than 700 products, including COVID-19 tests and collection kits, ventilators and other respiratory support devices, personal protective equipment (PPE), and 3 vaccines, as well as many other medical products. And we've maintained our high standards of review, applying the best available science to satisfy the relevant statutory standards, with FDA scientists carefully considering the known and potential benefits and risks.

Throughout, we've collaborated with and supported our partners in federal and state government, as well as with external stakeholders representing industry, academia,

patients, and the healthcare community, who play such an important role in this work.

Although a public health emergency may underscore the significance and value of the FDA's scientific work, this Forum serves to remind us that these efforts go on every day, in every area we regulate. Each day, we scrutinize new products and scientific advances that may shed light on medical challenges and that offer expanded possibilities for protecting patients and consumers.

It is the essence of what we do, informing our regulatory decision-making and supporting our mission to protect and promote the public health. It is our responsibility, but also our passion.

I thank you for your participation in this year's Science Forum, and I hope you have an enjoyable and productive meeting.

A Message from FDA's Chief Scientist



RADM Denise Hinton

Acting Chief Scientist, Office of the Chief Scientist, OC, FDA

It is my great honor to welcome you to the 2021 FDA Science Forum. As we begin to emerge from a pandemic that has put the world on pause and FDA on a 24/7 response to the crisis, the research presented at the 2021 Science Forum is a reminder that the unprecedented speed at which COVID-19 vaccines were developed and made available under EUAs is due in no small part to the critical role FDA plays every day in advancing biomedical innovation.

FDA's mission is broad and complex, and the science underpinning our regulatory decision-making is evolving at breakneck pace. This two-day FDA Science Forum gives the public a chance to see how FDA scientists are applying novel science and technologies to innovate and to ensure that the food we eat is safe, our medical products are safe and effective, and that harm from tobacco products is reduced.

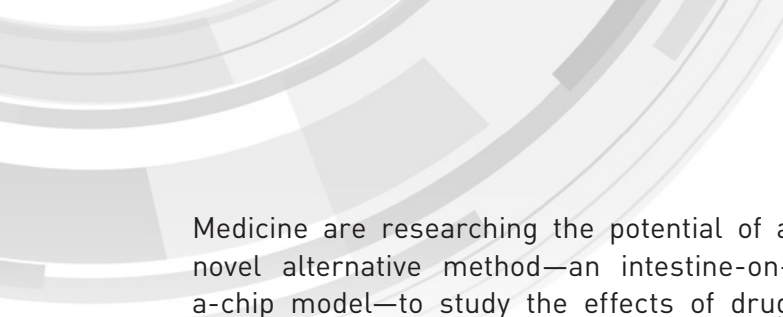
One example of FDA innovation highlighted in this Forum is the Biologics Effectiveness and Safety: Innovative Methods initiative—or BEST IM. Existing adverse-event reporting systems for biological products face multiple challenges, ranging from the burden of manual reporting to under-reporting for certain products and inconsistencies in the quality of reports.

FDA's Center for Biologics Evaluation and Research launched the BEST IM initiative to address these challenges. BEST IM is lever-

aging artificial intelligence, machine learning, natural language processing, and semi-automated medical chart review to advance and improve postmarket adverse event reporting and ensure the safety and effectiveness of biological products. BEST IM will also minimize the reporting burden.

An important contribution to patient safety in combating COVID-19 is the drug labeling tool FDALabel, developed through a collaboration between FDA's National Center for Toxicological Research and the Center for Drug Evaluation and Research. FDA drug product labeling provides essential scientific information for the safe and effective use of FDA-regulated products. A product's labeling typically contains information ranging from indications, dosage, and patient use instructions to important side effects and other warnings. The FDALabel database tool manages the full set of 135,000 FDA electronic digital labeling documents with powerful functions for querying and information retrieval. Among other capabilities it enables researchers, patients, pharmacists, doctors, and health care professionals to quickly search and identify the most up-to-date information on a drug product, including current FDA-regulated COVID-19 products and safety information.

Scientists at FDA's Center for Veterinary



Medicine are researching the potential of a novel alternative method—an intestine-on-a-chip model—to study the effects of drug residues on human intestinal microbiome and antimicrobial resistance development. The effects on the human intestinal microbiome of drug residues in or on animal-derived foods is an important human food safety issue that needs to be addressed during pre-approval evaluations of drug products intended for use in food-producing animals. Developing a validated intestine-on-a-chip model will provide a new and powerful tool for drug sponsors and FDA to address the effects of antimicrobial drug residues on the human intestinal flora. This effort is a substantial step forward in FDA's efforts to reduce or refine reliance on animals for research.

These three examples are but a snapshot of the work we do, as the 369 posters, 8 sessions, and more than 60 experts who participate in this Science Forum will attest. Together with our stakeholders in academia, industry, and sister agencies—as well as patient advocacy groups—FDA is preparing for the emerging technologies that will affect the products we regulate in the years to come.

We hope that all who attend our virtual 2021 Science Forum gain a deeper appreciation of the groundbreaking science we do at FDA to protect, promote, and advance the public health. We look forward to future opportunities to share more of the exciting advances we're making and to collaborate with our partners in the scientific community.

Keynote Speaker



Anthony S. Fauci, MD
NIAID Director
National Institutes of Health (NIH)

Anthony S. Fauci, MD is director of the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health, where he oversees an extensive research portfolio focused on infectious and immune-mediated diseases. As the long-time chief of the NIAID Laboratory of Immunoregulation, Dr. Fauci has made many seminal contributions in basic and clinical research and is one of the world's most-cited biomedical scientists. He was one of the principal architects of the President's Emergency Plan for AIDS Relief (PEPFAR), a program that has saved millions of lives throughout the developing world.

Keynote Speech

COVID-19 in 2021: Lessons Learned and Remaining Challenges

Dr. Fauci will discuss advances in understanding the epidemiology, natural history and pathogenesis of COVID-19; progress in developing and implementing therapeutics, vaccines and diagnostics; and the work that remains.



FDA: Science as the Foundation for Protecting and Promoting Public Health

Learning Objectives:

1. Discuss FDA contributions to the evolving science of clinical, non-clinical, and post-market evaluation
2. Explain how AI and big data together can improve public health.
3. Discuss how FDA leverages social and behavioral sciences to empower patients and consumers
4. Describe ways in which we are moving into the future.
5. Discuss the potential utility and challenges of new technologies, such as, microphysiological systems, microbiome, or combination of both, in advancing product development and integrating this knowledge in scientific communications with regulatory and research work.
6. Discuss the application of innovative tools and approaches to support pandemic response, development and evaluation of MCMs and the detection of adventitious agents.
7. Distinguish the varied levels of activity within FDA and with various external stakeholders in protecting public health.

2021 Science Forum Agenda: Day 1

May 26, 2021

[Webcast Mediasite link](https://fda.yorkcast.com/webcast/Play/b62823fe42f740dda1b386a401f08d061d)

<https://fda.yorkcast.com/webcast/Play/b62823fe42f740dda1b386a401f08d061d>

[YouTube links](https://youtu.be/G3mS-3pNWJo)

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|---------------------|--|
| 9:00 am – 9:05 am | Introduction
Sharron Watson - OSPD |
| 9:05 am - 9:15 am | Welcome
FDA Chief Scientist, RADM Denise Hinton |
| 9:15 am - 9:45 am | Opening Remarks and Introduction of Keynote Speaker
Acting FDA Commissioner, Janet Woodcock, MD |
| 9:45 am - 10:15 am | Keynote Speaker: COVID-19 in 2021: Lessons Learned and Remaining Challenges
NIAID Director, Anthony S. Fauci, MD,
National Institutes of Health (NIH) |
| 10:15 am - 10:30 am | Break |

10:30 am – 12:30 pm Concurrent Sessions 1 & 2

Concurrent Session 1: Improving Clinical and Post-market Evaluation

[Webcast Mediasite link](#)

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[YouTube links](#)

<https://youtu.be/G3mS-3pNWJo>

10:30 am – 12:30 pm

Session Chairs/Moderator: Julie Schneider, PhD and Steven Berman, MPH

Time	Presentation	Speaker
10:30 am - 11:05 am	Between Marketing Approval and Appropriate Use of Medical Products--Time to Transform the System	Robert M. Califf, MD, MACC Head of Clinical Policy and Strategy for Verily and Google Health Adjunct Professor, Duke University and Stanford University
11:05 am - 11:20 am	Applications for Surveillance: Interrogating Whole-Genome Sequence and CAERS Data	James Pettengill, PhD CFSAN/FDA
11:20 am - 11:35 am	Regulatory Science/Research Needs Related to Digital Health	Bakul Patel, MSEE, MBA CDRH/FDA
11:35 am - 11:50 pm	Regulatory Applications and Research of Model-Informed Drug Development (MIDD).	Yaning Wang, PhD CDER/FDA
11:50 pm - 12:05 pm	Including Non-Concurrent Control Data in Bayesian Adaptive Platform Trials When Temporal Changes Exist	Min (Annie) Lin, PhD Statistical Science Director Astra Zeneca
12:05 pm - 12:30 pm	Q&A/ Discussion	Robert M. Califf, MD, MACC James Pettengill, PhD Min (Annie) Lin, PhD Yaning Wang, PhD Bakul Patel, MSEE, MBA

Concurrent Session 2: Tools to Effectively Use Big Data

[Webcast Mediasite link](#)

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[YouTube link](#)

<https://youtu.be/v9z0iVfMaBQ>

10:30 am – 12:30 pm

Session Chairs/Moderator: Donna Mendrick, PhD

Time	Presentation	Speaker
10:30 am - 11:00 am	Democratizing Screening & Diagnostics with AI	Lily Peng, MD, PhD Product Manager Google Health
11:00 am - 11:15 am	Developing a Deep Learning MedDRA Encoder (MedDRA-DeepCoder) for Patient Narratives	Qais Hatim, PhD CDER/FDA
11:15 am - 11:30 am	CBER BEST: Leveraging AI to Build an Automated Adverse Event Reporting System	Hussein Ezzeldin, PhD CDER/FDA
11:30 am - 11:45 am	BE ASSESSMENT MATE (BEAM) - A Data Analytics Tool to Enhance Efficiency, Quality, and Consistency of Bioequivalence Assessment	Meng Hu, PhD CDER/FDA
11:45 am - 12:00 pm	Trade-off Between Explainability and Predictivity in Toxicity Assessment with AI	Leihong Wu, PhD NCTR/FDA
12:00 pm - 12:15 pm	Use of Machine Learning to Improve Food Safety Quantitative Microbial Risk Assessment	Hao Pang, PhD CFSSAN/FDA
12:15 pm - 12:30 pm	Role of AI in Medical Imaging	Berkman Sahiner, PhD CDRH/FDA
12:30 pm - 1:30 pm	Lunch	

1:30 pm- 3:30 pm Concurrent Session 3 & 4

Concurrent Session 3: Empowering Patients and Consumers

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[YouTube link](https://youtu.be/G3mS-3pNWJo)

<https://youtu.be/G3mS-3pNWJo>

1:30 am - 3:30 pm

Session Chairs/Moderator: Christine Lee, PhD/ Andrea Furia Helms, MPH

Time	Presentation	Speaker
1:30 pm - 1:40 pm	Introduction	Andrea Furia Helms, MPH OC/FDA
1:40 pm - 1:55 pm	Listening Sessions to Uncover Patient Questions: The COVID-19 Vaccine Confidence Project	Susan Winckler, JD Chief Executive Officer of Reagan Udall Foundation (RUF)
1:55 pm - 2:05 pm	Understanding Perceptions and Attitudes about COVID-19 Testing in Underrepresented Populations	Jessica Weinberg, MPP CDRH/FDA
2:05 pm - 2:15 pm	COVID-19 and Tobacco use: The latest from the Population Assessment of Tobacco and Health Study	Yu-Ching Cheng, PhD CTP/FDA
2:15 pm - 2:25 pm	Impact of COVID-19 on FDA Orphan Products Grants	Christine Mueller, DO OC/FDA
2:25 pm - 2:35 pm	COVID-19 Pandemic: Adjustments to Ongoing Clinical Trials	Wilson Bryan, MD CBER /FDA
2:35 pm - 2:45 pm	FDALabel – a FDA Product Labeling Tool Enabling Patients and Consumers Safety in Combating COVID-19	Hong Fang, PhD NCTR/FDA
2:45 pm - 2:55 pm	Patient Focus Groups to Enhance Communications Addressing Biosimilar Drug Products	Brian Lappin, MA CDER/FDA
2:55 pm - 3:05 pm	2019 FDA Food Safety and Nutrition Survey – Making Food Safety and Nutrition Accessible to Public Health Professionals	Amy Lando, MPP CFSAN/FDA
3:05 pm - 3:15 pm	Addressing Demographic Subgroup Underrepresentation in Oncology	Lola Fashoyin-Aje, MD, MPH OCE/FDA
3:15 pm - 3:25 pm	Advancing Health Equity through Outreach and Communications	Jovonni Spinner, MPH, CHES OMHHE/FDA
3:25 pm - 3:30 pm	Closing Remarks / Discussion	Christine Lee, PharmD, PhD OMHHE/FDA

Concurrent Session 4: Product Development and Manufacturing

[Webcast Mediasite link](https://fda.yorkcast.com/webcast/Play/cca6a93ebb15402d93438b11c79ed2381d)

<https://fda.yorkcast.com/webcast/Play/cca6a93ebb15402d93438b11c79ed2381d>

[YouTube link](https://youtu.be/v9z0iVfMaBQ)

<https://youtu.be/v9z0iVfMaBQ>

1:30 pm - 3:30 pm

Session Chairs/Moderator: Suzanne Fitzpatrick, PhD

Time	Presentation	Speaker
1:30 pm - 2:00 pm	21st Century Solutions for 21st Century Problems	Geoffrey Ling, MD, PhD Chief Executive Officer, On Demand Pharmaceuticals
2:00 pm - 2:15 pm	MALDI Imaging Mass Spectrometry: A New Imaging Modality for Use in Toxicological Studies	Elizabeth Jones, PhD NCTR/FDA
2:15 pm - 2:30 pm	Advancing New Alternative Methodologies at FDA: The Expanded Decision Tree	Szabina Stice, PhD CFSAN/FDA
2:30 pm - 2:45 pm	ISTAND: A Pilot Program to Address Novel Technologies as Drug Development Tools (DDTs)”	Christopher Leptak, MD, PhD CDER/FDA
2:45 pm - 3:00 pm	Medical Device Cybersecurity	Kevin Fu, PhD CDRH/FDA
3:00 pm - 3:15 pm	FDA’s Advanced Manufacturing Journey	Sau Lee, PhD CDER/FDA
3:15 pm - 3:30 pm	Understanding Ex Vivo Manufacturing of HSC-Based Therapeutics	Pankaj Mandal, PhD CBER/FDA

End of Day 1



2021 Science Forum Agenda: Day 2

May 27, 2021

[Webcast Mediasite link](#)

<https://fda.yorkcast.com/webcast/Play/4f169c55537f4e17b17dde8c2b2986f21d>

[YouTube link](#)

<https://youtu.be/GT2dN870hgY>

8:55 am – 9:00 am **Opening Remarks**
Rokhsareh Shahidzadeh

9:00 am 11:00 am

Concurrent Session 5 & 6

Concurrent Session 5: Advancing Products Based on Novel Technologies

[Webcast Mediasite link](#)

<https://fda.yorkcast.com/webcast/Play/4f169c55537f4e17b17dde8c2b2986f21d>

[YouTube link](#)

<https://youtu.be/GT2dN870hgY>

9:00 am - 11:00 am

Session Chair/Moderator: Beverly Lyn-Cook, PhD and Silvia Pineiro, PhD

Time	Presentation	Speaker
9:00 am – 9:05 am	Introduction	Silvia Pineiro, PhD CVM/FDA
9:05 am – 9:30 am	Overcoming Challenges in Co-Culture of Super Strict Anaerobes with a Healthy Human Colon Mucosal Barrier	Linda G. Griffith, PhD Professor, Biological and Mechanical Engineering, Massachusetts Institute of Technology
9:30 am – 9:40 am	Advancing Regulatory Science Through Organ on a Chip	Daniel Tadesse, PhD CVM/FDA
9:40 am – 9:50 am	Microbiome as an Additional Criterion for Safety Assessment	Sangeeta Khare, PhD OC/FDA
9:50 am – 10:05 am	Emergence of Nosocomial Associated Opportunistic Pathogens in the Gut Microbiome After Antibiotic Treatment Revealed by a Mouse Model Metagenome Analysis	Zhihua Li, PhD CDER/FDA
10:05 am – 10:15 am	Safety and Effectiveness of Fecal Microbiota Transplantation Products	Paul Carlson, PhD CBER/FDA
10:15 am – 10:30 am	Microphysiological System Regulatory Research Considerations: Evaluation of a Model System	Kirsten Eckstrum, PhD CFSAN/FDA
10:30 am – 10:40 am	Evaluation of Endothelial Cell Responses to Nanomaterials Using a Dynamic Flow Model	Shelby Skoog, PhD CDRH/FDA
10:40 am – 10:50 am	Microphysiological Systems to Assess the Functional Capacity of Regenerative Medicine Cellular Products	Kyung Sung, PhD CBER/FDA
10:50 am – 11:00 am	Closing remarks/Discussion	Beverly Lyn-Cook, PhD NCTR/FDA

Concurrent Session 6: Medical Countermeasures, Infectious Disease and Pathogen Reduction Technologies

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<https://fda.yorkcast.com/webcast/Play/a6528d3f063d432da5badc6398125e6a1d>

[YouTube link](https://youtu.be/hYiX4KVKi5E)

<https://youtu.be/hYiX4KVKi5E>

9:00 am - 11:00 am

Session Chairs/Moderator: Monica Young, PhD and CAPT Tracy MacGill, PhD

Moderator: Carol Weiss, MD, PhD

Time	Presentation	Speaker
9:00 am - 9:05 am	Introduction	Carol Weiss, MD, PhD CBER/FDA
9:05 am - 9:30 am	Outbreak Preemption and Response in the Genomic and Information Age	Pardis Sabeti, MD, PhD Institute Member, Broad Institute of the Massachusetts Institute of Technology (MIT)/ Harvard Medical School
9:30 am - 9:45 am	Evaluation of Pathogenesis of SARS-CoV-2 Variants	Tony Wang, PhD CBER/FDA
9:45 am - 10:00 am	Artificial Intelligence-Powered Drug Repurposing Against COVID-19	Zhichao Liu, PhD NCTR/FDA
10:00 am-10:15 am	Device Medical Countermeasure Activities During the COVID-19 Pandemic	Heather Agler, PhD CDRH/FDA
10:15 am - 10:30 am	Emerging Technologies for Adventitious Agent Detection and Their Application to CDER Products	Kathryn King, PhD CDER/FDA
10:30 am - 10:45 am	Ora's Work in Support of Medical Countermeasures	Elizabeth Miller, PharmD FDA/ORA
10:45 am - 10:55 am	Panel Discussion/Q&A	Heather Agler, PhD Kathryn King, PhD Zhichao Liu, PhD Elizabeth Miller, PharmD Pardis Sabeti, MD, PhD Tony Wang, PhD
10:55 am - 11:00 am	Closing Remarks	Carol Weiss, MD, PhD
11:00 am - 12:00 pm	Lunch	

12:00 pm – 2:00 pm Concurrent Sessions 7 & 8

**Concurrent Session 7:
Food and Cosmetic Safety: The Role of Innovation and Technology**

[Webcast Mediasite link](https://fda.yorkcast.com/webcast/Play/4f169c55537f4e17b17dde8c2b2986f21d)

<https://fda.yorkcast.com/webcast/Play/4f169c55537f4e17b17dde8c2b2986f21d>

[YouTube link](https://youtu.be/GT2dN870hgY)

<https://youtu.be/GT2dN870hgY>

12:00 pm – 2:00 pm

Session Chairs/Moderators: Chad Nelson, PhD, MSPH, Jeffrey Ward, DVM, Zhichao Lin, PhD

