



FASEB and AAVMC present:

Virtual Congressional Briefing -Non-Animal Models in Biomedical Research: We Aren't There Yet

Wednesday, March 16, 2022 12:00 – 1:30 pm (ET) <u>Registration Link</u>

Location: Virtual – Zoom Meeting [please use the link included in registration confirmation e-mail]

<u>Purpose</u>: To educate Congressional staffers on the value of animal research for scientific and economic progress and elucidate the challenges associated with broad use of non-animal alternatives.

Featuring:



Representative Kurt Schrader Congressman, Oregon's 5th District Co-Chair, Veterinary Medicine Caucus

Order of Keynote Speakers:



Dr. Sue VandeWoude Colorado State University



Dr. Szczepan Baran VeriSim Life, Inc.



Dr. Patrick Devine Novartis



Dr. Amy LeBlanc National Cancer Institute

Briefing Summary: Animal research plays a fundamental role in improving public health, upholding national security, and securing the nation's competitive edge on the global stage. Numerous biomedical advancements that enhance the quality of life are direct results of investments in scientific studies with animals. Examples include the discovery of insulin for patients with diabetes, invention of the cardiac pacemaker, and innovative technologies such as magnetic resonance imaging. More recently, research in rodents, hamsters, and nonhuman primates enabled researchers to produce the COVID-19 vaccines. Its rapid development serves as a testament to the decades of research on messenger RNA, virology, and the immune system, all of which required animals.

The use of non-animal models (often known as "new approach methodologies" or NAMs) is an emerging field of study that involves experimental techniques that do not require live animals. Examples include cell-based (*in-vitro*) tests, organs on a chip, and computer (*in-silico*) models. While scientists utilize these techniques when feasible, these approaches do not address critical aspects of animal or human physiology and behavior. In many cases, non-animal methods require further validation in animal models. Therefore, the scientific consensus remains that for the foreseeable future, non-animal alternatives can only supplement—not replace—ongoing biomedical work.

As competing nations progressively increase investments in biomedical research, it is critical to leverage and expand ongoing research with animals to advance clinical breakthroughs and revitalize economic return on investments. Understanding the advantages and limitations of animal and non-animal models in clinical and basic science contexts is essential to establish evidence-based policies governing the research enterprise and its effective stewardship of limited taxpayer funds. This Congressional briefing will convene scientific experts, animal care staff, policymakers, and regulators to clearly communicate ongoing challenges and misconceptions associated with animal research and understand the importance of implementing policies that prioritize human and animal health.

Audience:

- Congressional staffers
- Rare Disease Caucus Members
- Veterinary Medicine Caucus Members
- Agriculture Research Caucus Members
- Expert Scientists
- Government/Public Relations Staff Members Professional and Scientific Societies

Keynote Speaker Biographies



Representative Kurt Schrader *Congressman for Oregon's 5th District Co-Chair, Veterinary Medicine Caucus*

Congressman Kurt Schrader is currently serving his seventh term in the United States House of Representatives, representing Oregon's 5th Congressional District.

Schrader was a farmer and veterinarian for more than 30 years and served in both chambers of the Oregon State Legislature before being elected to the U.S. Congress in 2008. He currently serves as a member of the House Committee on Energy and Commerce (E&C), which oversees a wide portfolio of issues ranging from healthcare to the environment. In the 117th Congress, Congressman Schrader serves on the E&C Subcommittee on Health, the Subcommittee on Energy, and the Subcommittee on Communications and Technology. He uses his position on the E&C

Committee to advocate for healthcare reforms, including legislation that is targeted to lower prescription drug costs and ensure affordable, quality healthcare access for everyone.

As the only veterinarian serving in Congress, Schrader is also Co-chair of the Veterinary Medicine Caucus and a leader in Congress on issues pertaining to animal health and its relation to zoonotic disease prevention and safeguarding public health.



Sue VandeWoude, DVM

Lab Principal Investigator Director, One Health Institute Colorado State University

Sue VandeWoude is a veterinary virologist recognized for her studies of cross species transmission of infections between domestic and wild animals, and between animals and people. VandeWoude received her BS from California Institute of Technology, her DVM from Virginia-Maryland College of Veterinary Medicine, and completed a post-doctoral fellowship at the Johns Hopkins University School of Medicine. She is a diplomate of the American College of Laboratory Animal Medicine and has served as President of ACLAM and American Society of Laboratory Animal Practitioners, was chair of the American Association of American Veterinary

Medical Colleges Research Committee, and has served on the American Veterinary Medical Association Council on Research. VandeWoude is currently University Distinguished Professor at Colorado State University and Director of the CSU One Health Institute. She was elected to the National Academy of Sciences in 2019.



Szczepan Baran, MS, VMD Chief Scientific Officer VeriSim Life Inc.

