



Gene Editing in Livestock

»» LOOKING TO THE FUTURE

Presented by the Association of American Veterinary Medical Colleges
and the Association of Public and Land-Grant Universities

September 24-25, 2019 • Washington, D.C.

»» SPONSORS



The Association of American Veterinary Medical Colleges and the Association of Public and Land-grant Universities would like to thank Bio and Covington for providing the resources that have made this symposium possible.



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»» WELCOME

Thanks to advancements in biotechnology, we stand on the threshold of an era where unprecedented levels of progress can be made in the battle against hunger and disease.

But before that happens, we must thoughtfully examine a series of questions ranging from the nature and safety of this promising technology to its ethical implications. The answers to these questions will inform the public policy development process, and ultimately, lead to the development of appropriate regulatory policies.

To do this, we have invited some of the nation's leading experts from academia, government, industry, and professional groups to convene for this historic symposium on gene editing of livestock.

Evidence-based presentations during this symposium will focus on many different facets of the issue:

- Science and Research
- Industry Perspective
- Bioethics
- Public Policy and Regulation
- Communication and Public Engagement

The dialogue and substance we generate here will play a major role in shaping how this powerful technology is applied in a way that best serves humanity and the animal kingdom. We thank you for being here.



»» SCHEDULE

TUESDAY, SEPTEMBER 24

8:00 – 8:15 A.M.

Welcome Remarks & Introduction to CRISPR technology

Dr. Noelle Cockett, *President,
Utah State University*

Dr. Bryan Slinker, *Dean, Washington State
University College of Veterinary Medicine*

8:15 – 10:15 A.M.

Science & Research Panel

Moderator and Panelist: Dr. Jon Oatley,
*Director, Center for Reproductive
Biology, Washington State University*

Dr. Pablo Ross, *Department of
Animal Science, UC Davis*

Dr. Randall Prather, *Animal Science
Research Center, University of Missouri*

Dr. Chuck Long, *Department of
Veterinary Physiology & Pharmacology,
Texas A&M University*

Dr. Trish Berger, *Department of
Animal Science, UC Davis*

10:15-10:45 A.M.

Break

10:45 – NOON

Bioethics Panel

Moderator: Dr. Bryan Slinker,
*Dean, Washington State University
College of Veterinary Medicine*

Dr. Samantha Noll, *Assistant Professor of
Bioethics, Washington State University*

Dr. Paul Thompson, *W.K. Kellogg Chair
in Agricultural, Food and Community
Ethics, Michigan State University*

NOON – 1:00 P.M.

Lunch



»» SCHEDULE

1:00-2:30 P.M.

Industry Panel

Moderator: Clint Nesbitt, Senior Director of Science & Regulatory Affairs, Food and Agriculture Section, Biotechnology Innovation Organization (BIO)

Dan Carlson, Vice President of Development, Recombinetics

Steve Brody, Global Director of Regulatory Government Affairs, Genus PLC

Mark Walton, VP for Regulatory Affairs and Research, Aquabounty

Jeanne Perron, Partner, Food and Drug Practice Group, Covington & Burling

2:30 – 3:00 P.M.

Break

3:00 – 4:30 P.M.

Public Policy and Regulatory Affairs

Moderator: Kevin Cain, Director, Governmental Affairs, Association of American Veterinary Medical Colleges (AAVMC)

Dr. Heather Lombardi, Director, Division of Animal Bioengineering and Cellular Therapies, Food and Drug Administration (FDA)

Dr. Fan-Li Chou, Biotechnology Coordinator advising the Office of the Secretary, U.S. Department of Agriculture (USDA)

Rep. Kurt Schrader, (D-OR) Member of Congress

WEDNESDAY, SEPTEMBER 25

8:30 – 10:00 A.M.

Communications, Public Engagement and Consumer Advocacy

Moderator: Dr. Andrew Maccabe, Chief Executive Officer, Association of American Veterinary Medical Colleges (AAVMC)

Dr. Michael Dahlstrom, Greenlee School of Journalism/Communication, Iowa State University

David G. Fikes, Vice President of Communications, Food Marketing Institute Representative

Eva Greenthal, Policy Associate at the Center for Science in the Public Interest (CSPI)

Dr. Jennifer Kuzma, Goodnight-NC GSK Foundation Distinguished Professor, Co-Director, Genetic Engineering and Society Center, NC State University

10:00-10:30 A.M.

Break

10:30 – NOON

Discussion and Next Steps

Moderators: Dr. Noelle Cockett, President, Utah State University

Dr. Bryan Slinker, Dean, Washington State University College of Veterinary Medicine

NOON – 1:00 P.M.