Time	Presentation	Speaker
12:00 pm – 12:05 pm	Introduction	Chad P. Nelson, PhD, MSPH CFSAN/FDA
12:05 pm – 12:35 pm	One Health as a Collaborative Response to Food Safety Risks	Kalmia Kniel, PhD Professor, Animal and Food Sciences, University of Delaware
12:35 pm – 12:50 pm	CFSAN's Use of Innovative Science to Address Current and Emerging Public Health Priorities	Susan Mayne, PhD CFSAN/FDA
12:50 pm – 1:05 pm	FDA Support of Recent Foodborne Illness Outbreak Investigations	Daniel Rice, DrPH, MS ORA/FDA
1:05 pm – 1:20 pm	What Won't an Animal Eat? Innovation in Animal Diets	David Edwards, PhD CVM/FDA
1:20 pm – 1:35 pm	Mind the [Data] Gap: Contributions of FDA's NCTR to Evaluate Cosmetics Safety	Luisa Camacho, PhD NCTR/FDA
1:35 pm – 2:00 pm	Panel Discussion/ Q&A	<i>Moderator:</i> Jeffrey Ward, DVM Chad P. Nelson, PhD, MSPH Kalmia Kniel, PhD Susan Mayne, PhD Daniel Rice, DrPH David Edwards, PhD, MS Luisa Camacho, PhD

Concurrent Session 8: Substance Use, Misuse, and Addiction

Webcast Mediasite link

<https://fda.yorkcast.com/webcast/Play/a6528d3f063d432da5badc6398125e6a1d>

YouTube link

<https://youtu.be/hYiX4KVKi5E>

12:00 noon – 2:00 pm

Session Chair/Moderator: Marta Sokolowska, PhD

Time	Presentation	Speaker
12:00 pm – 12:05 pm	Introduction	Marta Sokolowska, PhD CDER/FDA
12:05 pm – 12:35 pm	Substance Use Disorders Linked to COVID-19 Susceptibility	Nora D. Volkow, MD Director, National Institute on Drug Abuse/National Institutes of Health (NIH)
12:35 pm – 12:50 pm	COVID-19 and the Opioid Crisis: A Social Media Perspective	Jill Settle, PhD CDER/FDA
12:50 pm – 1:05 pm	And the Kids Vaped on: Teens, Tobacco, and the National Youth Tobacco Survey	Karen Cullen, PhD, MPH CTP/FDA
1:05 pm – 1:20 pm	Investigation of Opioid Exposure and Neural Tube Defects – In Vivo and In Vitro Approaches	Amy Inselman, PhD NCTR/FDA
1:20 pm – 1:35 pm	Tobacco and Cannabis – Did EVALI Teach Us Anything?	Priscilla Callahan-Lyon, MD CTP/FDA
1:35 pm – 2:00 pm	Panel Discussion/Q&A	<i>Moderator:</i> Marta Sokolowska, PhD Nora Volkow, MD Jill Settle, PhD Karen Cullen, PhD Amy Inselman, PhD Priscilla Callahan-Lyon, MD

End of Day 2

Concurrent Session 1: Improving Clinical and Post-market Evaluation

Between Marketing Approval and Appropriate Use of Medical Products--Time to Transform the System



Robert M. Califf, MD, MACC

Head of Clinical Policy and Strategy, Verily and Google Health
Adjunct Professor, Duke University and Stanford University

Dr. Califf is the Head of Clinical Policy and Strategy for Verily and Google Health. Prior to this, Dr. Califf was the Vice Chancellor for Health Data Science for the Duke University School of Medicine; Director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

Abstract: Between Marketing Approval and Appropriate Use of Medical Products--Time to Transform the System

Medical products always carry a combination of benefits and harms. The estimation of benefits and harms and the balance between the two requires empirical evidence supplemented by models to interpolate where direct evidence is not available. The transition into the modern digital world creates the opportunity to improve both direct, empirical evidence and modeling and algorithms. It is now possible to improve every aspect of randomized trials: identification of research participants, collection of high-quality simple data at scale and capture of complex biological data, assessment of outcomes and completeness of follow up. Diverse populations can be enrolled without requirement for expensive and cumbersome travel to specialized research clinics and many trial procedures can be accomplished using digital collection of data rather than follow-up visits. Additionally, improvement in EHR/claims data and streaming of real-time data enables new procedures for identification of participants and application of algorithms to implement trial procedures. Finally, the vast increase in capacity for data with automated curation of data leads to the ability to model for expected outcomes, facilitating improved trial design and better estimates of synthetic control groups or "digital twins" in single arm studies. The use of real-world data and real-world evidence across the spectrum of designs, ranging from traditional RCTs to cluster randomization and observational comparisons is moving quickly, but the fundamental importance of randomization to control for unmeasured confounders and time bias should not be underestimated.

Applications for Surveillance: Interrogating Whole-Genome Sequence and CAERS Data



James Pettengill, PhD

Acting Director, Biostatistics and Bioinformatics Staff,
Office of Analytics and Outreach
FDA, Center for Food Safety and Applied Nutrition

Dr. James Pettengill earned his bachelor's degree from Earlham College and his PhD in evolutionary genetics from the University of Maryland College Park. After a post-doc at the University of Minnesota Twin Cities he joined the FDA's Center for Food Safety and Applied Nutrition (CFSAN) in 2011. Dr. Pettengill has been integral in the development of an analytical workflow for the analysis of whole-genome sequence data from foodborne pathogens that supports regulatory and outbreak response activities. He also supports metagenomic efforts through workflow development on high-performance computing resources. He is currently serving as Acting Director of the Biostatistics and Bioinformatics Staff within the Office of Analytics and Outreach at CFSAN.

Abstract: Applications for Surveillance: Interrogating Whole-Genome Sequence and CAERS Data

The world is awash in data and it is an ongoing challenge to extract and harness the information content of public databases. Here, I describe two dashboards written with R Shiny that have been developed to help interrogate and surveil data sources containing potential signals of interest to public health regarding foods, cosmetics, and dietary supplements. The AEFinder uses the openEBGM (Empirical Bayes Geometric Mean) method for determining disproportionality scores for adverse event data mining; the Pathogen Detection Surveillance application is a lightweight tool for querying a large whole-genome sequence database of foodborne pathogens. These applications highlight the use of statistical methodologies to mine data sources for a signal and illustrate the power of relatively simple applications to facilitate surveillance efforts in the interest of ensuring public health.

Regulatory Science/Research Needs Related to Digital Health



Bakul Patel, MSEE, MBA

Director, Digital Health Center of Excellence
Director, Digital Health Division
FDA, Center for Devices and Radiological Health

Bakul Patel is the Director for Digital Health Center of Excellence, at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies that include Artificial intelligence and Machine learning.

Mr. Patel, in 2013, created the term “software as a medical device” (SaMD) and under his leadership the International Medical Device Regulators Forum (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD.

Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program to reimagine a pragmatic regulatory approach for Digital health that that aims for patients and providers to have timely access to safe and effective digital health products.

Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

Abstract: Regulatory Science/Research Needs Related to Digital Health

The Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration protects and promotes public health by assuring timely patient access to high-quality, safe and effective medical technologies. The Digital Health Center of Excellence’s (DHCoE) goal is to Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation. Recent activities within (DHCoE) include holding public listeing session, publishing a AI/ML action plan that intends to further a practical regulatory framework for modifications to artificial intelligence/machine learning based software as a medical device. During this presentation, Mr. Patel will share some of the Regulatory science/research needs related to Digital Health -- that will be important to advance the goals of the DHCoE to foster responsible innovation of digital health technologies that are driven towards protecting and promoting public health.

Regulatory Applications and Research of Model-Informed Drug Development (MIDD)



Yaning Wang, PhD

Director, Division of Pharmacometrics in the Office of Clinical Pharmacology
FDA, Center for Drug Evaluation and Research

Dr. Yaning Wang is the Director of the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his PhD in Pharmaceutics and master's degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. Dr. Wang oversees reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his 18 years of service at FDA, Dr. Wang received numerous awards, including Award of Merit and FDA Outstanding Service Award.

Regulatory Applications and Research of Model-Informed Drug Development (MIDD)

Model-informed drug development (MIDD) strategy has been applied by the pharmaceutical industry for new drug development. The number of submissions including various applications of MIDD method has increased exponentially in the last two decades. Decisions related to dose optimization, patient selection and drug approval have been supported by MIDD methods ranging from empirical data-driven models, semi-mechanistic models to fully mechanistic pharmacology models. MIDD was incorporated into PDUFA VI as one of the key initiatives. This talk will provide an overview of regulatory applications and research of MIDD from the clinical pharmacology perspective.

Including Non-Concurrent Control Data in Bayesian Adaptive Platform Trials When Temporal Changes Exist



Min (Annie) Lin, PhD
Statistical Science Director
AstraZeneca

Dr. Lin is a Statistical Science Director at AstraZeneca. In her current role, she leads the statistical support for late phase clinical development and regulatory submissions. She also leads or participates in multiple key initiative working groups to provide innovative statistical strategies for cardiovascular, renal and metabolic disease studies.

Prior to moving to industry, Dr. Lin worked in the Division of Biostatistics at Center for Biologics Evaluation and Research (CBER), US FDA as Mathematical Statistician for around 10 years in conducting pre-marketing reviews of gene therapies, cancer vaccines and blood products as well as medical devices. Her expertise was in the area of complex innovative designs (CID), especially in adaptive designs and master protocols. She had participated in several FDA working groups to develop FDA guidances.

In addition, Dr. Lin was an Assistant Professor in the Department of Biostatistics and Bioinformatics at Duke University School of Medicine before joining the FDA. She served as the statistical investigator/co-investigator in various pharmaceutical-funded and government-funded Phase I-IV studies for a wide range of therapeutic areas.

Including Non-Concurrent Control Data in Bayesian Adaptive Platform Trials When Temporal Changes Exist

Temporal changes exist in clinical trials. As time evolves, shifts in patients' characteristics, trial conduct, and other features of a clinical trial may occur. In typical randomized clinical trials, temporal effect, i.e., the impact of temporal changes on clinical outcomes and study analysis, is largely mitigated by randomization and usually needs not be explicitly addressed. However, temporal effect can be a serious obstacle for conducting clinical trials with complex innovative designs (CID), such as the adaptive platform trials (APTs) that are gaining popularity in recent medical product development. The overarching design of APTs is capable of simultaneously studying multiple treatments for a disease indication using a shared control arm. With APTs, non-concurrent control data will be available for the pairwise comparisons between the shared control arm and any newly added treatment arms. How to utilize the non-concurrent data while adjusting the clinical heterogeneities caused by any temporal changes has been statistically challenging. In this talk, we introduce a Bayesian robust prior for mitigating temporal effects while incorporating non-concurrent control data in the APT framework. Simulation studies to evaluate the performance of the proposed method in various scenarios and illustration examples to further demonstrate the utility of the proposal will be presented.

Concurrent Session 2: Tools to Effectively Use Big Data

Donna L. Mendrick, PhD (Moderator)

Associate Director of Regulatory Activities
FDA, National Center for Toxicological Research

Dr. Donna L. Mendrick is the Associate Director of Regulatory Activities at the National Center for Toxicological Research (NCTR) and serves as the liaison between NCTR and the regulatory centers at the FDA. Her FDA-wide committee assignments include chairing the Emerging Sciences Working Group, the Artificial Intelligence Working Group and co-chairing the Alternative Methods Working Group.

Prior to becoming the Associate Director and locating to FDA's White Oak campus, Dr. Mendrick was the Director of the Division of Systems Biology at NCTR. Dr. Mendrick was an Assistant Professor of Pathology at Harvard Medical School and Brigham and Women's Hospital until 1995 when she joined Human Genome Sciences. Just prior to joining the FDA in 2008, she was a Scientific Fellow and Vice President of Pharmacogenomics at Gene Logic. Dr. Mendrick has over 25 years of experience in the fields of immunology, computational modeling, pathology, pharmacogenomics, pharmacology, toxicology and toxicogenomics (employing small-molecule drugs), in vivo efficacy, and safety assessment of recombinant therapeutic proteins and disease modeling using monoclonal antibodies.

Democratizing Screening and Diagnostics with AI



Lilly Peng, MD, PhD
Physician-Scientist, Product Manager
Google Health

Dr. Peng is a physician-scientist and product manager for Google Health. Her team works on applications of deep learning to increase the availability and accuracy of care. Some of her team's recent work includes building models to detect diabetic eye disease, predict cardiovascular health factors from retinal images, and detect breast cancer and lung cancer from screening scans. Before Google, Dr. Peng was a product manager at Doximity and a co-founder of Nano Precision Medical, a drug delivery device start-up. She holds a B.S. with honors and distinction in Chemical Engineering from Stanford University and an MD/PhD in Bioengineering from the University of California, San Francisco.

Abstract: Democratizing Screening and Diagnostics with AI

Deep learning has shown significant promise in healthcare. In particular, the technique has been able to yield highly accurate models and make novel predictions in a variety of medical imaging applications such as for the detection of cancer, skin, and eye disease. Despite this promise, much of the hard work of translating exciting research into tangible patient benefit still lies ahead. This talk covers lessons learned and work in progress, including concepts around model training, translation of research into products, and real-world implementation.

Developing a Deep Learning MedDRA Encoder (MedDRA-DeepCoder) for Patient Narratives

Qais Hatim, PhD

Data Scientist
FDA, Center for Drug Evaluation and Research

Dr. Hatim is an expert in industrial engineering, advanced statistical modeling, machine learning, data analytics, and operational research. A data scientist at FDA's Center for Drug Evaluation and Research, he performs work that has substantial merit and national importance. Dr. Hatim holds integrated BS/MS degrees in mechanical/nuclear engineering and dual PhD degrees in industrial engineering Operations research.

Abstract: Developing a Deep Learning MedDRA encoder (MedDRA-DeepCoder) for Patient Narratives

Patient narratives reported in clinical study reports provide evidence of adverse events and help scientific reviewers during pharmacovigilance activities. Manual review of these narratives can be a daunting task for safety reviewers because it is time-consuming and resource intensive. How can we improve the efficiency of identifying safety signals from patient narratives? Can deep-learning technology help to overcome the review challenges in an automated way? Using narratives from the FDA Adverse Event Reporting System (FAERS), we trained and validated models applying four deep-learning methodologies and one machine-learning methodology to see which methods could best assess a safety signal in the narrative data. We applied a misclassification rate for each of the methodologies to suggest a best approach. Our results indicated that both deep learning and machine learning can be applied to supplement existing response cycles to adverse events identified in clinical study reports, both for medical coding and to characterize issues associated with syndromes.

CBER BEST: Leveraging AI to Build an Automated Adverse Event Reporting System



Hussein Ezzeldin, PhD

Senior Staff Fellow, Office of Biostatistics and Epidemiology
FDA, Center for Biologics Evaluation and Research

Dr. Hussein Ezzeldin is a Senior Staff Fellow in the Office of Biostatistics and Epidemiology (OBE), in FDA's Center for Biologics Evaluation and Research (CBER). Since joining OBE in 2016, Dr. Ezzeldin has worked on multiple modeling and risk-assessment projects related to policy and regulatory research. He currently co-leads the Biologics Effectiveness and Safety: Innovative Methods (BEST IM) initiative in OBE. BEST IM aims to develop new and innovative methods and tools for automated reporting

of adverse events for CBER-regulated biological products using real-world data such as electronic health records.

Dr. Ezzeldin also works with OBE leadership to develop training workshops and seminars that aim to promote reproducibility of regulatory research projects. Dr. Ezzeldin is a member of the science of patient input (SPI) initiative. SPI is supporting studies on methods and tools to obtain robust patient input to support biological product regulatory reviews and provide CBER reviewers with assistance in regulatory review of patient input and patient-reported outcome data.

Abstract: CBER BEST: Leveraging AI to Build an Automated Adverse Event Reporting System

Current adverse-event reporting systems for biological products have multiple challenges related to the burden of manual reporting, no direct data connection, under-reporting for certain products, and inconsistencies in the quality of reports. CBER launched the Biologics Effectiveness and Safety Innovative Methods (BEST IM) initiative to address these challenges. BEST IM is leveraging automation and innovative technologies (Artificial Intelligence (AI), Machine Learning (ML), Natural Language Processing (NLP)) and semi-automated medical chart review to advance and improve post-marketing adverse event reporting and ensure safety and effectiveness of biological products while minimizing the reporting burden. BEST IM is leading multiple efforts to develop a portable and scalable infrastructure (BEST Prototype), and fit-for-purpose methods to automatically detect, validate, and report biological products adverse events from electronic health records (EHRs). The BEST prototype employs a robust Data Quality Assurance (DQA) plan with 200+ data quality checks to ensure that the data meet regulatory-grade data requirements. The BEST prototype utilizes AI, ML, and NLP to develop predictive models to detect exposures and outcomes of interest in EHRs. The development life cycle of these detection algorithms starts by simple value set-based algorithms to identify potential cases. Next, AI/ML is used to develop the complex algorithms using the structured and unstructured data from EHRs to enhance the positive predictive value of these algorithms. Then, the BEST chart review tool (CRT) extracts the data and evidence flagged by the algorithms and presents the suspect case for clinical review. Upon completion of review, the BEST CRT prepopulates an individual case safety report to be reviewed by a clinician or reporter for submission to the FDA. The BEST prototype is currently operational on BEST foundational data partners' networks. BEST IM leveraged AI/ML/NLP, to develop and validate six complex phenotypes, with an average positive predictive value greater than 90 percent. BEST CRT enabled a seamless and efficient validation and reporting of detected cases in EHRs. The BEST IM initiative is continuing to enhance DQA, detection, validation and reporting capabilities of the prototype infrastructure.

BE ASSESSMENT MATE (BEAM) - A Data Analytics Tool to Enhance Efficiency, Quality, and Consistency of Bioequivalence Assessment



Meng Hu, PhD

Scientific Lead

FDA, Center for Drug Evaluation and Research

Dr. Meng Hu received both his Bachelor of Engineering in Biomedical Engineering and PhD in Physics from the Zhejiang University, China. He conducted his post-doctoral training at Drexel University, Philadelphia. Dr. Hu joined the FDA's Center for Drug Evaluation and Research (CDER) as a staff fellow in 2015 and currently serves as Scientific Lead in CDER's Division of Quantitative Methods and Modeling under the Office of Research and Standards in the Office of Generic Drugs. His main research interests include the development and application of advanced data analytics tools to promote business intelligence in government, big data management, generation of real-world evidence, and quantitative methods to facilitate assessment for in vitro bioequivalence study.

Dr. Hu's published works include: machine learning-based time-to-event analysis, predictive analysis of first abbreviated new drug application (ANDA) submission for new chemical entities based on machine learning methodologies, equivalence assessment of complex particle size distribution, quantitative methods to facilitate active pharmaceutical ingredient sameness assessment for complex peptide products, and analysis of dissolution failure of solid oral drug products in field alert reports.

Abstract: Development of a Data/Text Analytics Tool to Enhance Quality and Efficiency of Bioequivalence Assessment

Enhancing quality and efficiency of bioequivalence (BE) assessment will facilitate generic drug approval, particularly considering the large number of abbreviated new drug application (ANDA) submissions received and the Office of Generic Drugs (OGD)'s commitment to meet regulatory assessment timelines under the Generic Drug User Fee Amendments (GDUFA) II program. - To address the need for more efficient, consistent, and high-quality assessments, OGD led efforts to develop a data/text analytics tool - Bioequivalence Assessment Mate (BEAM). The BEAM tool automates labor-intensive work during the BE assessment. Examples of BEAM functions are represented by streamlining the categorization of submission documents, data preparation, routine BE statistical analyses, and table-filling using information supplied by applicants. With several mouse clicks, the tool can generate a data and text-populated BE assessment report that assessors can use to finalize the review. The developed functions are derived from R and SAS data analytics, text mining, machine learning, and artificial intelligence technologies. Functions are integrated within the R-shiny framework to provide a user-friendly graphic user interface for BE assessors. The tool has been used by BE assessors for ANDA reviews during the pilot. The tool has made the ANDA BE assessment process more efficient and consistent. This work demonstrates promising potential to use advanced data/text analytics tools to enhance regulatory assessment, thus facilitating business intelligence improvement in the FDA.