Szczepan is a scientist and veterinarian turned "technology geek." He is passionate about transforming the delivery of innovative medicines to patients through digital technologies and data enablement while pushing the scientific envelope and reimagining patient engagement. Szczepan currently serves as a Chief Scientific Officer at VeriSIM Life where he leads the research and development strategy and oversees scientific functions, including basic and applied research projects, and develops new processes, technologies, and products. He previously served as a Head of Emerging Technologies within Comparative Medicine at Novartis. In this position, he led an integrated digital

enterprise strategy with a focus on the development and incorporation of patient-relevant AI technologies and digital endpoints. In parallel, Szczepan focused on stakeholder engagement to identify adaptation hurdles and develop regulatory qualification pathways for Microphysiological Systems (MPS) technologies. He has played instrumental roles in establishing Global MPS and Preclinical Digital Biomarkers Groups with a vision for strategic alignment and data agility. Szczepan is a graduate of the University of Delaware and the University of Pennsylvania School of Veterinary Medicine. He completed his residency in Laboratory Animal Medicine and received a Master of Science degree in Comparative Medicine from the University of Washington. Before joining VeriSIM Life, Szczepan held multiple start-up and faculty positions and served on numerous boards. He chaired the IQ MPS Affiliate and led the IQ MPS Affiliate Regulatory Outreach Group. Currently, he serves as a co-chair of the MPS and Translational Biomarker Initiatives of the North American 3Rs Collaborative and serves as a Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) ad hoc member.



Patrick "PJ" Devine, PhD

Senior Investigator Discovery and Investigative Safety - Preclinical Safety Department Novartis

Patrick Devine current serves as a Senior Investigator within the Discovery and Investigative Safety Division of the Department of Preclinical Safety at Novartis Institutes for Biomedical Research Inc. in Cambridge, Massachusetts. Devine received his Bachelors in Chemistry and Biology from the University of Delaware in 1992 and his PhD in Toxicology from the University of Maryland in 1999.

Devine studied reproductive toxicology as a post-doctoral fellow and as a

professor at the INRS (Laval, QC). Major projects included evaluating mechanism(s) of chemotherapydependent ovarian toxicity, fertility biomarkers, and effects of pollution on frog development. Devine joined Novartis in 2010 focusing on investigating endocrine and reproductive toxicity and has expanded his focus over the years. He advises drug discovery teams in multiple disease areas on safety and is focusing on investigative toxicology, advanced therapies, and safety biomarkers. Research has involved both simple and complex *in vitro* models, as well *in vivo* models, examining mechanisms of toxicity that have been seen in preclinical or clinical studies. Devine is also involved in cross-industry consortia involving biomarkers (Preclinical Safety Testing Consortium) and evaluating microphysiological systems (Innovation and Quality consortium, IQ MPS).



Amy K. LeBlanc, DVM Diplomate ACVIM

Director, Comparative Oncology Program Center for Cancer Research, National Cancer Institute National Institutes of Health

Dr. Amy LeBlanc is a board-certified veterinary oncologist, Senior Scientist and the Director of the intramural NCI's Comparative Oncology Program. In this position she conducts preclinical mouse and translational pet dog studies that are designed to inform the drug and imaging agent development path for human cancer patients, specifically those with osteosarcoma. She directly oversees the NCI Comparative Oncology Trials Consortium (COTC), which provides infrastructure necessary to connect participating veterinary academic institutions with stakeholders in drug development to execute fit-for-purpose comparative clinical trials in novel therapeutics and imaging agents. Her

program provides support to several extramural NCI-funded initiatives including the Integrated Canine Data Commons and Cancer Moonshot-funded canine immunotherapeutic clinical trials.

Resources:

To learn more about the role of animal research in biomedical progress, please visit the broad range of resources from FASEB and AAVMC:

Factsheets:

- Animal Research: Necessary for Scientific Progress [Link] Factsheet explains the limitations of non-animal methods and illustrates the continued need for animals in research
- **Biomedical Research Breakthroughs: 2010-2019** [Link] Factsheet examines many of the biomedical discoveries, innovations, and treatments that were made possible because of scientific animal research. It also highlights some common drugs that started with animal research and the process used to approve the drugs.
- Animal Research FAQs [Link]
- Animal Research Saves Lives and Cures Diseases Series: Series of three factsheets that examines the use of animals in research and provides examples of how research with each species has led to improved human and animal health.
 - Part I: Canines, Rabbits, and Guinea Pigs [Link]
 - Part II: Felines, Pigs, and Goats [Link]
 - Part III: Nonhuman Primates, Sheep, and Llama [Link]

Webinars:

- Combatting COVID-19: The Critical Role of Nonhuman Primate Research [Link]
- Animal Research Regulations A Two-Part Series
 - Part I: Understanding the Federal Oversight Mechanisms [Link]
 - Part II: The Role of IACUC and AAALAC in Animal Research Oversight [Link]
- Diversifying the Research Organism Landscape A Webinar with NIH [Link]
- Animal Research: Still Necessary for Understanding Human Disease [Link]
- The Case for Canines in Biomedical Research [Link]
- Understanding Federal Versus Institutional Requirements for Animal Research [Link]

Questions / Comments:

Any questions or comments related to the 2022 FASEB/AAVMC Congressional Briefing or the above resources on animal research, please contact:

FASEB: Naomi Charalambakis, PhD (<u>ncharalambakis@faseb.org</u>) AAVMC: Kevin Cain (<u>kcain@aavmc.org</u>)