Lunch will be furnished in boxes to go

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Dr. Trish Berger

University of California, Davis



Trish Berger is a UC Distinguished Professor in the Department of Animal Science at the University of California, Davis. Her research focuses on reproductive physiology of food

animals with much of this research concentrated on male reproductive physiology. Recent work has addressed regulation of Sertoli cell proliferation in boars. Her interest in practical applications of advances in basic science developed during her childhood on a western Kansas family farm. She received a BA in Biochemistry from the University of Kansas, and MS and PhD degrees in Animal Science from Purdue University.

Mr. Steve Brody

Genus PLC



At Genus PLC, Steve Brody leads the regulatory and government affairs efforts, focusing on developing and implementing global regulatory and policy

strategy, as well as stewardship and compliance activities. This includes working directly with Genus' two operating businesses — PIC and ABS — to develop and implement strategies with policy-making bodies, global regulatory agencies and industry associations to obtain global regulatory market access for products to advance animal genetic improvement. Prior to his work with Genus PLC, he led global biotechnology affairs and other initiatives at DuPont Pioneer. Besides

Genus and DuPont Pioneer, his career includes ten years' experience in Washington, D.C. as legislative & staff director for an Iowa congressman, and at the U.S. Department of Agriculture in Washington D.C. where he was a Special Assistant to the Secretary of Agriculture and USDA's Farm Service Agency during the Clinton Administration. Brody earned a master's degree in Agribusiness from Kansas State University and another Master's degree in administration from the University of Iowa.

Mr. Kevin Cain

AAVMC



Kevin Cain joined the AAVMC in 2012 as Director of Governmental Affairs. In that role, he works to educate Congress and the administration on the challenges and

opportunities facing academic veterinary medicine. Prior to coming to the AAVMC, Kevin worked as Vanderbilt University's Director of Governmental Affairs for Health and Biomedical Sciences. Kevin served as a key aid to two members of Congress and, over the course of his 16-year career, he has worked as a policy leader and advocate, advising lawmakers and staff on legislative and regulatory changes that could impact critical business decisions. He earned a bachelor's degree in journalism with a minor in political science from Georgia State University.

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Dr. Dan Carlson

Recombinetics



Dan is a “farm kid” from southwestern Minnesota who took an interest in biotechnology when his family began planting genetically modified crops in the 90’s. In pursuit of this interest,

Dan attended the University of Minnesota where he earned a PhD in Animal Sciences with an emphasis in biotechnology and molecular genetics. The focus of his research is the refinement and application of methodology for genetic engineering in livestock. Through his 15 years in biotechnology research, Dan has led the development of transposon systems and gene editing technology in livestock. As the Chief Scientific Officer at Recombinetics, he directs the application of gene editing in livestock to develop solutions for agriculture and biomedicine with an eye towards commercial opportunities and emerging technologies.

Dr. Fan-Li Chou

United States Department of Agriculture



Fan-Li Chou serves as the Biotechnology Coordinator advising the Office of the Secretary at the United States Department of Agriculture (USDA). She provides leadership,

coordination, and strategic planning of USDA’s biotechnology policy. She works closely with decision makers in USDA, in other Federal agencies, and in Congress. She is a key contact point for biotechnology policy with industry, non-governmental organizations, other federal and state

government agencies, farmers, and other stakeholders. Fan-Li has over ten years of experience at the USDA, including positions with the Foreign Agricultural Service and the Animal and Plant Health Inspection Service (APHIS). Fan-Li has represented the USDA at various bilateral and multilateral negotiations, including for the Cartagena Protocol on Biosafety. Fan-Li is an American Association for the Advancement of Science Diplomacy Fellow (2005-2006).

Dr. Noelle Cockett

President, Utah State University



Noelle E. Cockett was appointed as Utah State University’s (USU) 16th president in October 2016. Prior to that appointment, Cockett was serving as executive vice president and

provost at USU, a position she had held since 2013. Prior to that, she served USU as vice president for Extension, dean of the College of Agriculture and Applied Sciences, and director of the Utah Agriculture Experiment Station. Cockett joined USU in 1990 as a researcher and assistant professor in the College of Agriculture and Applied Sciences. Cockett has built a distinguished career in sheep genomics research, maintaining an active research program even while serving in various leadership positions at USU. Her research program has centered on the identification of genetic markers associated with economically important traits in sheep, as well as the development of resources that advance research on the sheep genome. Cockett and her colleagues published an article describing the sheep genome sequence in *Science* in 2014. Cockett has served as the United States coordinator for sheep genome

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mapping since 1993 and is an active member of the International Sheep Genomics Consortium. She holds MS and PhD degrees in Animal Breeding and Genetics from Oregon State University.