Trade-off Between Explainability and Predictivity in Toxicity Assessment with AI



Leihong Wu, PhD

Visiting Scientist

FDA, National Center for Toxicological Research

Dr. Leihong Wu received his bachelor's degree in bioinformatics in 2008 from Zhejiang University in China. He then received his PhD degree in pharmacology from Zhejiang University in 2013. In the same year, he joined the Division of Bioinformatics and Biostatistics at FDA's National Center for Toxicological Research (NCTR) as an ORISE postdoctoral fellow and, in 2017, he officially joined NCTR as Visiting Scientist. Dr. Wu has published over 30 peer-reviewed journal articles, with more than 10 publications as the first or corresponding author.

Dr. Wu's research interest is to apply bioinformatics — particularly, artificial intelligence (AI) and machine learning (ML) — to biomedical research and informatics. Specifically, Dr. Wu's work has focused on the development of algorithms for biological and pharmaceutical research tasks such as drug safety, quantitative structure–activity relationship models (QSAR) modeling, and genomics. Dr. Wu's research addresses some of the most pressing issues in understanding and applying novel bioinformatics database tools and frameworks that enhance the accuracy, safety, and efficiency of drug discovery, repositioning, and efficacy studies. His current interests focus on developing AI/ML algorithms in various drug- and food-associated research areas including hepatotoxicity, genomics, and text mining.

Abstract: Trade-off Predictivity and Explainability for Machine Learning-Powered Predictive Toxicology: An In-Depth Investigation with Tox21 Data Sets

Selecting a model in predictive toxicology often involves a trade-off between prediction performance and explainability: should we sacrifice the model performance to gain explainability, or vice versa? Here we present a comprehensive study to assess algorithm and feature influences on model performance in chemical toxicity research. We conducted over 5000 models for a Tox21 bioassay dataset of 65 assays and approximately 7600 compounds. We employed 7 molecular representations and 12 modeling approaches varying in complexity and explainability to systematically investigate the impact of various factors on model performance and explainability. We demonstrated that endpoints dictated a model's performance, regardless of the chosen modeling approach including deep-learning and chemical features. Overall, more complex models such as (LS-)SVM and random forest performed marginally better than simpler models such as linear regression and KNN in the presented Tox21 data analysis. Because a simpler model with acceptable performance is often also easy to interpret for the Tox21 dataset, it clearly was the preferred choice due to its better explainability. Given that each dataset had its own error structure for dependent and independent variables, we strongly emphasize the importance of conducting a systematic study with a broad range of model complexity and feature explainability to identify models and balance predictivity and explainability.

Use of Machine Learning to Improve Food Safety Quantitative Microbial Risk Assessment



Hao Pang, PhD

**Biologist, Office of Analytics and Outreach
FDA, Center for Food Safety and Applied Nutrition**

Dr. Hao Pang is a biologist at the Office of Analytics and Outreach in FDA's Center for Food Safety and Applied Nutrition. In 2017, Dr. Pang joined the Risk Analysis Branch in the Division of Risk and Decision Analysis. His research is on developing and facilitating the use of risk tools to support policy and resource allocation, with a focus on food safety risk assessments and multi-criteria decision analysis. He leads or collaborates in the development of various FDA risk models including the machine learning survival model enteric pathogens in untreated Biological Soil Amendments of Animal Origin (BSAAO) and FDA risk tools including the Product Decision Analysis Tool (PDAT) and the Referral Decision Analysis Tool (RDAT). Prior to joining FDA, he received an M.Sc. and a PhD degree in food science from University of Maryland.

Abstract: Use of Machine Learning to Improve Food Safety Quantitative Microbial Risk Assessment

Quantitative Microbial Risk Assessment (QMRA) can inform food safety decisions by evaluating the magnitude of the change in risk from application of different mitigations or control measures. One key component in QMRA is to develop predictive microbiological models to estimate the survival and growth or die-off of microorganisms under different environmental or food storage conditions during the farm-to-fork continuum. Machine learning can be effectively used to improve the accuracy of predictive microbiological models and QMRA estimates. In this talk, I will demonstrate the application of machine learning in QMRA research using one of our recent studies as an example. To estimate the survival of *E. coli* O157:H7 in soil amended with untreated biological soil amendments of animal origin, we developed a machine learning model using a large-scale dataset from a multi-year longitudinal field experiment. With the power of machine learning, we were able to include a large number of explanatory variables representing the environmental and agricultural conditions during the field experiment. The developed machine learning model captured various *E. coli* O157:H7 survival patterns and accurately predicted the concentration of *E. coli* O157:H7 over time in amended soil under dynamic environmental conditions. In summary, machine learning can be a powerful modeling approach and it can be used in combination with mechanistic models to embrace the strength of both methods to improve predictive microbiology, QMRA, and food safety research.

Role of Artificial Intelligence in Medical Imaging



Berkman Sahiner, PhD

**Biomedical Research Scientist
FDA, Center for Devices and Radiological Health**

Dr. Sahiner is a senior biomedical research scientist with the Office of Science and Engineering Laboratories (OSEL) at FDA's Center for Devices and Radiological Health (CDRH). He has a PhD in electrical engineering and computer science from the University of Michigan, Ann Arbor. Before joining FDA, he was an Associate Professor with the Department of Radiology at the University of Michigan. At the Division of Imaging, Diagnostics, and Software Reliability at CDRH/OSEL, he performs research related to the evaluation of medical imaging and computer-assisted diagnosis devices, including devices that incorporate machine learning and artificial intelligence. He has authored/co-authored over 130 peer-reviewed journal publications and is a Fellow of SPIE, the international society for optics and photonics and the American Institute for Medical and Biological Engineering. His interests include machine learning, computer-aided diagnosis, image perception, clinical study design, and performance assessment methodologies.

***Abstract: Role of Artificial Intelligence in Medical Imaging
(Berkman Sahiner, Nicholas Petrick)***

There is great potential for artificial intelligence/machine learning (AI/ML) in medical imaging to improve healthcare. As a reflection of this potential, a large percentage of the AI/ML-enabled devices that have been authorized by the FDA have focused on the analysis of medical images. AI/ML was originally used in this area for computer-aided detection and computer-aided diagnosis, which aim to help clinicians improve image interpretation. Recent years have seen a rapid expansion of the use of AI/ML in medical imaging, with newer applications that include computer-aided triage, clinical decision support, image reconstruction/denoising, image acquisition guidance, quantitative imaging, and now potentially autonomous devices. Rapid advances in the medical imaging AI/ML area are accompanied by challenges in how the FDA can further foster the development of these devices while ensuring they are safe and effective. This talk will first provide illustrative examples of recently authorized medical imaging AI/ML devices, followed by an exploration of the newer challenges and regulatory questions brought about by the use of data-driven methods for AI/ML-enabled device training and testing. The final part of the talk will be devoted to a discussion of research conducted at CDRH to address these AI/ML challenges, including those in image triage, image reconstruction, quantitative imaging, training/test data sets, the definition/generation of the ground truth, and new studies in computer-aided detection and diagnosis.

Speaker Bios and Abstracts

Concurrent Session 3: Empowering Patients and Consumers



Andrea Furia-Helms, MPH (Moderator)

**Director, Office of Patient Affairs
FDA, Office of Clinical Policy and Programs**

Andrea Furia-Helms, Director of the Office of Patient Affairs, collaborates with patient communities, the FDA medical product centers and other offices to incorporate patient and caregiver perspectives in cross-cutting regulatory meetings. Ms. Furia-Helms spent over 10 years in FDA's Office of Health and Constituent Affairs, where she directed the FDA Patient Representative Program and coordinated patient engagement activities for the agency.

Before FDA, Ms. Furia-Helms was Director of the Back to Sleep (now Safe to Sleep) campaign, a public-private partnership to educate communities on Sudden Infant Death Syndrome (SIDS), at the National Institutes of Health. She developed SIDS outreach initiatives for African American, American Indian, and Latino communities.

Ms. Furia-Helms has a B.A. in psychology from Framingham State University, a B.S. degree in community health education from University of Maryland, and a Master of Public Health from the George Washington University.



Christine Lee, PharmD, PhD (Moderator)

**Strategic Research Engagement Lead
FDA, Office of Minority Health and Health Equity**

Christine Lee earned her PharmD from the University of Buffalo and her PhD in Pharmaceutical Outcomes and Policy from the University of Florida.

Dr. Lee is an expert in social and behavioral sciences, decision analysis, and human behavioral theories. She is also classically trained in measurement, psychometrics, focus group testing, and outcome analysis.

A leader in the national effort to reduce adverse drug events across the healthcare industry, Dr. Lee is an expert in coalition-building and partnership development within the public and private sectors. She is an expert in translating quantitative and qualitative research to inform policy, educational interventions, and communication strategies.

Dr. Lee is the lead for Strategic Research Engagement for FDA's Office of Minority Health and Health Equity (OMHHE) in the Office of the Commissioner. She leads minority health and health disparity-focused research and develops strategic partnerships to advance the health of diverse populations. Before joining OMHHE, Dr. Lee's work included structuring unstructured FDA materials as well as social media data to inform regulatory decision-making. She aims to develop research and strategic innovations that advance the health of all populations.

Listening Sessions to Uncover Patient Questions: The COVID-19 Vaccine Confidence Project



Susan C. Winckler, RPh, Esq

CEO, Reagan-Udall Foundation for the Food and Drug Administration

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration, the non-profit organization created by Congress to advance the mission of FDA.

Before accepting the Foundation post, Winckler served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. She directly advised C-suite executives on public policy/regulation, business strategy, investments, and other matters. A pharmacist and attorney by training, she was, earlier, CEO of the Food & Drug Law Institute.

As Chief of Staff for FDA (2007-2009), Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association.

Abstract: Listening Sessions to Uncover Patient Questions: The COVID-19 Vaccine Confidence Project

With the advent of publicly available COVID-19 vaccines, the number of vaccine hesitant Americans is concerning. The objective of these sessions was to understand COVID-19 vaccine concerns and inform FDA's Center for Biologics Evaluation and Research about messages and messengers they might employ to respond effectively to those concerns.

A landscape analysis was conducted to analyze how Americans feel about the emerging COVID-19 vaccine in mainstream and social media. Fourteen (14) listening sessions were organized from September to November 2020 representing people from under-represented communities and essential workers. Each session had moderators ask participants' viewpoints for a set of questions. Through themes that emerged from the listening sessions, 10 messages were developed, tested, and refined. Experts and target populations were asked which messages and messengers would be most effective at convincing Americans to receiving the COVID-19 vaccine. These messages were developed into recommendations for FDA to propose for use by public health experts to encourage vaccination.

There were four primary and five secondary themes that emerged from the 14 sessions. Five messages were found to be the most effective. The top messengers were local doctors, nurses, and pharmacists as well as other health experts.

The recommendations provided through this study are an effective way to understand vaccine hesitancy, help start a conversation, and provide consumers information they need to decide about receiving a COVID-19 vaccine.

Understanding Perceptions and Attitudes about COVID-19 Testing in Underrepresented Populations



Jessica Weinberg, MPP

Social Science Analyst
FDA, Center for Devices and Radiological Health

Jessica Weinberg is a social science analyst in the Center for Devices and Radiological Health (CDRH), Patient Science and Engagement, at FDA. She is a qualitative researcher with expertise in surveys, interviewing, and focus groups. Ms. Weinberg provides expertise in qualitative analysis related to the use of Clinical Outcomes Assessments and Patient Preference Information in regulatory decision-making.

Ms. Weinberg has spent her career in health research, evaluation, and policy development across the United States Department Health and Human Services. Before joining FDA, she served as a policy advisor at the Centers for Medicare and Medicaid Services, working on price transparency and other insurance policy. She also spent several years as a communications researcher in FDA's Office of the Commissioner, working on cross-cutting FDA communications issues, including a strategic plan for plain language and health literacy across the Agency and conducting message testing for all FDA centers. She began her career as a researcher at the Health Resources and Services Administration (HRSA) conducting research and evaluation on safety net programs.

Ms. Weinberg has a Master's in Public Policy with a focus in health policy, and a Bachelor of Arts in Psychology from the University of Maryland, College Park.

Abstract: Understanding Perceptions and Attitudes about COVID-19 Testing in Underrepresented Populations

Racial and ethnic minorities are disproportionately affected by COVID-19, with a higher number of COVID-19 cases, hospitalizations, and deaths. To better reach these populations and mitigate the spread of COVID-19, it is critical to develop accurate and meaningful communications about COVID-19 testing and encourage participation in national data collection efforts. The FDA Center for Devices and Radiological Health (CDRH) partnered with the University of Maryland Center of Excellence in Regulatory Science and Innovation to conduct a qualitative study using virtual focus groups and key informant interviews to gather information from underrepresented populations in the greater Baltimore area.

The aim of the focus groups was to better understand the attitudes of underrepresented populations toward COVID-19 testing and sharing data in national databases. Underrepresented populations of interest included African Americans, native Spanish speakers, older adults, individuals with lower literacy, individuals with chronic conditions, and asymptomatic individuals with COVID-19 test positive household member(s).

The findings focus on participants' knowledge and experiences with COVID-19; perceived benefits and concerns about testing; enabling and hindering factors to getting tested; motivations for getting tested or not; and understanding COVID-19 test results. Results also highlight conditions that cultivate comfort in sharing data in national databases, including the specific data collector and the purpose of the collection. Participants also shared suggestions for content and modes of communicating with their community. These results may help CDRH tailor its approach to communicating about COVID-19 diagnostic testing and real-world data collection.

COVID-19 and Tobacco Use: The Latest From the Population Assessment of Tobacco and Health Study



Yu-Ching Cheng, PhD

Lead Health Scientist, Population Assessment of Tobacco and Health
FDA, Center for Tobacco Products

Dr. Yu-Ching Cheng is a Lead Health Scientist of the Population Assessment of Tobacco and Health (PATH) Branch in the Division of Population Health Sciences in the Office of Science, at the Food and Drug Administration's Center for Tobacco Products (CTP). Dr. Cheng joined the FDA in 2014, first in CTP and then in the Center for Devices and Radiological Health, as an epidemiologist responsible for the regulatory research and reviews of tobacco products and cardiovascular devices before joining the PATH Branch as a Team Lead in 2020. The PATH Branch supports the PATH Study, a large, national, longitudinal cohort study on tobacco use and health conducted in collaboration with the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH). Prior to joining FDA, Dr. Cheng was an Assistant Professor at the University of Maryland, Baltimore and a research scientist at the Baltimore VA Medical Center. In these roles, she led and conducted research in areas of cardiovascular epidemiology, genomics and biomarkers. Dr. Cheng received her PhD in Epidemiology from the Johns Hopkins Bloomberg School of Public Health.

Abstract: COVID-19 and tobacco use: The latest from the Population Assessment of Tobacco and Health Study

The Population Assessment of Tobacco and Health (PATH) Study collects information on tobacco-use patterns, health, and other factors. This nationally representative, longitudinal cohort study of approximately 46,000 youth and adults in the United States began in 2013, with data collection occurring annually. In late 2020, the PATH Study added a special collection among a nationally representative sample of adults 20 years and older to examine tobacco use and explore COVID-19 issues. This presentation will examine cigarette and ENDS use in adults. We will also report preliminary data on the relationship between tobacco use and the COVID-19 pandemic using the late 2020 special data collection. This presentation will 1) provide prevalence estimates of tobacco products for adults over multiple waves of data (2013 to 2020); 2) describe initiation, cessation and transition across selected tobacco products; 3) describe product characteristics such as brand, device types, and flavor use; and 4) report on tobacco use during the COVID-19 pandemic.

Impact of COVID-19 on FDA's Orphan Products Grants



Christine M. Mueller, DO

**Medical Officer, Office of Orphan Products Development
FDA, Center for Drug Evaluation and Research**

Christine M. Mueller, DO is a Medical Officer in FDA's Center for Drug Evaluation and Research (CDER) in the Office of Orphan Products Development (OOPD). She primarily focuses on the clinical trials and natural history grants programs and works closely with researchers and organizations to advance promising medical products to market approval. Dr. Mueller has also worked on orphan drug designations and related issues, such as personalized medicine and tissue agnostic therapies.

Dr. Mueller joined CDER in the Division of Gastroenterology Products in 2008 as a medical reviewer for products to treat inborn errors of metabolism, and then joined OOPD in January of 2010. Dr. Mueller completed her medical education at the Ohio University College of Osteopathic Medicine and completed a residency in Family Medicine in the Cleveland Clinic Health System and a Clinical Genetics fellowship at the University of Pittsburgh Medical Center. Before joining FDA, Dr. Mueller was Assistant Clinical Professor in the Department of Family Medicine and Center for Medical Genetics at the University of Pittsburgh Medical Center, and a Clinical Cancer Genetics Research Fellow and Staff Clinician in the Clinical Genetics Branch, Division of Cancer Epidemiology and Genetics at the National Cancer Institute and Program Director in the National Institute of Health's Common Fund in the Office of Strategic Coordination. Dr. Mueller is board certified in Family Medicine and Clinical Genetics.

Abstract: Impact of COVID-19 on FDA's Orphan Products Grants

FDA's Office of Orphan Products Development (OOPD) in the Center for Drug Evaluation and Research (CDER) funds clinical trials and natural history grants to defray the costs of developing drugs, biologics, medical devices, and medical foods for rare diseases or conditions (21 U.S. Code § 360ee). The ~\$17 million Orphan Products Grants Program is an incentive program that has been supporting clinical trial research since 1983 and has facilitated the marketing approval of over 70 products for rare diseases. The program has also committed funding to natural history studies since 2016 to help address the lack of natural history data for rare disease product development. These grants support both academic- and industry- sponsored research, domestic or foreign, public or private, and for-profit or nonprofit entities. The disease must be rare as defined in the U.S. Orphan Drug Act (21 U.S. Code § 360ee(b)(2)). At any one time, there are typically 60 to 85 ongoing grant-funded projects. OOPD began hearing concerns about study progress due to the COVID-19 pandemic at its onset in March 2020. OOPD began tracking these issues to demonstrate the effect of the pandemic on the program and supported studies. This presentation will provide a review of the impact of COVID-19 on funded studies and OOPD's response to COVID-19- related study challenges.

COVID-19 Pandemic: Adjustments to Ongoing Clinical Trials



Wilson Bryan, MD

Director, Office of Tissues and Advanced Therapies (OTAT)
FDA, Center for Biologics Evaluation and Research

Wilson Bryan, M.D., neurologist, graduated from the University of Chicago Pritzker School of Medicine. He served on the neurology faculty of the University of Texas Southwestern Medical School for 13 years. Dr. Bryan has been an investigator on clinical trials in cerebrovascular disease and neuromuscular disorders, particularly amyotrophic lateral sclerosis. Dr. Bryan joined FDA in 2000, and now serves as Director of the Office of Tissues and Advanced Therapies (OTAT) in FDA's Center for Biologics Evaluation and Research.

Abstract: COVID-19 Pandemic: Adjustments to Ongoing Clinical Trials

FDA's Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT) regulates the development of a diverse portfolio of products, including cellular and gene therapies, for the treatment of a wide variety of clinical disorders. The COVID-19 pandemic has had dramatic effects on the number of Investigational New Drug applications (INDs) submitted to OTAT. Several factors have also forced or enabled adjustments to ongoing clinical trials. These factors include the risks associated with in-person study visits during the pandemic, the expense of conducting trials in the setting of the pandemic, and the emergence of telemedicine and wearable devices. As a result of these factors, clinical trial sponsors have proposed and/or implemented changes in both the conduct and analysis of their trials. Adjustments in ongoing trial conduct have had an impact on study recruitment and enrollment, informed consent, monitoring, and endpoints. Proposed adjustments to the analysis of ongoing trials have included reconsiderations of sample size, study duration, interim analyses, and missing data. Based on our experience with ongoing trials during the pandemic, lessons learned focus on the usefulness of telemedicine and the importance of communication between regulators and drug developers.

FDALabel – An FDA Product Labeling Tool Enabling Patients and Consumers Safety in Combating COVID-19



Hong Fang, PhD

Health Information Scientist
FDA, National Center for Toxicological Research

Dr. Hong Fang received her Ph.D. in chemistry from the University of Missouri, St. Louis, in 1995. After graduation, Dr. Fang joined the St. Louis County Police Department Crime Laboratory as a forensic scientist for two years. In 1997, she was hired by FDA's National Center for Toxicological Research (NCTR) as a postdoctoral fellow. From 2000 to 2008 she worked as a senior computational scientist at Northrop Grumman, a contracting firm at NCTR/FDA. In 2008, Dr. Fang was an ICF international manager for leading NCTR Bioinformatics Group contract work. In 2012, Dr. Fang accepted a senior bioinformatician and project manager role with FDA, assuming the position of health information scientist in 2020.

Dr. Hong Fang has over 20 years of experience in computational science, data science, chemoinformatics, toxicoinformatics, and bioinformatics. She leads bioinformatics research and development of tools supporting NCTR's and FDA's health informatics initiatives. Most of the currently available software tools/informatics systems are described on NCTR's webpage: <https://www.fda.gov/science-research/bioinformatics-tools>. These include (1) FDALabel: a full-text search web-based database of FDA's drug labeling documents for efficient retrieval of drug efficacy and safety information for drug review, regulatory science, healthcare professionals, and research to promote public health; (2) ArrayTrack: an integrated platform for genomics data analysis and interpretation; and (3) LTKB (Liver Toxicity Knowledge Base): a database to assess the risk of drug-induced liver injury. Dr. Fang is a prolific writer, having authored and co-authored 151 manuscripts with 13,800 citations and an H-Index of 55 by Google Scholar.

Abstract: FDALabel – a FDA Product Labeling Tool Enabling Patients and Consumers Safety in Combating COVID-19

FDA drug product labeling provides essential scientific information for safe and effective use of FDA-regulated products. It consists of a broad range of information, including indications, warnings and precautions, dosage and administration, and patient use instructions. COVID-19 has imposed an urgency of rapid labeling revision for drug products under Emergency Use Authorization (EUA).

The FDALabel database tool, developed by NCTR in collaboration with CDER, manages the full set of ~135,000 FDA SPL (Structured Product Labeling, i.e., electronic digital labeling) documents with intuitive and powerful functions for querying and information retrieval.

For example, FDALabel allows full-text and/or customized searches to combine labeling sections and subsections, document types, and more. FDALabel, hosted through Amazon Cloud, enables the public (e.g., researchers, patients, pharmacists, doctors, and healthcare professionals) to quickly search and identify drug information, including current FDA-regulated COVID-19 products (e.g., prescription drugs, vaccines, OTC drugs) and safety information.

Currently, of FDALabel's 4,205 COVID-19-related labeling documents, 4,191 are hand sanitizers and disinfectant wipes registered as OTC drugs, and 14 are prescription drugs and vaccines. Using vaccines as an example, we analyzed labeling data for the Pfizer-BioNTech and Moderna COVID-19 Vaccines (authorized under FDA's EUA), which includes their safety data (clinical trial data, storage information, dose administration, etc.). In summary, FDALabel, a user-friendly tool with up-to-date information, provides quick and reliable access to COVID-19-related product information for patients, researchers, regulators, and healthcare professionals.

Patient Focus Groups to Enhance Communications Addressing Biosimilar Drug Products



Brian Lappin, MA

**Social Scientist, Office of Communications
FDA, Center for Drug Evaluation and Research**

Brian Lappin is a social scientist with the Research and Risk Communication team in the Office of Communications at FDA's Center for Drug Evaluation and Research (CDER). He has 19 years of experience conducting quantitative and qualitative social science research studies for the federal government to inform decision-making and improve communications. Mr. Lappin has been the FDA project lead on multiple federally funded studies focusing on healthcare professionals' and patients' knowledge of biosimilar biological products. He is involved in several other risk communication research studies investigating a variety of public health issues, including opioids, benzodiazepines, and drug labeling. Mr. Lappin established FDA's Internal Message Testing Network. He also conducts testing with external target audience members of many types of CDER communications to improve them before they are made public.

Mr. Lappin received his Master's in Industrial/Organizational Psychology from George Mason University and his Bachelor's in Psychology from the University of Maryland at College Park. Before joining FDA in 2009, Mr. Lappin was Chief of the Program Evaluation Branch at the Defense Manpower Data Center, where he conducted personnel surveys and research.

Abstract: Patient Focus Groups to Enhance Communications Addressing Biosimilar Drug Products

Chronic diseases, such as cancer, are the leading cause of death and disability in the U.S. It is critical to develop evidence-based educational materials that can raise awareness, understanding, and appropriate use of medical treatments to improve the quality of life for individual patients and society more broadly. This can be challenging when novel treatments become available. To communicate more effectively about new drugs called biosimilars, which are expected to increase access to treatments that target some chronic diseases, FDA conducted 10 focus groups (N=78) with patients that could be treated with these products to collect evidence related to their knowledge, attitudes, experiences and desires when communicating with healthcare professionals, and about information needs. Patients reported little to no knowledge about biosimilars. The information desired most included their effectiveness compared to a current medication, whether side effects are different or fewer than their current medication, and reasons for switching to a biosimilar aside from potential cost savings. Patients provided feedback on a draft infographic concerning language; message meaning, comprehension and relevance; format, and images. Understanding patients' baseline knowledge, attitudes, and information needs is key to identifying effective ways to educate them about novel treatments that can improve individual and public health. FDA is soliciting and using input from patients to develop and enhance materials, particularly by providing basic information in plain language needed to answer their questions and allay fears and uncertainties. This kind of effective communication can enhance patient decision-making and increase access to lifesaving treatments.

2019 FDA Food Safety and Nutrition Survey – Making Food Safety and Nutrition Accessible to Public Health Professionals



Amy M. Lando, MPP

**Social Scientist
FDA, Center for Food Safety and Applied Nutrition**

Amy M. Lando is a social scientist in the Consumer Studies branch at FDA's Center for Food Safety and Applied Nutrition. She earned a Bachelor of Arts in Public Policy and a minor in chemistry from Duke University. Amy then attended Georgetown University and completed her Master's in Public Policy with an emphasis on food and nutrition policy. She is the project director of the Food Safety and Nutrition Survey, a national survey of consumers' food safety and nutrition attitudes and behaviors. Amy has also directed studies on a variety of consumer food and nutrition topics.

***Abstract: 2019 FDA Food Safety and Nutrition Survey
– Making Food Safety and Nutrition Accessible to Public Health Professionals***

The Food Safety and Nutrition Survey (FSANS) is FDA's premier, national probability consumer survey designed to assess consumers' awareness, knowledge, understanding, and self-reported behaviors relating to a variety of food safety and nutrition-related topics. The survey findings are intended to help FDA make better-informed regulatory, policy, education, and other risk-management decisions aimed at promoting and protecting public health.

FSANS uses an address-based sampling method and is "mail-push-to-web." The survey population is adults (18 years and older) in the 50 U.S. states and the District of Columbia. A total of 4,398 responses were collected during October and November 2019. Previous FDA food safety and nutrition consumer surveys had been collected using telephone interviews. This presentation will discuss the motivation for conducting the survey, the methods, and some key findings.

Addressing Demographic Subgroup Underrepresentation in Oncology



Lola A. Fashoyin-Aje, MD, MPH

Deputy Division Director
Division of Oncology 3
FDA, Center for Drug Evaluation and Research

Lola A. Fashoyin-Aje, MD, MPH, is a medical oncologist and Deputy Division Director in FDA's Center for Drug Evaluation and Research, Division of Oncology 3, Office of Oncologic Diseases. Dr. Fashoyin-Aje is also Associate Director of Scientific and Policy initiatives to address disparities in drug development, in the Oncology Center of Excellence.

At FDA, Dr. Fashoyin-Aje has served as clinical reviewer in the Gastrointestinal (GI) Malignancies team, and as team leader for the Breast Malignancies, Melanoma, and Sarcoma, and Gastrointestinal Malignancies clinical teams. In her current roles, she provides scientific and policy guidance and oversight to multidisciplinary teams reviewing drugs and biologics under development for the treatment of solid tumor (GI, sarcoma, melanoma) malignancies. She also provides direction and oversight on all scientific and policy efforts related to improving the inclusion of underrepresented demographic subgroups, including racial, ethnic, and sex/gender minorities in oncology medical product development programs.

Before joining FDA, Dr. Fashoyin-Aje completed her undergraduate and graduate training at Columbia University and Yale University, respectively, and received her MD from the University of Rochester School of Medicine and Dentistry. Dr. Fashoyin-Aje completed her training in internal medicine and medical oncology at Johns Hopkins.

Abstract: Addressing Demographic Subgroup Underrepresentation in Oncology

The presentation will describe the landscape of oncology trials submitted to FDA to support approval in terms of the representativeness of historically underrepresented demographic subgroups, and provide the Oncology Center of Excellence's perspective on balancing inclusivity and efficiency to develop therapeutics that work for all.

Advancing Health Equity through Outreach and Communications



Jovonni Spinner, DrPH, MPH, CHES

Associate Director, Outreach and Communications
FDA, Office of Minority Health and Health Equity

Dr. Jovonni Spinner is an award-winning public health strategist and thought leader with a deep passion for improving health equity across the lifespan through research, communication, multi-sector partnerships, and leadership coaching. She creates culturally competent programming, excels at telling public health stories, and gives voice to those rarely heard, while providing programmatic strategic direction to stakeholders.

She is the Associate Director of Outreach and Communications at FDA's Office of Minority Health and Health Equity, overseeing the strategic direction of the outreach and communications team. She has led state and national health equity-driven programs like the Diversity in Clinical Trials Initiative and Community Health Worker Health Disparities Initiative, which have reached millions of consumers to help them make informed health decisions, obtain services, and advocate for healthier communities. She is an alumna of Virginia Commonwealth University, Emory University, and Morgan State University.

Abstract: Advancing Health Equity Through Outreach and Communications

Health disparities continue to exist in this country for racial and ethnic minority, tribal, and other under-represented groups. To address these disparities, FDA's Office of Minority Health and Health Equity (OMHHE) uses culturally and linguistically tailored strategies to raise awareness around these concerns. OMHHE's Outreach and Communication Program (OCP) aims to 1) drive improvements in FDA's outreach to minority communities and 2) strengthen awareness of FDA's role in public health, and 3) promote and facilitate engagement between diverse groups and FDA. OCP uses digital and print media as well as interpersonal interactions to reach diverse audiences with information on key health and regulatory issues affecting diverse groups. All communications have an emphasis on addressing cultural competency and low literacy needs. For example, OCP has developed multi-media health education campaigns to address clinical trial diversity that has reached millions through videos, podcasts, and social media; held public meetings on opioids, diabetes, and rural health; disseminated thousands of health education materials for community outreach; implemented staff trainings on cultural competency and bias; and built formidable partnerships with stakeholders to extend our reach. We are committed to addressing health disparities by ensuring diverse groups have credible health information they can act on. Success has been evidenced by deepened stakeholder engagement and increased dialogue around clinical trial diversity, materials requests, and downloads.

Concurrent Session 4: Product Development and Manufacturing



Suzanne Fitzpatrick, PhD (Session Chair/ Moderator)

Senior Advisor for Toxicology
FDA, Center for Food Safety and Applied Nutrition

Dr. Suzanne Fitzpatrick is the Senior Advisor for Toxicology at the FDA's Center for Food Safety and Applied Nutrition. She is a board-certified toxicologist in the United States and Europe. Dr. Fitzpatrick chairs the FDA's Alternative Methods Work Group that is currently focusing on in vitro microphysiological systems. This workgroup published the recently released FDA Report on Advancing Alternative Methodologies. She also helped develop the FDA/Defense Advanced Research Projects Agency/NIH, National Center for Advancing Translational Science (NCATS) program on Organs on a Chip and continues to work and give presentations on this evolving area. Dr. Fitzpatrick chaired the FDA Predictive Toxicology Roadmap Committee. She is the principal FDA representative to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and to the Tox 21 partnership with the Environmental Protection Agency, NCATS, and NIH, National Institute of Environmental Health Sciences. Dr. Fitzpatrick is an Adjunct Professor at Johns Hopkins University. She received her B.A. from the University of California at San Diego and her PhD from Georgetown University.

21st Century Solutions for 21st Century Problems



Dr. Geoffrey Ling, MD

CEO, On Demand Pharmaceuticals

Dr. Ling is a pharmacologist and physician who is co-founder and CEO of On Demand Pharmaceuticals. Clinically, he is a professor of neurology, neurosurgery, and anesthesiology and critical care medicine at Johns Hopkins University and the Uniformed Services University of the Health Sciences. He is also an attending neuro critical care physician at Johns Hopkins Hospital and serves as the Chair of the Veterans Administration's National Research Advisory Council.

Dr. Ling is a retired U.S. Army colonel after 21 years on active duty. He served as an intensive care physician with the 452nd CSH (combat support hospital) in OEF-Afghanistan (2003) and 86th CSH and 10th CSH in OIF-Iraq (2005). In addition, COL Ling has had four in-theater missions as a member of the Joint Chiefs of Staff "Gray Team" to assess traumatic brain injury (TBI) care in both combat theaters (2009, 2011). The 10th CSH named him their first "Physician of the Month." Dr. Ling was also a "requested by name" consultant to Congresswoman Gabby Gifford's trauma team following her tragic attack.

Dr. Ling was the Founding Director of the Biological Technologies Office at the Defense Advanced Research Projects Agency (DARPA), where he was previously a program manager and Deputy Director of the Defense Sciences Office. He served as an Assistant Director in the Science Division of President Obama's White House Office of Science, Technology and Policy. His B.A. with honors is from Washington University in St. Louis; MD from Georgetown University (elected to AOA) and his PhD in neuropharmacology is from Cornell University. He completed his neurology residency at Walter Reed Army Medical Center, neuro critical care fellowship at Johns Hopkins and research fellowship in neuropharmacology at the Memorial Sloan Kettering Cancer Center. He is board certified in both neurology and neuro critical care. He has published more than 200 peer-reviewed articles and book chapters.

Abstract: 21st Century Solutions for 21st Century Problems

On Demand Pharmaceuticals (ODP) is transforming how medicines are made and delivered to deployed U.S. military. Through its proprietary technology, ODP seeks to establish medicine manufacture on demand— whatever medicines our service members need, whenever, and wherever they need them. To meet this goal, ODP is developing the Pharmacy on Demand (PoD) pharmaceutical manufacturing unit. PoD is a robust, man-transportable, miniaturized manufacturing unit that features proprietary micro-reactors and continuous- flow synthetic chemical processes to make key starting materials (KSMs), active pharmaceutical ingredients (APIs), and final formulated medicines. A significant advantage of PoD machines is their flexibility; they can be reconfigured from one type of drug to another in just a couple of hours. Another advantage is automation; PoD can be operated in extreme environments with minimal training. Importantly, PoD's advanced in-process monitoring system will ensure superior quality control through on-line, real-time, "every" dose monitoring. This on-line process supports a real-time release of medicine, ensuring quality standards beyond what is required in traditional batch processing methods. Quality is essential for our Nation to receive the best each and every time.

It is unacceptable that our Nation has a vulnerable reliance on potential peer adversary nations for any aspect of the medicine supply chain, including KSM or APIs. ODP's technology eliminates this vulnerability because PoD starts with U.S. domestically sourced material. The reliability of our supply chain not only has implications for DoD, but also for vulnerable populations in the United States who suffer from disproportional lack of access to medicines. PoD democratizes and ensures quality, improving access for vulnerable populations living in underserved urban communities, rural areas, and tribal territories. Likewise, PoD has humanitarian implications for underserved developing nations.

U.S.-based, fixed facility, large acreage production factories cannot compete with low wage and less regulated foreign drug manufacturers. The automated PoD technology gives the U.S. military an advantage.

Like the U.S. military, the FDA exists to protect Americans. ODP, by establishing an adaptive, transparent quality assurance, presents a model by which the FDA can demand the same of "all" drug purveyors. The goal of documented transparent quality assurance of every single dose can and must be realized. The FDA must protect Americans against poor quality drugs by demanding quality through every dose testing and remote monitoring. New incentives are needed to support manufacturing innovation and accelerate implementation to guarantee quality. These market incentives would help reward mature quality management systems, such as the creation of a rating system and methods to enforce transparency in the supply chain.

Nothing less should be given to our military; nothing less should be given to every American.

MALDI Imaging Mass Spectrometry: A New Imaging Modality for Use in Toxicological Studies



E. Ellen Jones, PhD

Fellow
FDA, National Center for Toxicological Research

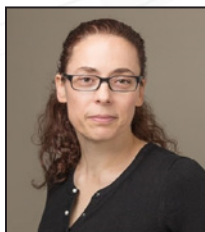
Dr. E. Ellen Jones is a Staff Fellow at the FDA's National Center for Toxicological Research (NCTR). She has been at NCTR for more than 4 years within the Division of Systems Biology, in the Biomarkers and Alternative Models Branch. Prior to her arrival at NCTR, Dr. Jones worked in both academia and industry doing research across a variety of disciplines. In 2011, she was recruited to begin a new state of the art Matrix Assisted Laser Desorption Ionization (MALDI) imaging mass spectrometry (IMS) lab in South Carolina. Since 2011, she has focused on utilizing this technique across a variety of research fields. Within academia MALDI IMS was used primarily to better understand disease initiation and progression. In industry MALDI IMS was utilized within drug development to make PK/PD assessments and monitor any adverse or off-target events. Upon her arrival at NCTR she was tasked with helping to establish MALDI IMS as a helpful and informative approach to better understand drug toxicities. Interest in using this approach across the FDA centers has steadily increased, and with the addition of a new high-resolution Fourier transform ion cyclotron (FTICR) mass spectrometer to the lab, NCTR's imaging studies have more than doubled. The MALDI IMS group has projects both within the FDA and at academic institutions, including those interested in the toxicities of opioids, tobacco, and chemotherapeutic drugs. Other studies are focused on assessing parent drug and metabolite tissue distributions in relation to disease, and a very recent study which has just been initiated will utilize this technique to assess n-linked glycan changes in human COVID-19-positive blood and tissue samples.

Dr. Jones obtained her Bachelor of Science from Baylor University in Waco, Texas and her doctorate from Eastern Virginia Medical School in Norfolk, VA in Immunology, Virology and Microbiology, the track now known as Biomedical Sciences.

Abstract: MALDI Imaging Mass Spectrometry: A New Imaging Modality for Use in Toxicological Studies

Matrix-assisted laser desorption ionization (MALDI) imaging mass spectrometry (IMS) is a label-free, robust, and emerging technique that produces 2D ion density maps representing the distribution of an analyte(s) across a tissue section in relation to tissue histopathology. MALDI IMS was initially developed to spatially profile proteins and peptides, however, the variety of detectable analytes has greatly increased due to advancements in both instrumentation and software. For example, incorporation of high-resolution instruments such as the Fourier-transform ion cyclotron resonance (FTICR) mass spectrometer within imaging workflows has made the detection of unique and low-abundant classes of analytes such as neurotransmitters and small-molecule drugs feasible at high spatial resolution (10 μm) and specificity. One main advantage of MALDI IMS over other imaging modalities is its ability to determine the spatial distribution, not only of a drug and its metabolites but also other endogenous compounds within a single imaging run, without the need for a label or any a priori knowledge. Within drug-centric studies this feature has been extremely impactful and highlights the vast potential of using this approach to further our mechanistic understanding of disease initiation and progression, drug distribution, pharmacology, and toxicology by providing snapshots of temporal and causal changes. This presentation will focus on efforts to use MALDI IMS to better understand drug tissue distribution and gain insights into correlated toxicities. Case studies from the literature assessing pharmacology and PK/PD effects on the drug development side along with ongoing toxicology studies within the FDA at NCTR will be presented to provide an overall view of the true value of this technology to the field.

Advancing New Alternative Methodologies at FDA: The Expanded Decision Tree



Szabina Stice, PhD

**Toxicologist
FDA, Center for Food Safety and Applied Nutrition**

Dr. Szabina Stice has been a toxicologist in FDA's Center for Food Safety and Applied Nutrition's Office of Food Additive Safety (OFAS) for over 6 years. She is responsible for leading OFAS's efforts to update and expand the Cramer et al. Decision Tree (CDT) designed to screen orally ingested chemically defined substances according to their relative toxic potential. The Expanded Decision Tree allows for much improved correlation between toxicity and chemical structure compared to that in the CDT and has a much broader chemical applicability domain and the potential to reduce the reliance on animal testing.

Stice is a member of OFAS's Genetic Toxicology Team, FDA's expert representative to OECD's Expert Group on Toxicokinetics, and serves as a World Health Organization (WHO) expert toxicologist on the Joint FAO/WHO Expert Committee on Food Additives. She also performs toxicological reviews of various types of OFAS submissions. Before joining FDA, Dr. Stice conducted research and development in private industry and in academia.

Dr. Stice obtained her Master of Science in Pharmacy and Pharmaceutical Sciences from the University of Florida and her PhD in Chemistry from Florida International University. She also completed graduate certificates in clinical toxicology, pharmaceutical chemistry, drug discovery and development, ADMET, forensic drug chemistry, and is currently completing one in regulatory affairs.

Abstract: Advancing New Alternative Methodologies at FDA: The Expanded Decision Tree

FDA scientists have been taking steps to upgrade FDA's toxicology toolbox, to expand its toxicology predictive capabilities, and to reduce the use of animal testing whenever possible. One of FDA's potential tools aiming to achieve these goals is the Expanded Decision Tree (EDT), a state of the science update and expansion of the Cramer et al. (1978) Decision Tree (CDT). The CDT sorts and prioritizes substances according to their relative chronic oral toxic potential using a sequence of 33 mainly structure-based binary questions to which the answer either refers the user to another question within the CDT or assigns the substance to one of three structural classes of relative toxic potential.

To revise the CDT, we used mode of action information and a newly created database composed of toxicity, metabolism, and other data for over 1,900 substances with a broader variety of defined chemical structures and a wider range of No Effect Levels. Compared to the CDT, the questions in the EDT are more specific. This enables improved separation of classes of relative toxic potential, allows the doubling of the number of classes, and results in a broader chemical applicability domain. The EDT is suitable as a screening and prioritization tool in the safety evaluation of substances with low exposures as well as in the safety assessment of mixtures.

ISTAND: A Pilot Program to Address Novel Technologies as Drug Development Tools (DDTs)



Christopher Leptak, MD, PhD

Director, Biomarker Qualification Program
FDA, Center for Drug Evaluation and Research

Dr. Leptak completed his MD and PhD in microbiology/immunology at UCSF. After residency in Emergency Medicine at Harvard's combined Mass General and Brigham program, he joined FDA in 2007 as a primary reviewer in the Office of New Drugs' (OND's) Division of Gastroenterology Products, focusing on immunomodulators for inflammatory bowel diseases. In 2010, he joined OND's Guidance and Policy Team and became OND's Biomarker and Companion Diagnostics Lead. Then in 2017, Chris became the Director of CDER's Biomarker Qualification Program with a focus on biomarker and diagnostic device utility in clinical trials and drug development.

Abstract: ISTAND: A Pilot Program to Address Novel Technologies as Drug Development Tools (DDTs)

Biomarkers are frequently used by different stakeholder communities. We, as regulators, use them to aid in drug development including incorporation for specific uses in clinical trials. The presentation will introduce the following:

- Biomarkers, Endpoints, and Other Tools (BEST) resource
- Components of a biomarker development effort
- Pathways for introduction of biomarker information
- Qualification of biomarkers as Drug Development Tools (DDTs)
- Resources related to biomarkers used as surrogate endpoints.

Medical Device Cybersecurity



Kevin Fu, M.Eng., PhD

Acting Director of Medical Device Cybersecurity
 FDA, Center for Devices and Radiological Health
 Associate Professor, University of Michigan

Dr. Kevin Fu is Associate Professor of EECS at the University of Michigan where he directs the Security and Privacy Research Group (SPQR.eecs.umich.edu). During 2021, Dr. Fu is also Acting Director of Medical Device Cybersecurity at FDA's Center for Devices and Radiological Health (CDRH) and Program Director for Cybersecurity, Digital Health Center of Excellence (DHCoE). He is most known for the original 2008 cybersecurity research paper showing vulnerabilities in an implantable cardiac defibrillator by sending specially crafted radio waves to induce uncontrolled ventricular fibrillation via an unintended wireless control channel. <https://www.secure-medicine.org/hubfs/public/publications/icd-study.pdf> The prescient research led to over a decade of revolutionary improvements at medical device manufacturers, global regulators, and international healthcare safety standards bodies just as ransomware and other malicious software began to disrupt clinical workflow at hospitals worldwide.

Dr. Fu was recognized as an IEEE Fellow, Sloan Research Fellow, MIT Technology Review TR35 Innovator of the Year, Fed100 Award recipient, and recipient of an IEEE Security and Privacy Test of Time Award. He has testified in the U.S. House and Senate on matters of information security and has written commissioned work on trustworthy medical device software for the U.S. National Academy of Medicine. He co-chaired the AAMI cybersecurity working group to create the first FDA-recognized standards to improve the security of medical device manufacturing. Dr. Fu founded the Archimedes Center for Healthcare and Device Security (secure-medicine.org). He is a founding member of the N95decon.org team for emergency reuse decontamination of N95 masks during PPE shortages. In addition, Dr. Fu served as a member of the U.S. NIST Information Security and Privacy Advisory Board and Federal science advisory groups. Eleven years ago, Fu served as a visiting scientist at the U.S. Food & Drug Administration. Fu received his B.S., M.Eng., and PhD from MIT. He earned a certificate of artisanal bread making from the French Culinary Institute and is an intermediate-level salsa dancer.

Abstract: Medical Device Cybersecurity

Today, it would be difficult to find medical device technology that does not critically depend on computer software. Network connectivity and wireless communication has transformed the delivery of patient care. The technology often enables patients to lead more normal and healthy lives. However, medical devices that rely on software (e.g., drug infusion pumps, linear accelerators, pacemakers) also inherit the pesky cybersecurity risks endemic to computing. What's special about medical devices and cybersecurity? What's hype and what's real? What can history teach us? How are international standards bodies and regulatory cybersecurity requirements changing the global manufacture of medical devices? This talk will provide a glimpse into the risks, benefits, and regulatory issues for medical device cybersecurity and innovation of trustworthy medical device software.

FDA's Advanced Manufacturing Journey



Sau (Larry) Lee, PhD

Deputy Director of Science
Chair, Emerging Technology Program
FDA, Center for Drug Evaluation and Research

Dr. Sau (Larry) Lee directs the activities of staff members in FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Quality (OPQ) sub-offices responsible for the quality assessment of regulatory submissions. He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and FDA's Office of Regulatory Affairs. Dr. Lee also serves as the point-person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval. Dr. Lee has been with the FDA since 2005, serving as Regulatory Scientist, Team Lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a PhD in Chemical Engineering from Princeton University.

Abstract: FDA's Advanced Manufacturing Journey

FDA is undertaking a new approach by working closely with drug makers and other relevant stakeholders to ensure that cutting-edge, scientifically sound methods are used in drug manufacturing (including both biotechnology and small-molecule products). The new FDA approach aims to help the pharmaceutical industry adopt novel technologies in producing medicines that are consistently safe and effective. The new approach emphasizes the utilization of (1) FDA's Emerging Technology Program to provide opportunities for early FDA-industry interactions during technology development, (2) regulatory science and research to enhance scientific understanding of novel technologies and support risk assessments, and (3) close collaborations and coordination with other regulatory agencies to support harmonization of scientific and regulatory approaches or standards. This presentation will discuss FDA's approach and experience with advanced manufacturing technologies.

Understanding Ex Vivo Manufacturing of HSC Based Therapeutics



Pankaj K. Mandal, PhD

Senior Staff Fellow
FDA, Center for Biologics Evaluation and Research

Dr. Mandal is a Senior Staff Fellow in the Tumor Vaccines and Biotechnology Branch, Division of Cellular and Gene Therapies in the Office of Tissues and Advanced Therapies at FDA's Center for Biologics Evaluation and Research (CBER). Dr. Mandal's research interests include understanding hematopoietic stem cell (HSC) biology and developing genetically engineered HSC-based therapeutics.

Dr. Mandal received his PhD in Veterinary Medicine from Ludwig Maximilian University, Munich (2009). He conducted his postdoctoral research training at Harvard Medical School and Boston Children's Hospital (2010-2014), studying cellular reprogramming, generating HSC-specific reporter strains of mice, and evaluating the efficacy of CRISPR/Cas9 genome editing in human cells. From 2014-2018, he served as Instructor in Pediatrics at Harvard Medical School. He joined CBER's Division of Cellular and Gene Therapies in 2019. In his current role as Senior Staff Fellow in the Division, Dr. Mandal leads a research group studying advanced manufacturing of CRISPR-edited HSC-based therapeutics.

Abstract: Understanding Ex Vivo Manufacturing of HSC-Based Therapeutics

Hematopoietic stem cell (HSC)-based cellular therapeutics hold great promise for treatment of hematological disorders, such as hemoglobinopathies, primary immune deficiencies, lysosomal storage and metabolic disorders, and congenital cytopenias. Despite significant advances in the development of HSC-based therapies over the past decade, the lack of optimized protocols for HSC expansion ex vivo has delayed their widespread use. Our research program is focused on understanding advanced manufacturing of genome-edited HSC-based therapeutics. In my presentation, I will discuss challenges associated with manufacturing HSC-based therapeutics and provide an overview on on-going research activities in my lab. Our goal is to identify and define optimal conditions for cost-effective, large scale manufacturing of genome-edited, HSC-based therapeutics.

Speaker Bios and Abstracts**Concurrent Session 5: Advancing Products
Based on Novel Technologies**

**Beverly D. Lyn-Cook, PhD (Moderator)****Senior Interdisciplinary Research Biologist
FDA, National Center for Toxicological Research**

Beverly Lyn-Cook, PhD is a senior interdisciplinary research biologist at FDA's National Center for Toxicological Research (NCTR), in Jefferson, Arkansas. She received her MS in 1979 and PhD in 1981 from Atlanta University, Atlanta, Georgia. Dr. Lyn-Cook conducted post-doctoral studies in the Department of Biochemistry at the University of North Carolina School of Medicine, Chapel Hill from 1981 to 1984 and later was a research associate scientist at the Lineberger Cancer Center, Chapel Hill before joining FDA in 1988. For the last 32 years at NCTR, her research interests have included sex differences in adverse drug reactions; epigenetics; and health disparities in diseases (pancreatic cancer, cardiovascular disease, lupus, and breast cancer). She has published and presented widely. Currently, her laboratory addresses sex/gender differences in adverse drug reactions, triple-negative breast cancer, and the role of epigenetics in lupus, with the goal of identifying new targets for drug therapy. Currently, Dr. Lyn-Cook serves on FDA's IRB committee, FDA Precision Medicine Working Group, FDA's Office of Women's Health Steering Committee, and as the NCTR-Office of Women's Health liaison. She also plays an active role in FDA mentoring programs, including the recruitment of students as interns and participants in NCTR's summer research programs; outreach and mentoring of junior scientists (post-docs); and as a mentor for FDA's Fellows program. Dr. Lyn-Cook is very active with the American Association for Cancer Research (AACR), where she has served as Chair of the Minority in Cancer Research Council, a member of Women in Cancer Research, and currently serves on the AACR Science Education Committee.



Silvia A. Piñeiro, PhD (Moderator)

**Senior Regulatory Review Scientist
FDA, Center for Veterinary Medicine**

Dr. Piñeiro received her PhD from the University of Bahia Blanca, Argentina before serving as a post-doctoral research associate at the pharmaceutical biotech company BioSidus in Argentina, and later, at the University of Iowa's Department of Biological Sciences. Dr. Piñeiro subsequently held the positions of assistant professor, professor, and senior scientific associate at the University of Buenos Aires School of Medicine, University of Salvador School of Chemical Engineering, and BioSidus, as well as the University of Maryland's School of Medicine and Dental School, Baltimore. In 2009, Dr. Piñeiro joined FDA's Center for Veterinary Medicine, Division of Human Food Safety, where she is a senior regulatory review scientist in the area of microbial food safety, and holds a faculty visiting scientist position at the Johns Hopkins University School of Medicine. Currently, she serves as co-chair of the FDA Interagency Microbiome Working Group and FDA's representative for the NIH-FDA Joint Agency Microbiome Committee.

Dr. Piñeiro was as an expert member, co chair, and chair of the Microbiological Acceptable Daily Intake Expert Working Group at the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products, a trilateral (E.U.-Japan U.S.) program aimed at harmonizing technical requirements for veterinary product registration. Since 2009, she has served as American Society for Microbiology (ASM), Maryland branch board of directors and currently serves as ASM COMS member and chair of the Antimicrobial Agents and Resistance community. Since 2016, Dr. Piñeiro has served as a scientific expert for the Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives.

Overcoming Challenges in Co-culture of Super Strict Anaerobes with a Healthy Human Colon Mucosal Barrier



Linda G. Griffith, PhD

**Professor of Biological and Mechanical Engineering
MIT**

Linda G. Griffith is Professor of Biological and Mechanical Engineering and MacVicar Fellow at the Massachusetts Institute of Technology (MIT), where she directs the Center for Gynepathology Research. She has pioneered approaches in tissue engineering and organs-on-chips and now integrates these platform technologies with systems biology to humanize drug development. She has chaired numerous scientific meetings, including the 2020 Keystone Tissue Organoids Conference and the 2016 Signal Transduction by Engineering Extracellular Matrix Gordon Research Conference, and has co-chaired the Open Endoscopy Forum at MIT annually since 2015. She is a member of the National Academy of Engineering and recipient of a MacArthur Foundation Fellowship, as well as several awards from professional societies. Dr. Griffith currently serves on the advisory board of the Society for Women's Health Research and has served on the advisory committee to the Director of the National Institutes of Health. She received her B.S. from Georgia Tech and PhD from U.C. Berkeley, both in chemical engineering.

Abstract: Overcoming Challenges in Co-culture of Super Strict Anaerobes with a Healthy Human Colon Mucosal Barrier

The relative lack of technologies for long-term co-culture of a human colonic mucosal barrier with super oxygen-sensitive commensal microbes hinders the study of human-microbe interactions. This talk will describe interactions between an abundant super oxygen-sensitive commensal anaerobe, *Faecalibacterium prausnitzii*, with a primary human mucosal barrier, using a gut-microbiome (GuMI) physiome platform that we designed and fabricated for the purpose of hosting the strictest anaerobes and pathogens in continuous culture with a healthy mucosal barrier. A major challenge is maintaining continuous flow of totally anoxic culture medium to the apical space, to provide continuous nourishment of the microbes, while simultaneously maintaining delivery of fresh oxygenated medium to the basal side of the epithelial cells. To address this, we leveraged on-board pneumatically activated microfluidic pumps that we developed and commercialized for a companion technology, the Liver chip, and which we have used for a multi-microphysiological system platform connecting gut and liver. Long-term continuous co-culture of *F. prausnitzii* for two days with colon epithelia, enabled by continuous flow of completely anoxic apical media and aerobic basal media, resulted in a strictly anaerobic apical environment fostering growth of and butyrate production by *F. prausnitzii*, while maintaining a stable colon epithelial barrier. The effects of bacterial co-culture on the state of the epithelium are consistent with some clinical observations regarding *F. prausnitzii*, thus motivating further studies employing this platform. Our studies were limited by the longevity of colon epithelia monolayers, a challenge we are addressing by adapting a new synthetic hydrogel extracellular matrix that we developed for growing colon organoids to the create 3D mucosal barriers incorporating intestinal fibroblasts and immune cells, thus providing a natural stem cell-to-differentiated cell axis suitable for longer-term mucosal barrier culture.

Advancing Regulatory Science Through Organ on a Chip



Daniel A. Tadesse, DVM, PhD

Research Microbiologist
FDA, Center for Veterinary Medicine Office of Research

Dr. Daniel Tadesse is a Research Microbiologist at FDA's Center for Veterinary Medicine, Office of Research. His research programs focus on mapping the microbiomes and resistomes of food animals, animal products, and environment. Current areas of his research include studying the effect of antimicrobials on the composition of the gut microbiota and its subsequent effect on shaping the reservoirs of antibiotic resistance genes accessible to pathogens along the 'farm to fork' continuum; exploring the potential of metagenomics; non-culture-based approach, for antimicrobial resistance monitoring; and developing alternative methods for microbiome research. Dr. Tadesse is co-chair of FDA's High-Performance Computing Governance Advisory Board and serves on multiple Agency and interagency scientific working groups, review panel for research grant proposals, and as a peer reviewer for scientific journals.

Abstract: Advancing Regulatory Science Through Organ on a Chip

The effects of drug residues in or on animal-derived foods on the human intestinal microbiome (disruption of the bacterial colonization barrier and antimicrobial resistance development) is an important human food safety endpoint of concern that needs to be addressed during pre-approval evaluations of drug products intended for use in food-producing animals. Animal models, culture models, and static in vitro transformed cell lines have been used to study the contribution of antimicrobial drug-microbiome interaction to intestinal pathophysiology and antimicrobial resistance development. These in vivo and in vitro models have been used to predict the effects of drug residues on disruption of the bacterial colonization barrier and antimicrobial resistance development among bacteria resident in the human colon. However, recent advances in microphysiological systems present an opportunity to recreate the structure and function of a human organ in vitro. This contemporary technology could substantially improve the mimicking of human intestinal physiology and microbial complexity, allowing study of organ-microbiome-drug interactions. We are exploring the potential of an intestine-on-a-chip model as an alternative method to study the effects of drug residues on human intestinal microbiome and antimicrobial resistance development. Developing a validated intestine-on-a-chip model would provide a new and powerful tool for drug sponsors and FDA to address the effects of antimicrobial new animal drug residues on the human intestinal flora; it represents a substantial step forward in FDA's efforts to reduce or refine reliance on animals for research.

Microbiome as an Additional Criterion for Safety Assessment



Sangeeta Khare, PhD

Research Microbiologist
FDA, National Center for Toxicological Research

Dr. Sangeeta Khare is a research microbiologist at FDA. Her team focuses on host-pathogen/host-microbiome interaction during perturbations with xenobiotics. Dr. Khare received her PhD in the area of infectious diseases from the All India Institute of Medical Sciences, New Delhi, India. She worked extensively in Biosafety Level-3 and A-biosafety Level-3 laboratories during her tenure at the University of Saskatchewan, Canada and Texas A&M University, College Station Texas to determine host interaction with intracellular and drug-resistant pathogens. Dr. Khare's current research focuses on: 1) risk-assessment of exposure to xenobiotics on the gastrointestinal tract using animal (gestational and developmental exposure), in vitro, and ex vivo models to assess effects on the commensal microbiota and intestinal barrier, and 2) the use of advanced technologies, such as NGS, omics, and systems biology approaches for drug-discovery and in establishing a decision tree for intestinal toxicity.

Dr. Khare has received numerous awards and honors for her research. In 2019, she was the recipient of both the American Society of Microbiology-sponsored "ASM-INDO-US Teaching Professorship" award and the NCTR/FDA Special-Act Award for exemplary research in highlighting the importance that microbiomes play in the toxicity of nanomaterials and for her outstanding contributions to the NTP/NIEHS/NCTR research initiatives.

Abstract: Microbiome as an Additional Criterion for Safety Assessment

The intestinal microbiome is a key contributor in the metabolism of drugs, food additives, pesticides, herbicides, and other contaminants, collectively known as xenobiotics. However, the commensal microbiome itself could also be impacted by xenobiotics. An in-depth understanding of the experimental model, dose, route, and frequency of exposure is required when evaluating the safety of xenobiotics that humans are exposed daily. Moreover, there is a need to establish a nonanimal model of the gastrointestinal tract (GIT) to address knowledge-gaps related to the interaction of the xenobiotic with the host and microbiome. The aim of this research is to determine novel risk assessment criteria for gastrointestinal toxicity. Interactions of these products with the GIT may have an adverse effect on the commensal microbiota, affect antimicrobial resistance, and alter the host xenobiotic metabolism, immune responses, and intestinal permeability. This presentation will discuss current approaches, challenges, and opportunities in establishing science-based minimum standards for conducting hazard analyses of such products using the animal model as well as in vitro and ex vivo models. Furthermore, developmental effects (from gestational stages to adult stage) during exposure to xenobiotics will also be discussed. This presentation will provide an example of the interaction of one such xenobiotic with the host using innovative methods of risk assessment that could lead to the discovery of biomarkers, improved food safety, and personalized treatment. Moreover, this comprehensive research provides insight into the mechanistic interaction of the xenobiotics-host-microbiome to determine end points to be included in the decision tree for the risk assessment of such products.

Emergence of Nosocomial Associated Opportunistic Pathogens in the Gut Microbiome After Antibiotic Treatment Revealed by a Mouse Model Metagenome Analysis



Zhihua Li, PhD

Biologist

FDA, Center for Drug Evaluation and Research

Dr. Zhihua Li is the principal investigator of several systems biology/pharmacology projects in FDA's Center for Drug Evaluation and Research, Office of Translational Sciences. Dr. Zhihua Li received his Bachelor of Medicine degree from West China University of Medical Sciences and a PhD in Biochemistry and Molecular Biology from the Chinese Academy of Science. He also completed a postdoctoral fellowship at the University of Pittsburgh's Department of Computational and Systems Biology, focusing on large-scale genomic data and biological pathway analysis. Dr. Zhihua Li joined FDA in 2012 as a computational systems biologist.

Abstract: Emergence of Nosocomial Associated Opportunistic Pathogens in the Gut Microbiome After Antibiotic Treatment Revealed by a Mouse Model Metagenome Analysis

According to the Centers for Disease Control's 2015 Hospital Acquired Infection Hospital Prevalence Survey, 1 in 31 hospital patients was infected with at least one nosocomial pathogen while being treated for unrelated issues. Many studies associate antibiotic administration with nosocomial infection occurrence. However, to our knowledge, there is little to no direct evidence of antibiotic administration selecting for nosocomial opportunistic pathogens.

This study aims to confirm gut microbiota shifts in an animal model of antibiotic treatment to determine whether antibiotic use favors pathogenic bacteria. We used next-generation sequencing and in-house metagenomic assembly and taxonomic assignment pipelines on the fecal microbiota of a urinary tract infection mouse model with and without antibiotic treatment.

Antibiotic therapy decreased the number of detectable species of bacteria by at least 20-fold. Furthermore, the gut microbiota of antibiotic treated mice had a significant increase of opportunistic pathogens that have been implicated in nosocomial infections, like *Acinetobacter calcoaceticus/baumannii* complex, *Chlamydia abortus*, *Bacteroides fragilis*, and *Bacteroides thetaiotaomicron*. Moreover, antibiotic treatment selected for antibiotic resistant gene enriched subpopulations for many of these opportunistic pathogens.

The study concluded that oral antibiotic therapy may select for common opportunistic pathogens responsible for nosocomial infections. In this study opportunistic pathogens present after antibiotic therapy harbored more antibiotic resistant genes than populations of opportunistic pathogens before treatment. Our results demonstrate the effects of antibiotic therapy on induced dysbiosis and expansion of opportunistic pathogen populations and antibiotic resistant subpopulations of those pathogens. Follow-up studies with larger sample sizes and potentially controlled clinical investigations should be performed to confirm our findings.

Safety and Effectiveness of Fecal Microbiota for Transplantation Products



Paul Carlson, PhD

**Principal Investigator, Office of Vaccines Research & Review
FDA, Center for Biologics Evaluation and Research**

Paul Carlson, PhD, is a principal investigator in FDA's Center for Biologics Evaluation and Research (CBER), Laboratory of Mucosal Pathogens and Cellular Immunology. Dr. Carlson received his PhD from the University of Pittsburgh; he performed postdoctoral research at the University of Michigan in the laboratory of Phil Hanna. His research at FDA has focused on infections caused by the enteric pathogens *Clostridium difficile* and Vancomycin resistant *Enterococcus* (VRE) species, specifically, 1) mechanisms of *C. difficile* pathogenesis; 2) development of genetic tools to study *C. difficile*; 3) host response to *C. difficile*; 4) the role of the host microbiota in *C. difficile* colonization resistance; 5) the interactions between the host immune system and the microbiome; 6) bacteriophage therapy against VRE.

Dr. Carlson is a member, and former co-chair, of both FDA's microbiome working group and the Joint Agency Microbiome (JAM) working group, as well as a member of the Microbiome Interagency Working Group (MIWG). His regulatory responsibilities include product (Chemistry, Manufacturing, and Control) review for fecal microbiota transplantation (FMT), defined live biotherapeutic products, and bacteriophage therapies.

Abstract: Safety and Effectiveness of Fecal Microbiota for Transplantation Products

Fecal Microbiota for Transplantation (FMT) has become a therapy of interest for a wide range of indications from colonization resistance against bacterial pathogens, to inflammatory conditions, and even metabolic and neurological disorders. The most well studied indication for FMT is the treatment of recurrent *Clostridioides difficile* infections (CDI), with some studies reporting >90% efficacy. From a regulatory perspective, FMT presents unique challenges. Since the "active ingredient" in these drugs is currently unknown and likely different for each indication FMT is intended to treat and being studied, it is difficult to develop the types of assays and tools that would facilitate an understanding of important product characteristics. An increased understanding of the mechanisms controlling effective FMT could aid researchers and FDA in understanding these processes and facilitate product development in this arena. The project to be presented here seeks to advance our understanding of FMT safety (donor screening, including the risk of SARS-CoV-2), manufacturing (how do manufacturing methods/ conditions alter microbiome composition), and effectiveness (identification of markers important for potency).

Microphysiological System Regulatory Research Considerations: Evaluation of a Model System



Kirsten Eckstrum, PhD

**Research Biologist
FDA, Center for Food Safety and Applied Nutrition**

Kirsten Eckstrum is a research biologist in FDA's Center for Food Safety and Applied Nutrition, Division of Toxicology/Office of Applied Research and Safety Assessment. Dr. Eckstrum joined FDA as an ORISE fellow in 2017 after receiving a PhD in Molecular and Integrative Physiology from the University of Illinois Urbana-Champaign, where she studied the effects of bisphenol A (BPA) on the neonatal pituitary gland in mice. At FDA, she has been working on the Liver-Chip team since 2017, focusing on evaluating microphysiological systems (MPS) or organ-on-a-chip models for a regulatory toxicology testing environment. This work includes assessing the working components of the organ-on-a-chip system; developing standard operating procedures; assessing the health and viability of the liver cells in the chip; and assessing the response to toxic stimuli. The team has completed preliminary evaluation of the two-cell Liver-Chip system, with one current publication and two pending.

***Abstract: Microphysiological System Regulatory Research Considerations:
Evaluation of a model system***

Microphysiological systems (MPS) or organ-on-a-chip models employ the use of multiple cell types and flow of media to mimic physiological stimuli. With the use of human cells, these systems have the potential to become more predictive tools for drug safety and toxicity testing than current animal models. To assess the usefulness of these systems in determining toxicity we examined one such platform, the Emulate two-cell Liver-Chip, which used primary human hepatocytes and liver sinusoidal endothelial cells (LSECs). In evaluating the performance of this system, we explored the necessary components and considerations for Liver-Chip studies; the predictivity, sensitivity, and specificity, power or sample size requirement; and variability within the system using eight compounds of known hepatotoxic potential, including usinc acid, benzbromarone, tamoxifen, acetaminophen, diglycolic acid, dimethyl sulfoxide, theophylline, and aminohippurate. This was accomplished through analysis of traditional biochemical and imaging markers of hepatocyte toxicity. Our findings demonstrated that Liver-Chip studies could easily be performed in a regulatory testing environment with proper SOPs in place, including proper analysis of chemical-chip interaction. For the compounds tested, the Liver-Chip model accurately predicted toxicity with most tested compounds; sensitivity and specificity were high, Liver-Chips needed a sample size of 3-4 chips, depending on the endpoint analysis, and variability was low both within and between experiments. These results suggest that MPS could provide useful information in a regulatory research setting; however, further studies are necessary to fully understand the usefulness of the platform.

Evaluation of Endothelial Cell Responses to Nanomaterials Using a Dynamic Flow Model



Shelby Skoog, PhD

**Biomedical Engineer
FDA, Center for Devices and Radiological Health**

Dr. Shelby Skoog is a biomedical engineer in the Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories. She works in the Toxicology and Biocompatibility Program in the Division of Biology, Chemistry, and Materials Science (DBCMS). Dr. Skoog received her PhD from the Joint Department of Biomedical Engineering at the University of North Carolina and North Carolina State University in 2015. She then joined CDRH, where she worked as an ORISE postdoctoral fellow, assessing the biological impact of polymeric degradants evolving from biodegradable medical devices. Since joining DBCMS as a staff fellow in 2016, Dr. Skoog has served as a biocompatibility expert for regulatory review of medical devices. Additionally, she conducts regulatory research, including her current work on biocompatibility evaluation of bioabsorbable medical devices, development of advanced in vitro alternatives for evaluation of nanomaterials, and hemocompatibility assessment of medical devices.

Abstract: Evaluation of Endothelial Cell Responses to Nanomaterials Using a Dynamic Flow Model

With expanding applications of nanomaterials in innovative drugs and medical devices, there is a need for improved test methods to evaluate their safety before clinical use. Traditional in vitro biological evaluation approaches do not account for the complex interactions of nanomaterials with the physiological environment. Furthermore, in vivo animal studies are expensive, time-consuming, may not reflect human responses, and include ethical considerations for use of animals. Advanced in vitro test methods, such as organ-on-a-chip microphysiological systems (MPS), have demonstrated potential in toxicological research by providing a more physiologically relevant environment. These dynamic, in vitro models using human cells may help bridge the gaps between traditional in vitro cell studies and in vivo animal evaluation as well as provide better prediction of clinical responses for safety assessment of medical products containing nanotechnology. Our preliminary research has focused on the use of an endothelium-on-a-chip fluidic model to evaluate biological responses to nanoparticles under shear flow conditions similar to human vasculature, since nanomaterials are being increasingly used in medical devices and drugs using intravascular administration. In these studies, we evaluated the effects of silver nanoparticles on human cerebral microvascular endothelial cells under dynamic flow conditions compared to static conditions. Our results demonstrate the dynamic flow conditions affect the nanomaterial aggregation, and the endothelial cell responses to the nanoparticles is dependent on the nanomaterial concentration and the experimental flow conditions (e.g., dynamic vs. static). This study highlights the impact of physiologically relevant environment in safety evaluation of nanomaterials.

Microphysiological Systems to Assess the Functional Capacity of Regenerative Medicine Cellular Products



Kyung Sung, PhD

Principal Investigator
FDA, Center for Biologics Evaluation and Research

Kyung Sung is a principal investigator in FDA's Center for Biologics Evaluation and Research, Cellular and Tissue Therapies Branch, Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies. Her research focuses on developing new quantitative assays using microphysiological systems to study the impact of interactions between living cells and biomaterials used in the manufacture and characterization of regenerative medicine cellular products. She received her PhD in Chemical Engineering from the University of Michigan, Ann Arbor and did her postdoctoral training at the University of Wisconsin, Madison. She also worked as a patent examiner in Biotechnology at the U.S. Patent and Trademark Office before she joined FDA in 2015.

Abstract: Microphysiological Systems to Assess the Functional Capacity of Regenerative Medicine Cellular Products

As described in the 21st Century Cures Act, products eligible for Regenerative Medicine Advanced Therapy (RMAT) designation include cellular therapies, therapeutic tissue engineered products, human cell and tissue products, or any combination products that use such therapies or products.

Multipotent stromal cells (MSCs) and induced Pluripotent Stem Cells (iPSCs) have been popular sources for manufacturing RMAT products due to their ability to undergo lineage-specific differentiation. For successful clinical translation of such cell-based products, there is a paucity of reliable markers that can predict the products' in vivo performance. For instance, MSCs are heterogeneous and responsive to their surrounding environment, resulting in distinct subpopulations of cells with potentially different qualities needed for product potency.

Since there are numerous biochemical and biomechanical factors regulating the functions of MSCs, it is critical to develop reliable high-throughput assays that enable the efficient exploration of large and complex parameters for evaluating cellular function.

Microphysiological systems offer the practicality to fulfill this unmet need. Several simple microfluidic channel arrays have been successfully implemented in screening the influence of paracrine mediators and various tissue microenvironment components in the regulation of cellular functions. Further, microphysiological three-dimensional organoids and tissue-like structures, such as chondrogenic cell aggregates and blood vessels have been incorporated into high-throughput, cell-based screening platforms in efforts to provide functionally relevant conditions. This presentation will give an overview of practical microscale technologies that are simple to operate while enhancing throughput, relevance, and reliability. How such technologies could be employed in the assessment of cell-based products will be discussed.

Speaker Bios and Abstracts

Concurrent Session 6: MCM, Infectious Disease and Pathogen Reduction Technologies



Monica L. Young, PhD (Session Chair/ Moderator)

Senior Scientific Advisor
FDA, Center for Biologics Evaluation and Research

Dr. Monica Young serves as a Senior Scientific Advisor in the Office of the Director within the Center for Biologics Evaluation and Research (CBER). In this capacity, she works with the CBER leadership and other scientific staff within the Center and across the Agency to develop and implement policies and procedures to strengthen infrastructure and support the accomplishments of the CBER research program. She is involved in various initiatives to foster scientific research communication and outreach. Dr. Young received her B.S. in Biology from the University of Tennessee, Knoxville and a Ph.D. in Microbiology from the University of Chicago where she worked on *Staphylococcus aureus* (S. aureus), identifying a novel peptide transport system involved in pathogenesis. She performed her post-doctoral research training at St. Jude Children's Research Hospital, Department of Infectious Diseases where she studied the role of co-infection of influenza A and S. aureus in pulmonary distress syndrome and pneumonia. Dr. Young is appointed to numerous committees and serves as a liaison for various CBER and Agency initiatives. Dr. Young has several awards in recognition of her contributions to FDA including the Award of Managerial Excellence and the Process Improvement Award.



CAPT Tracy Macgill (Session Chair/ Moderator)

Director, Medical Countermeasure (MCM) Regulatory Science

CAPT Tracy MacGill is the Director of MCM Regulatory Science for the Office of Counterterrorism and Emerging Threats in the Office of the Chief Scientist, and the Medical Countermeasures Initiative. She leads the MCMi Regulatory Science Program which includes intra-and extramural research programs. CAPT MacGill's work involves close collaboration with FDA product centers, Public Health Emergency Medical Countermeasures Enterprise stakeholders, and a wide range of domestic and international partners.

She previously served as a program officer in the Office of Biodefense Affairs, National Institutes of Allergy and Infectious Diseases at NIH; and as a microbiologist in the Office of Counter-Terrorism and Emergency Coordination, CDER, FDA. Before coming to FDA, she was an officer in the U.S. Army. CAPT MacGill received a BA in Biology from Wittenberg University, and a PhD in Molecular and Cellular Biology from the University of Nevada, Reno. She also holds a Graduate Certificate in Project Management from George Washington University.



Carol Weiss, MD, PhD (Moderator)

**Senior Scientific Advisor
FDA, Center for Biologics Evaluation and Research**

Dr. Weiss is a researcher-reviewer in the Division of Viral Products, Office of Vaccine Research and Review, CBER. Her research focuses on virus entry and antibody neutralization of HIV, influenza, and coronaviruses. Her regulatory responsibilities involve review of viral vaccines.

Outbreak Preemption and Response in the Genomic and Information Age



Pardis Sabeti, MD, PhD

**Professor
Broad Institute**

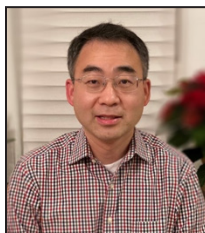
Dr. Pardis Sabeti is a Professor at Harvard University, the Harvard T.H. Chan School of Public Health, the Broad Institute of Harvard and MIT, and a Howard Hughes Investigator. Her computational genomic lab has contributed to widely varying fields including human and microbial genomics, information theory, and rural infectious disease surveillance and education efforts in West Africa. Dr. Sabeti completed a B.S. at MIT, M. Sc. and D.Phil at Oxford University, and MD summa cum laude from Harvard Medical School. Dr. Sabeti is a National Academy of Medicine member; World Economic Forum Young Global Leader; National Geographic Emerging Explorer; recipient of the National Academy of Sciences Richard Lounsbery Award; Smithsonian American Ingenuity Award winner for Natural Science; TIME magazine “Person of the Year” as one of the Ebola fighters; and TIME’s 100 Most Influential. She is the host of ‘Against All Odds’ included as part of AP stats classes nationwide and is the lead singer of the rock band Thousand Days.

Abstract: Outbreak Preemption and Response in the Genomic and Information Age

Just as the COVID-19 crisis has emphasized the critical importance of rapidly detecting and containing pathogens, we are on the cusp of a new era in infectious disease surveillance and response. Ultra-sensitive genomic technologies have the unprecedented ability to detect virtually any pathogen, including those circulating under the radar, and can be leveraged to create simple, rapid, and highly affordable point-of-care diagnostics to be deployed anywhere. In parallel, powerful, cloud-based information systems allow us to continuously collect, integrate, and, most importantly, broadly share viral surveillance data with those who need it most to guide critical public health decisions and actions. By unifying these tools into a coherent system, we can

detect and prevent pandemics on the ground before they start. As a global community we need to: Detect infections with genomics-based tests that can identify high priority viruses within an hour, any known human virus within a day, and previously unknown viruses within a week. Connect frontline healthcare workers, hospitals, laboratories, and public health institutions to ensure efficient coordination, robust data sharing, and real-time analytics for rapid response. Empower the entire public health community – from frontline workers to national authorities – to deploy Sentinel anywhere in the world. Altogether we need to build and deploy a pandemic early warning and response system that detects viral threats in real time and allows the global community to stop infectious diseases before they spread.

Evaluation of Pathogenesis of SARS-CoV-2 Variants



Tony Wang, PhD

**Principal Investigator
FDA, Center for Biologics Evaluation and Research**

Tony Wang is the principal investigator of the laboratory of vector-borne viral diseases of Division of Viral Products, Office of Vaccines Research and Review, FDA Center for Biologics Evaluation and Research (CBER). Dr. Wang received his bachelor's degree in medicine from the Beijing Medical University in 1996 and his PhD degree in microbiology in 2001 from the Department of Microbiology at Ohio State University. He completed two postdoctoral fellowships at the Howard Hughes Medical Institute/UCLA, and then at the Los Alamos National Laboratory, New Mexico. Before joining CBER in 2018, Dr. Wang served as a faculty member at the University of Pittsburgh and a program director in virology at SRI International, a non-profit research institute. Dr. Wang's laboratory studies how human pathogenic RNA viruses infect host cells. Starting from February 2020, the laboratory began to investigate the severe respiratory syndrome coronavirus 2 (SARS-CoV-2), which has caused a global pandemic. Dr. Wang's group has been instrumental to FDA's role in fighting the public health crisis caused by the COVID-19 pandemic. Materials and results generated in the laboratory have been used in support of reference reagent production and evaluation of vaccine safety and efficacy.

Abstract: Evaluation of Pathogenesis of SARS-CoV-2 Variants

The outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has quickly turned into a global pandemic. FDA has been at the very frontline in the fight during this public health crisis from Day 1. The Center for Biologics Evaluation and Research (CBER) has issued Emergency Use Authorizations (EUA) for three COVID-19 Vaccines, all of which express the viral spike protein as immunogen. With widespread infection and delayed vaccine rollout, SARS-CoV-2 variants of concerns have unfortunately emerged in many parts of the world. Some of these variants have shown signs of partial escape of the immunity elicited by existing vaccines. This seminar intends to cover experimental results on the pathogenesis of SARS-CoV-2 variants, and the implications in designing and conducting the vaccine pre-clinical trials.

Artificial Intelligence-Powered Drug Re-Purposing Against COVID-19



Zhichao Liu, PhD

Senior Technical Leader, Artificial Intelligence Research Force
FDA, National Center for Toxicological Research

Zhichao Liu is the senior technical leader at Artificial Intelligence Research Force (AIRForce) in the Division of Bioinformatics & Biostatistics of FDA's National Center for Toxicological Research (NCTR). Dr. Liu's background spans the fields of chemistry, biology, and computer science. He led many cutting-edge projects in the past decade by designing, implementing, and deploying AI/machine-learning solutions for advanced regulatory sciences. Specifically, Dr. Liu developed the standard pipeline with AI-powered drug repositioning to help industry seek the optimal route to accelerate the drug-development efficacy from an advanced regulatory-sciences perspective. Furthermore, Dr. Liu unleashed the AI/machine-learning solutions for promoting predictive toxicology with a few successful models adopted by the industry and regulatory process. His accomplishment has been reflected in five FDA-wide Awards, nine NCTR-level Awards, two scientific community-level awards, and more than 80 peer-reviewed publications.

Abstract: Artificial Intelligence-Powered Drug Repurposing Against COVID-19

Emerging infectious diseases have been an ever-present threat to public health, and COVID-19 is a recent example. There is an urgent need to develop a robust framework of safe and effective therapeutic options for the disease. The interplay between immune systems and mitochondria plays an essential role in COVID-19 etiology. Here, we proposed a modified DeepFake model framework to unravel the immune and mitochondria continuums for precision medicine-based drug repurposing in COVID-19. Specifically, we integrated over 3 million multi-omics data points associated with immune, mitochondria, and drug transcriptomic responses for the model development. Consequently, we obtained a list of 21 immune and mitochondria continuums. The functional analysis demonstrated that the 21 immune and mitochondria continuums highly associated with the severity and pre-existing conditions of COVID-19 patients. We further map the FDA-approved drugs and investigated compounds onto the obtained immune and mitochondria continuums, enriching a list of repurposing candidates for the COVID-19 patients with different manifestations. Altogether, the proposed DeepFake model could effectively uncover the interplay between immune and mitochondria systems and pave a new way for precision medicine-based drug repurposing against COVID-19.

Device Medical Countermeasure Activities During the COVID-19 Pandemic



Heather Agler, PhD

Senior Program Manager
FDA, Center for Devices and Radiological Health

Dr. Heather Agler is a Senior Program Manager in the All Hazards Readiness, Response, and Cybersecurity (ARC) group in FDA's Center for Devices and Radiological Health (CDRH) and has been working for the FDA for 16 years. Dr. Agler develops collaborations and works as a liaison between medical device developers in Government agencies, DoD, academia, and industry and the CDRH review divisions to reduce the regulatory hurdles that often accompany bringing new, high-risk/high-benefit, medical countermeasure technology to market. At the beginning of the COVID-19 pandemic response, Dr. Agler worked on ways to make ventilators accessible and on the emergency use authorization process. She continues to work on critical supply-chain issues such as low dead-volume safety needles and syringes for vaccine administration. Prior to joining ARC, she worked on interoperability of medical devices, wireless technology in medical devices, health IT, and device classification. Dr. Agler was also an engineering reviewer and lead reviewer in CDRH's Office of Device Evaluation. She reviewed interventional cardiology devices such as drug-eluting stents and cardiac occluders in CDRH's Division of Cardiovascular Devices. Prior to her work at the FDA, Dr. Agler was Christine Mirzayan Fellow at the National Academies. She also received a National Science Foundation Fellowship for graduate school. Dr. Agler has a B.S. in chemical engineering from the University of South Carolina and a PhD in biomedical engineering from the Johns Hopkins School of Medicine.

Abstract: Device Medical Countermeasure Activities During the COVID-19 Pandemic

The FDA is playing a critical part in the COVID-19 pandemic response. Many devices such as diagnostic tests, personal protective equipment, ventilators, monitoring devices, injection devices, and numerous others have played important roles. The response has also emphasized the need for the development of new medical countermeasures. The Center for Devices and Radiological Health (CDRH) has issued Emergency Use Authorizations (EUAs) and provided regulatory flexibility through immediately-in-effect enforcement discretion policies applicable to certain devices. The issuance of EUAs and the implementation of enforcement discretion policies provides an opportunity for early access to new innovative solutions for better patient care. Having the devices on the market creates opportunities to collect real-world evidence on those devices available during the pandemic. This experience can lead to the creation of innovative products that will prepare us for the next event.

Emerging Technologies for Adventitious Agent Detection and Their Application to CDER Products



Kathryn E. King, PhD

Staff Scientist/Product Quality Assessor
FDA, Center for Drug Evaluation and Research

Kathryn King earned her Ph.D. from the Department of Biochemistry and Molecular Biology at the University of Manchester in the U.K. Following a post-doc in the Department of Medicine at Cambridge University in the U.K., she moved to the FDA where she is employed as a Staff Scientist/Product Quality Assessor in the Office of Biotechnology Products. In this capacity she conducts CMC review of recombinant therapeutic protein products and carries out research on epithelial cancers. Dr. King has been involved in external efforts pertaining to cell substrate safety including: co-leading a Parenteral Drug Association (PDA) Cell Substrate Task Force that wrote Technical Reports on Emerging Molecular Methods for Virus Detection (#71) and Virus Contamination (#83); representing CDER on the revision of the International Council for Harmonisation (ICH)Q5A; acting as FDA liaison on a USP chapter on cell banking; and serving as a member of the PDA's Advanced Technologies for Virus Detection Users Interest Group.

Abstract: Emerging Technologies for Adventitious Agent Detection and Their Application to CDER Products

In addition to the infectious agents that are currently the target of novel biotechnology therapies, adventitious agents can impact the manufacture of products. Adventitious agents are microorganisms that are unintentionally introduced into a manufacturing process/drug product. Biotechnology products must be shown to be free from adventitious agent contamination. Contamination events not only pose the risk of transmission of pathogenic agents to patients but also can impact drug supply due to the need for event remediation. Traditional routine tests for adventitious agents have relied on culture methods, which are subject to long incubation periods. Use of novel rapid technologies for adventitious agent detection has been steadily evolving over time towards both more rapid and broader methods designed to detect unanticipated as well as predicted potential contaminants. Some of these technologies are capable of detecting microbes that were not detected by the traditional methods, indicating a gap in traditional testing methods. Thus, there is enhanced interest in novel testing methods to ensure biosafety, while cutting down on time to results. This presentation will focus on examples of novel technologies that are being considered or have been accepted for routine use for the detection of bacteria, mycoplasma and adventitious viruses.

ORA's Work in Support of Medical Countermeasures



Elizabeth Miller, PharmD

Assistant Commissioner for Medical Products
and Tobacco Operations
FDA, Office of Regulatory Affairs

Dr. Elizabeth Miller rejoined the FDA in March 2020. In her role as Assistant Commissioner for Medical Products and Tobacco Operations, Dr. Miller provides leadership and managerial direction to Office of Regulatory Affairs' (ORA's) Office of Biologics Products Operations, Office of Pharmaceutical Quality Operations, Office of Medical Device and Radiological Health Operations, Office of Bioresearch Monitoring Operations, and the Tobacco Operations Staff. Dr. Miller returned to FDA from the U.S. Pharmacopeia (USP) where she helped guide USP's working relationship with the FDA. At USP, Dr. Miller was vice president, U.S. Public Policy & Regulatory Affairs, with responsibility to deliver executive leadership for developing and achieving USP's U.S. regulatory science and intelligence, government affairs, and public policy programs' goals. She also created strategic change focused on impacts and results stemming from engagement with federal, state, and international regulators, as well as senior leadership in industry, academia, and patient-focused alliances. Before rejoining USP in 2016, Dr. Miller began her federal career with FDA's Center for Drug Evaluation and Research in 2007 in the Office of Unapproved Drugs and Labeling Compliance (OUDLC). She began her CDER career working on online pharmacy and health fraud issues, and ultimately served as director for OUDLC's Division of Nonprescription Drugs & Health Fraud. Prior to federal service, Dr. Miller worked at USP as a scientific liaison on medication safety standards for nomenclature, labelling, and packaging, and as the director of drug information for the USP Drug Information publication. She started her pharmacy career working as a clinical pharmacist at MedStar Washington Hospital Center in Washington D.C. Dr. Miller holds a bachelor's degree in biology from the Johns Hopkins University and received her Doctor of Pharmacy degree from the University of Maryland.

Abstract: ORA's Work in Support of Medical Countermeasures

FDA and its component centers routinely collaborate to advance public health through thorough review of submitted applications and on-site regulatory inspections to ensure manufacturing readiness, among other items. The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides authority for FDA to grant an emergency use authorization (EUA) during the effective period of a declaration issued pursuant to section 564(b) of the FD&C Act by the Secretary of the Department of Health and Human Services, for a medical product intended for use in an actual or potential emergency (emergency use). An EUA allows unapproved medical products and approved products with unapproved uses to be introduced into interstate commerce if they may be effective as medical countermeasures during declared public health and other national emergencies and there is no available, approved alternative. FDA's authority to issue an EUA is separate and distinct from the use of a medical product under an investigational application, section 561 expanded access authorities, and section 564(a) emergency use

authorities. Interactions between a sponsor and FDA before or after submission of an EUA request may include investigations by an FDA investigator(s) of a facility that will manufacture, package, label, or test a medical product subject to an EUA, in order to gather information requested by the Center to inform their decision-making process on an EUA. This presentation will provide a high-level overview of the novel regulatory framework during the pandemic, including ORA's efforts to evaluate manufacturing operations for vaccines and therapeutics. Examples of real-world impact supporting emergency use authorization will be discussed and lessons learned from our investigative teams.



Speaker Bios and Abstracts

Concurrent Session 7: Food and Cosmetic Safety: The Role of Innovation and Technology



Chad P. Nelson, PhD, MSPH (Session Chair/ Moderator)

Toxicologist
FDA, Center for Food Safety and Applied Nutrition

Dr. Chad P. Nelson is a toxicologist at FDA's Center for Food Safety and Applied Nutrition (CFSAN). As part of the Senior Science Advisor Staff in the Office of the Center Director, he provides leadership and coordination to sustain and enhance CFSAN's scientific research enterprise. This includes facilitating and advancing effective cooperation within the Center, with other FDA operatives, as well as with external stakeholders. One of his primary responsibilities is serving as the project officer for the Joint Institute for Food Safety and Applied Nutrition, one of CFSAN's academic Centers of Excellence.

He has previously worked as a senior analyst in the Office of Foods and Veterinary Medicine (OFVM), a project manager and member of the FVM Science and Research Steering Committee, the Chair of the FVM Toxicology Research Coordination Group, the Co-lead for the Food Safety Modernization Act Reports and Studies Team, and a toxicologist in the CFSAN Office of Food Additive Safety. Before joining FDA, Dr. Nelson was a research biologist and postdoctoral research associate at the National Institute of Standards and Technology. He received his B.S. in Biology and his MSP.H. in Toxicology and Health Risk Assessment, both from Tulane University. He earned his PhD in Toxicological Sciences from Johns Hopkins University and also has a Master's Certificate in Project Management from George Washington University.



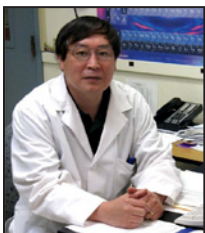
Jeffrey Ward, DVM, MS, PhD (Session Chair/ Moderator)

Senior Science Advisor for Regulatory Science
FDA, Center for Veterinary Medicine

Dr. Jeffrey Ward received a B.A. in Biology from The Johns Hopkins University in 1982. He attended the Virginia-Maryland Regional College of Veterinary Medicine and received a D.V.M. degree in 1987, after which he completed an Internship in Large Animal Medicine and Surgery. He then spent 9 years at the College of Veterinary Medicine at Cornell University, where he completed a Residency in Large Animal Surgery, an M.S. in Veterinary Medicine, and a Ph.D. in Pharmacology. In 1997 he returned to Baltimore and The Johns Hopkins University School of Medicine, where he completed a post-doctoral research fellowship in the molecular characterization of intestinal nucleoside transporters, and he remained there as a faculty research associate in the Department of Medicine / Division of Gastroenterology. In June 2002, Dr. Ward started his career at the FDA's Center for Veterinary Medicine, sequentially serving as a research pharmacologist, Supervisory Veterinary Medical Officer, the



Attending Veterinarian, the Director of the Division of Applied Veterinary Research, and the Deputy Director of the CVM Office of Research. During his tenure with the Office of Research, he led a research program in pharmacokinetics/pharmacodynamics and was extensively involved in studying the biological effects of melamine. Moving to the FDA Office of Foods and Veterinary Medicine in May 2015, he served as a Senior Science Advisor with the Science and Research Team, working on cross-cutting issues involving CVM, CFSAN, and ORA. Dr. Ward returned to CVM in 2018 as a Senior Science Advisor for Regulatory Science, in the Office of the Center Director, focusing on various science, research, and laboratory issues. He has participated in the Excellence in Government program and has attended the Federal Executive Institute.



Zhichao Lin, PhD (Session Chair/ Moderator)

Research Chemist

Winchester Engineering and Analytical Center (WEAC)

FDA, Office of Regulatory Affairs

Dr. Lin is a senior research chemist in FDA's Winchester Engineering and Analytical Center. He has interdisciplinary expertise in radiochemistry, radiation detection, reference material development, interlaboratory collaborative study, regulatory science, and statistical analysis. Serving as FDA's leading expert on radiological food safety, he directs mission-critical projects to support FDA's food safety compliance and radiological emergency response programs, which include radioanalytical metrology research, interlaboratory collaborative study, and radiological proficiency testing. He also collaborates with instrument manufacturers and scientific organizations on developing and validating novel radiation detection technologies and methods. As an accomplished research scientist, he has received 14 achievement awards, co-authored 29 peer-reviewed articles, presented at 68 scientific conferences, and served as a subject matter expert at national and international technical workshops. Prior to joining the FDA, he worked at the National Institute of Standards and Technology (NIST) where he conducted research on radioanalytical metrology, development of radioactive standard reference materials, and radioanalytical measurement traceability. Dr. Lin earned a Ph.D. in analytical, nuclear, and environmental chemistry from University of Maryland.



One Health as a Collaborative Response to Food Safety Risks



Kalmia (Kali) Kniel, PhD
Professor of Microbial Food Safety
University of Delaware

Dr. Kali Kniel is a Professor in the Department of Animal and Food Sciences at the University of Delaware, where she has been since 2004. She obtained her B.S. in Biology, MS in Molecular Cell Biology, and PhD in Food Science from Virginia Tech in Blacksburg, Virginia. From 2002-2004, Kali served as a postdoctoral research microbiologist with the Animal Parasitic Diseases Laboratory at the U.S. Department of Agriculture Agricultural Research Service. Her current teaching responsibilities include courses on epidemiology and foodborne disease; government regulations pertaining to food safety and quality; controversial and social issues of food science; and food security.

Dr. Kniel current serves as the co-chair of the One Health Program at the College of Agriculture and Natural Resources and the Director of the Center for Environmental and Wastewater Epidemiological Research. Dr. Kniel's research interests include understanding mechanisms of environmental persistence by zoonotic and human bacteria, protozoa, and viruses in pre-harvest agricultural environments, focusing on water and soil amendments and in the study of human norovirus surrogates. Dr. Kniel also leads research projects on the integration of food safety into secondary educational programs and for higher education non-science majors. Her curriculum development includes games and case studies on outbreak investigations. Kali currently serves as the past-president for the International Association for Food Protection.

Abstract: One Health as a Collaborative Response to Food Safety Risks

One Health is a scientific perspective that considers human, animal, and environmental health as an integrated whole. In today's society, One Health enables a collaborative approach towards solving many of the world's most pressing challenges and health-related issues. The goal of One Health is to reduce disease and maximize health by considering the myriad interactions and connections within the human, animal, and environmental triad. Food safety may be considered the epitome of One Health. We must approach feeding the world as a way to ensure the well-being of people, animals, and the environment through collaborative problem-solving. Emerging infectious disease can be discussed in the context of ecosystems. We encounter One Health issues every day, and this has been renewed by the ongoing COVID-19 crisis. It is estimated that more than 75% of emerging and re-emerging diseases are either zoonotic or vector-borne. Critical One Health issues to food safety and food security include Salmonella and avian influenza, among others. We can practice awareness and learn to control infections and risks more efficiently through a One Health lens. This includes understanding the interconnectedness that exists within our world so that we can grow our human population through advances in agriculture while protecting the natural world at the same time.



CFSAN's Use of Innovative Science to Address Current and Emerging Public Health Priorities



Susan T. Mayne, PhD

**Center Director
FDA, Center for Food Safety and Applied Nutrition**

Susan T. Mayne, PhD, is FDA's Director of the Center for Food Safety and Applied Nutrition (CFSAN) at FDA. In this position, Dr. Mayne leads the Center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, food and color additives, and cosmetics. CFSAN also oversees diet and health initiatives, which include fostering the development of healthier foods and ensuring that consumers have access to accurate and useful information to make healthy food choices. The FDA foods program is responsible for approximately 80% of the U.S. food supply, which includes some \$400 billion in domestic food and \$50 billion in imported food. The Center is composed of 1,000 staff, with a budget of over \$300 million.

An internationally recognized public health leader and scientist, Dr. Mayne received a BA in chemistry from the University of Colorado. She earned a PhD in nutritional sciences, with minors in biochemistry and toxicology from Cornell University. Dr. Mayne came to FDA from Yale University, where she was the C.E.A. Winslow Professor of Epidemiology and the Associate Director of the Yale Comprehensive Cancer Center.

Abstract: CFSAN's Use of Innovative Science to Address Current and Emerging Public Health Priorities

The U.S. Food and Drug Administration (FDA) is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. FDA's Center for Food Safety and Applied Nutrition (CFSAN) conducts regulatory science-related research to increase our understanding of the underlying factors and variables that may contribute to or pose a risk to human safety and health for CFSAN-regulated products which are human foods, including dietary supplements, as well as cosmetics. In addition to traditional approaches to laboratory science, CFSAN also engages in and encourages the development of novel technologies for the detection, reduction, inactivation, or elimination of hazards from FDA-regulated products. We embrace a variety of innovative scientific methods including: predictive toxicology to inform better decisions while reducing or eliminating the use of animals in toxicity testing; consumer studies in nutrition and labeling as well as food safety to recognize consumer views and understanding in order to provide information that will empower consumers to make the most informed decisions; genomics, metagenomics and bioinformatics to clarify the root cause of foodborne outbreaks, support investigations, and prevent future outbreaks; development of more rapid analytical methods to set the global standards for measuring chemicals of concern, such as cannabidiols (CBD), per- and polyfluoroalkyl substances (PFAS), and metals; and risk assessments to inform policy decisions and prioritization aimed at reducing consumer exposure to potential hazards in food. Dr. Mayne will discuss how CFSAN uses innovative science to address current and emerging public health priorities related to FDA-regulated foods, including dietary supplements, as well as cosmetics.



FDA Support of Recent Foodborne Illness Outbreak Investigations



Dan Rice, MS, DrPH

Associate Director, Office of Food and Feed Laboratory Operations
FDA, Office of Regulatory Affairs

Dr. Dan Rice is the Associate Director of FDA's Office of Food and Feed Laboratory Operations, in the Office of Regulatory Affairs (ORA). Previously, he held the positions of director of FDA's ORA ORS Pacific Northwest Laboratory, director of the New York State Food Laboratory, Department of Agriculture and Markets, and research program manager at Washington State University College of Veterinary Medicine. His career path and research interests align with a One Health approach to addressing public health issues. Dr. Rice's primary research focus has been on control of zoonotic pathogens through interventions at food animal production and food production to reduce the incidence of foodborne illness and zoonotic infections in both humans and animals. He has a B.S. in Wildlife Biology, MS in Veterinary Epidemiology from Washington State University and a Doctor of Public Health in Epidemiology from the State University of New York at Albany.

Abstract: FDA Support of Recent Foodborne Illness Outbreak Investigations

FDA is a significant partner in the response to outbreaks of foodborne illness associated with most human and animal food products in the United States. FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine, compliance programs, inspection programs, and laboratories collectively work towards outbreak response, surveillance, and post-response activities related to incidents involving illnesses linked to FDA-regulated human and animal food products.

Early identification of illness clusters; rapid and effective regulatory response to remove contaminated food from distribution; and targeted outreach activities to inform consumers are instrumental to an effective public health impact. Investigations of multi-state outbreaks of foodborne illness are complex and require coordinated efforts among regulatory and public health partners spanning federal, state, and local government agencies who collectively contribute to identifying outbreaks and mitigating impact on consumers. These agencies coordinate epidemiological investigations, inspections, sampling, testing and evaluate implicated product distribution. In recent years, FDA has provided technical, epidemiological, inspectional, and laboratory support for several outbreaks of foodborne illness, including *E. coli* O157:H7 in leafy greens, *Cyclospora cayetanensis* in fresh produce, *Salmonella enterica* in a variety of products and Hepatitis and Norovirus in fresh berries and fresh produce. This presentation will provide an overview of successes, challenges, and strategies FDA uses to respond to outbreaks of foodborne illnesses, and to assess the safety of food consumed in the U.S.



What Won't an Animal Eat? Innovation in Animal Diets



David Edwards, PhD

Director, Division of Animal Feeds
FDA, Center for Veterinary Medicine

Dr. Dave Edwards is the Director for the Division of Animal Feeds in the Office of Surveillance and Compliance at FDA's Center for Veterinary Medicine (CVM). The Division regulates animal food, including premarket ingredient approvals, medicated feed, and postmarket animal food safety monitoring. CVM works to "protect human and animal health."

Before joining CVM, Dr. Edwards was the Director, Animal Biotechnology at the Biotechnology Innovation Organization (BIO) in Washington, D.C. BIO is the world's largest biotechnology trade association. He has also worked on the majority professional staff of the U.S. Senate Committee on Agriculture, Nutrition, and Forestry.

Dr. Edwards grew up in Iowa and raised pigs, sheep, and specialty crops. He received his B.S. in genetics and agricultural biochemistry from Iowa State University and his MS and PhD in animal science breeding and genetics at Michigan State University. He is also a graduate of the U.S. Federal Executive Institute.

Abstract: What Won't an Animal Eat? Innovation in Animal Diets

Animal food is a \$297 billion U.S. market that includes food for livestock, aquaculture, and pets, and affects both animal and human health. Ingredients in these products are becoming more complex. The food that a food-producing animal eats becomes part of our food. And companion animals are members of our family whose lives we want to be long and healthy. Innovative ingredients continue to be developed for the animal food market. Although animals have always consumed byproducts from production of human food (e.g. extra bakery products not put into the human food supply), newer ingredients derive from partitioning foods into fractions for specific nutritional needs.

Other animal food ingredients start out in fermentation tanks, where microbes may produce specific nutrients or be fed as ingredients themselves. FDA recently reviewed the use of oil from single cell algae to serve as an alternative source of docosahexaenoic acid (DHA) for dog food. FDA also reviewed black soldier fly larvae, which are raised on food scraps that would otherwise have gone to waste. The insects are turned into high-quality food for poultry, swine, dogs, and salmon. Animals generally eat a very limited and defined diet as their sole nutrition over their whole lifetime. Reviewing new animal food ingredients enables FDA to evaluate new ingredients for safety and to make sure they function as intended. This helps ensure that people provide optimal nutrition to help keep animals healthy, while also ensuring that the meat, milk, and eggs from animals are safe for people to eat.



Mind the [Data] Gap: Contributions of FDA's NCTR to Evaluate Cosmetics Safety



David Edwards, PhD

Senior Staff Fellow

FDA, National Center for Toxicological Research

Dr. Luísa Camacho is a senior staff fellow at FDA's National Center for Toxicological Research (NCTR). She received a B.Sc. in Applied Plant Biology and a PhD in Cell Biology from the University of Lisbon, Portugal. Dr. Camacho was a research associate at the University of Durham, UK, and an academic visitor at the University of Oxford, UK. In 2007, she joined NCTR, where she has served as principal and co-principal investigator on multiple toxicity and mechanistic studies of products of interest to FDA, including the indirect food additive bisphenol A (BPA) and dietary supplements nattokinase and lumbrokinase. More recently, her research has focused on the evaluation of the dermal absorption of cosmetic ingredients using *in vivo* and *in vitro* testing systems. Dr. Camacho has authored over 30 peer-reviewed articles in international journals and five book chapters. She is the Associate Editor for the *Journal of Environmental Science and Health, Part C: Toxicology and Carcinogenesis*, and Section Editor for "Pharmacology, Toxicology, Pharmaceutical Sciences" of the journal *Data in Brief*. She has served as an expert member of the International Agency for Research on Cancer (IARC) programs "Handbooks of Cancer Prevention" and "Monographs on the Evaluation of Carcinogenic Risks to Humans".

Abstract: Mind the [Data] Gap: Contributions of FDA's NCTR to Evaluate Cosmetics Safety

FDA's NCTR conducts scientific research and develops and evaluates innovative scientific tools to support FDA's regulatory processes. NCTR's research portfolio includes multiple research programs designed specifically to address regulatory data gaps on the safety of cosmetics. Examples of studies conducted at NCTR in the context of cosmetics safety include the microbiological survey of commercial tattoo inks; characterization of the genotoxicity, mutagenicity, and toxicity of ingredients used in skincare and personal care products; and evaluation of the skin permeation profiles of cosmetic ingredients using *in vivo* and *in vitro* methods. This presentation will give an overview of NCTR's scientific expertise and illustrate how this has been applied to evaluate multiple aspects of cosmetics safety in support of FDA's mission to protect and promote individual and public health.

Concurrent Session 8: Substance Use, Misuse, and Addiction



Marta Sokolowska, PhD (Moderator)

Associate Director for Controlled Substances
FDA, Center for Drug Evaluation and Research

Marta Sokolowska, PhD, joined FDA in 2018 as Associate Director for Controlled Substances at FDA's Center for Drug Evaluation and Research. She provides strategic leadership in development and implementation of policies related to controlled substances, including advising on all matters related to domestic and international drug scheduling.

Dr. Sokolowska is a recognized expert in drug abuse potential assessment and scheduling strategies. Throughout her career she has focused on facilitating initiatives to improve public health by advancing the science of assessing abuse liability. Her past leadership roles include serving as Vice President of Medical and External Affairs at Depomed, Inc. and Head of Medical Affairs and the Center for Abuse Prevention and Evaluation at Grunenthal, USA. Dr. Sokolowska earned her doctoral degree in psychology from McMaster University in Canada.

Substance Use Disorders Linked to COVID-19 Susceptibility



Nora D. Volkow, MD

Director, National Institute on Drug Abuse
National Institutes of Health

Nora D. Volkow, MD, is the Director of the National Institute on Drug Abuse (NIDA), which supports most of the world's research on the health aspects of drug abuse and addiction. Dr. Volkow's scientific research was instrumental in demonstrating that drug addiction is a disease of the human brain and, as NIDA Director, her work has promoted research that improves the prevention and treatment of substance use disorders. As a research psychiatrist, Dr. Volkow pioneered the use of brain imaging to investigate the toxic and addictive effects of abusable drugs. Her studies documented disruption of the dopamine system in addiction with its consequential functional impairment of frontal brain regions involved with motivation, executive function, and self-regulation. She has also made important contributions to the neurobiology of obesity, and ADHD and has published more than 820 peer-reviewed articles, written more than 100 book chapters and non-peer-reviewed manuscripts, co-edited a Neuroscience Encyclopedia and edited 4 books on neuroimaging for mental and addictive disorders.

Abstract: Substance Use Disorders Linked to COVID-19 Susceptibility

The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—have resulted in a national crisis of overdose deaths that we have not been able to control. In parallel, an alarming resurgence in stimulant use--

including cocaine and methamphetamine—is further contributing to the rise in overdose fatalities. This crisis is now exacerbated by the COVID-19 pandemic, which has resulted in increased drug use and relapse of those in treatment and highlights the urgency to characterize the unique social and structural challenges faced by those with substance use disorders and to develop strategies to overcome them.

This presentation will highlight such challenges as the increased use of fentanyl by itself or in combination with other opioids or stimulant drugs like cocaine and methamphetamine. It will also focus on how NIH researchers are using scientific advances to address the opioid crisis amidst the COVID pandemic, which includes the development of new medications and formulations to help treat opioid use disorders and overdoses; prevention strategies to mitigate an individual's vulnerability to addiction; and implementation science to guide optimal deployment of therapeutic interventions including the use of telehealth in diverse settings (healthcare, justice setting, and rural communities).

COVID-19 and the Opioid Crisis: A Social Media Perspective



Jill Settle, PhD

**Social Scientist
FDA, Center for Drug Evaluation and Research**

Jill Settle, PhD, is a social scientist in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications Research and Risk Communications Team. She leads the social media research program, identifying and applying best practices to detect trends and emerging issues related to opioids and other substances within FDA's purview, and participates in conducting many other research projects. Before joining FDA, she served as a social scientist at the Health Resources and Services Administration, designing and analyzing performance measures and conducting program evaluations. Dr. Settle's previous research focused on neurology and neuropsychology: she conducted research at the Veterans Affairs Medical Center in Washington, D.C., related to multiple sclerosis and at Walter Reed National Military Medical Center in Bethesda, MD, related to traumatic brain injury. Dr. Settle holds a PhD and an MA in Applied Experimental Psychology from The Catholic University of America and a B.A. in Psychology from the College of William and Mary.

Abstract: COVID-19 and the Opioid Crisis: A Social Media Perspective

Negative outcomes at the intersection of the opioid crisis and the COVID-19 pandemic are evident, including increased substance use, decreased treatment seeking, and rising overdoses. However, little is currently known about how those affected by opioid abuse and addiction feel about these or other aspects of the pandemic. To that end, we conducted an in-depth, systematic, exploratory qualitative analysis of 1,623 online and social media posts that included personal experiences with both the pandemic and opioid abuse and addiction from the early months of the pandemic, between March 1 and April 30, 2020. Social media research permits collection of the personal perspectives and experiences of a large and heterogeneous group of people, enabling discovery of broad and detailed information

without the practical limitations of other types of research. Our analyses have identified unexpected findings as well as contributed to a broader understanding of how affected individuals are handling the intersection of these two public health crises.

And the Kids Vaped on: Teens, Tobacco, and the National Youth Tobacco Survey



Karen A. Cullen, PhD, MPH
Supervisory Epidemiologist
FDA, Center for Tobacco Products

Dr. Karen Cullen is a supervisory epidemiologist at FDA's Center for Tobacco Products (CTP). After over a decade as an epidemiologist at the Centers for Disease Control and Prevention, she joined CTP in 2015. Dr. Cullen served as FDA lead for the National Youth Tobacco Survey (NYTS). She is one of the epidemiology branch chiefs in CTP's Division of Population Health Science, Office of Science. Dr. Cullen serves as FDA co-chair for the Tri-Agency workgroup (CDC, NIH, and FDA) focusing on tobacco surveillance. Her areas of expertise include surveillance, youth tobacco use, and flavored tobacco use. She has a PhD in Epidemiology and a Master of Public Health in Epidemiology from Tulane University. In her free time, she enjoys baking and traveling.

Abstract: And the Kids Vaped on: Teens, Tobacco, and the National Youth Tobacco Survey

Most tobacco use behaviors are initiated during youth and young adulthood; nearly 9 in 10 U.S. adult cigarette smokers first try smoking by age 18. E-cigarette use has increased considerably among youth since 2011; according to data from the National Youth Tobacco Survey (NYTS), e-cigarettes have been the most commonly used tobacco product among youth since 2014. The alarming increase in current (past 30-day) use of e-cigarettes by middle and high school students between 2017 and 2018 reversed the declines in youth use of any tobacco observed in prior years. In 2019, NYTS data showed that current e-cigarette use remained high, while current cigarette smoking among high school students declined to historic lows.

School closures from the COVID-19 pandemic meant data collection for the 2020 NYTS ended early. From the data collected January to March 2020, 23.6% of high school and 6.7% of middle school students reported current tobacco product use, with 19.6% of high school and 4.7% of middle school students reporting current e-cigarette use. Cigarette smoking among youth remained at historic lows—4.6% of high school and 1.6% of middle school students reported smoking cigarettes in 2020. Ongoing surveillance of tobacco product use is critical to inform evidence-based public health policy, planning, and practice to reduce the initiation and use of all forms of tobacco products among U.S. youth. In this presentation, we will examine data on youth tobacco product use from the NYTS and will discuss recent policies implemented in response to the high levels of youth tobacco use.

Investigation of Opioid Exposure and Neural Tube Defects – In Vivo and In Vitro Approaches



Amy Inselman, PhD

**Research Biologist
FDA, National Center for Toxicological**

Dr. Amy Inselman is a research biologist at FDA's National Center for Toxicological Research (NCTR) in the Division of Systems Biology, Biomarkers, and Alternative Models Branch. She received her PhD from the University of Tennessee and completed her postdoctoral training at the National Institute for Environmental Health Sciences (NIEHS), Laboratory of Developmental and Reproductive Toxicology, focusing on male reproduction. Dr. Inselman joined FDA in 2010 and has worked with various product centers investigating the developmental and reproductive toxicity of regulated products, using both in vivo and in vitro test systems. Her current work is primarily focused on opioid exposure during pregnancy; she has recently received funding to investigate COVID-19 during pregnancy in a mouse model. Dr. Inselman has served as the principal investigator on National Toxicology Program-funded guideline studies in their investigation of sunscreen compounds, leading studies on fertility and early embryonic development, embryo/fetal development, and pre- and postnatal development. Dr. Inselman serves on numerous HESI Developmental and Reproductive Toxicology committees, on an OECD expert group for developmental neurotoxicity, and the Botanical Safety Consortium's DART subsection.

Abstract: Investigation of Opioid Exposure and Neural Tube Defects – In Vivo and In Vitro Approaches

Opioid exposure during early pregnancy has been associated with an increased risk of neural tube defects (NTDs). Limitations with previous epidemiological study designs, conflicting results from human and animal studies, and incomplete maternal toxicity data have complicated risk assessment for the drug class. To better understand the risks of early pregnancy exposures, in vivo and in vitro approaches are being employed to address existing data gaps. In vivo studies have focused on maternal toxicity, specifically hypoxia, on neural tube development. CF-1 mice were given a single injection of morphine [100 or 400 mg/kg bw], methadone [10 or 30 mg/kg bw] or the positive control valproic acid [300 or 500 mg/kg bw] on gestational day (GD) 8 of pregnancy. Changes in uterine artery blood flow and statistically significant changes in blood gas parameters, suggestive of maternal hypoxia, were observed following opioid administration. Teratological assessments (GD 18) found the highest incidence of NTDs in fetuses exposed to 400 mg/kg bw morphine. In vitro studies have examined direct opioid exposure on differentiating neural precursor cells (NPCs). NPCs, derived from human-induced pluripotent stem cells (hiPSCs), were treated with various concentrations of opioids during embryoid body (EB) formation and assessed for their ability to form neural rosettes, a surrogate endpoint for neural tube development. Preliminary results indicate little effect of opioid exposure on cell proliferation or neural rosette formation. Together, the two lines of investigation may help to address the current data gaps and provide useful supplemental data regarding opioid risks during pregnancy. This work, in part, was funded by the Perinatal Health Center of Excellence (PHCE) Intramural Funding Program, U.S. FDA.

Tobacco and Cannabis: Did Evali Teach Us Anything?



Priscilla Callahan-Lyon, MD

Senior Science Advisor
FDA, Center for Tobacco Products

Dr. Priscilla Callahan-Lyon is an internist and pulmonologist. After 20 years of private medical practice, she joined FDA in 2008 as a medical reviewer in Center for Drug Evaluation and Research, where she worked extensively on nicotine replacement therapies. She moved to the Office of Science in the Center for Tobacco Products (CTP) in 2012 as a senior medical officer. During her years in Office of Science, Dr. Callahan served as technical project lead for the IQOS Premarket Tobacco Product Application as well as the program lead for the Investigational Tobacco Products program. She represented CTP on several FDA and Agency-wide initiatives, including the Nicotine Steering Committee and the HHS Tobacco Cessation Workgroup. Additionally, she has presented at several major conferences, including the American Thoracic Society, National Association of School Nurses, and Society for Research on Nicotine and Tobacco. Currently, Dr. Callahan serves as senior science advisor in the Office of the Center Director for CTP. In this position, she works with CTP leadership to provide scientific input and expertise on policy and regulatory matters and to continue CTP's efforts to make tobacco-related death and disease part of America's past, not America's future.

Abstract: Tobacco and Cannabis: Did Evali Teach Us Anything?

In late summer of 2019, healthcare providers across the country began noticing a disturbing trend of youth and young adults with a serious respiratory illness requiring aggressive medical treatment. The common factor was use of aerosolized (or vaping) products – usually identified with nicotine-containing electronic cigarettes. As the E-cigarette or Vaping product use Associated Lung Injury (EVALI) investigation moved forward, the association with cannabis products was recognized. The coordinated taskforce investigation conducted by the Centers for Disease Control, FDA, and state health officials identified Vitamin E Acetate as a likely causative agent for many of the described cases. In addition, it was also noted that many of the EVALI patients used multiple products and there was significant overlap in the populations of nicotine and cannabis users. Data from the International Tobacco Control Policy Evaluation Project, the Population Assessment of Tobacco and Health (PATH) study, and Monitoring the Future demonstrate the extent of the dual use problem. There are health effects and other concerns associated with use of each type of product that may be accentuated when individuals use both product types. The scientific community should collaborate on work to reduce nicotine and cannabis use as the user populations have significant overlap.

Virtual Poster Exhibition

2021 FDA Science Forum virtual posters will be exhibited on FDA's Science Forum website on May 26, 2021. The posters will be published and available for download to all FDA Science Forum registrants. The audience will have the opportunity to e-mail their questions directly to the designated authors of the posters for their response from May 26 through June 9, 2021.

The virtual poster exhibition will showcase researches conducted by the FDA scientists on the Science Forum's eighth topic areas:

1. Improving Clinical and Postmarket Evaluation
2. Tools to Effectively Use Big Data
3. Empowering Patients and Consumers
4. Product Development and Manufacturing
5. Advancing Products Based on Novel Technologies
6. Medical Countermeasures, Infectious Disease and Pathogen Reduction Technologies
7. Food and Cosmetic Safety
8. Substance Use, Misuse, and Addiction

For more information on the 2021 FDA Virtual Poster Exhibition go to:

<https://www.fda.gov/science-research/fda-science-forum/2021-fda-science-forum-05262021-05272021>

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Session 1: Improving Clinical and Post-market Evaluation

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Session 2: Tools to Effectively Use Big Data

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Hussein Ezzeldin, PhD, CBER
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Session 3: Empowering Patients and Consumers

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Session 4: Product Development and Manufacturing

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Session 5: Advancing Products Based on Novel Technologies

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Session 6: MCM, Infectious Disease and Pathogen Reduction Technologies

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Session 7: Food and Cosmetic Safety: The Role of Innovation and Technology

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Session 8: Substance Use, Misuse, and Addiction

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