Dr. Michael Dahlstrom

Iowa State University



Michael Dahlstrom is the Interim Director of the Greenlee School of Journalism and Communication and holds a Liberal Arts and Sciences Dean's Professorship at Iowa

State University. His research explores how storytelling impacts the communication of science and the ethical considerations involved. Dahlstrom's work extends across diverse scientific contexts, including risk, health, agricultural and environmental communication and has been published in leading journals, such as the Proceedings of the National Academy of Sciences, PLOS Biology, Communication Research and Science Communication. He is co-editor of "Ethics and Practice in Science Communication," an edited volume focusing on the often-overlooked ethical challenges underlying science communication. He is also a past head of the Communicating Science, Health, Environment and Risk Division of the Association for Education in Journalism and Mass Communication. Dahlstrom received a BS in biophysics, a BA in journalism, a MS in biophysics from Iowa State University and a joint PhD in journalism and mass communication and environmental resources from the University of Wisconsin-Madison.

Mr. David G. Fikes

Food Marketing Institute



David Fikes is the Executive Director of the FMI Foundation, which has the mission of supporting food retailers through a focus on research and education in the areas of food safety,

nutrition and health. His position allows him to act upon his conviction that humans have a right to safe food and consumers have a right to clear information and choice. Formerly, David served as FMI's Vice President for Communication and Consumer/Community Relations and before joining FMI he was the Director of Communications for the American Frozen Food Institute. Prior to entering the world of food trade associations, he worked for 20 years as an Episcopal priest, serving parishes in Georgia, Tennessee and Texas.

Ms. Eva Greenthal

Center for Science in the Public Interest



Eva Greenthal is a Policy Associate at the Center for Science in the Public Interest where she works on issues including biotechnology, food labeling, food safety, and more. Prior to

joining CSPI, Eva served as a Program Coordinator for Let's Go! at Maine Medical Center and as an AmeriCorps VISTA Member at HealthReach Community Health Centers in Waterville, Maine. She holds a dual MS/MPH degree in Food Policy and Applied Nutrition from the Tufts Friedman School of Nutrition Science and Policy and a BA in Environmental Studies from the University of Michigan.

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Dr. Jennifer Kuzma

North Carolina State University



Jennifer Kuzma is the Goodnight-NCGSK Foundation Distinguished Professor in the School of Public and International Affairs, and co-founder and co-director of the

Genetic Engineering and Society (GES) Center at North Carolina State University. Prior to her current position, she was associate professor of science and technology policy at the Humphrey School of Public Affairs, University of Minnesota; study director for several U.S. National Academy of Sciences, Engineering and Medicine (NASEM) reports related to biotechnology and bioterrorism; and an American Association for the Advancement of Science (AAAS) Risk Policy Fellow at the U.S. Department of Agriculture. She has over 120 scholarly publications on emerging technologies, social science, and governance and has been studying this area for 25 years. In 2019 she was elected a AAAS Fellow for distinguished work in anticipatory governance of new technologies, and methods for oversight policy analysis. She obtained her PhD in biochemistry from the University of Colorado in 1995.

Dr. Heather Lombardi

Food & Drug Administration



Dr. Heather Lombardi is the Director of the Division of Animal Bioengineering and Cellular Therapies in the Office of New Animal Drug Evaluation at the Food and Drug

Administration's Center for Veterinary Medicine (CVM). This Division reviews intentional genomic alterations in animals and animal cell, tissue, and cell- or tissue-based products. She has participated in many center and agency efforts to bring innovative products to market in a predictable and efficient manner, such as the Innovation Exploration Team (IVET), numerous technology teams and working groups, and through development of the Veterinary Innovation Program (VIP). Dr. Lombardi has developed guidance and policy specific to the regulation of new and emerging technologies. Dr. Lombardi holds a PhD in biological chemistry from the University of Pennsylvania and a BS in chemistry (biochemistry track) from the University of North Carolina at Chapel Hill.

Dr. Charles Long

Texas A&M University



Dr. Charles Long is a professor in the Department of Veterinary Physiology and Pharmacology in the Texas A&M University College of Veterinary Medicine and Biomedical

Sciences. His research interests are focused on reproductive biotechnologies. His laboratory investigates the developmental program during early embryonic development, particularly in livestock species with a focus on the role of epigenetic modifications and how these may be altered by external stress and exposure to adverse conditions. The lab utilizes and develops innovative new methods in assisted reproductive technologies, including in vitro fertilization, somatic cell nuclear transfer, and cryopreservation. The lab is also working on the genetic engineering of

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livestock to enhance production efficiency and disease resistance. Their studies in genetic engineering of livestock also focus on the use of large animal models of human disease and the lab is also interested in using livestock as bioreactors to produce human pharmaceuticals. He received his BS and MS degrees from the University of Missouri, his PhD from the University of Massachusetts, and conducted Post Doctoral Training with ARS-USDA.

Dr. Andrew T. Maccabe

AAVMC



Dr. Andrew T. Maccabe brings a broad range of experience—the military, law, public health, veterinary medicine—to his current leadership position as the Chief Executive Officer of the

Association of American Veterinary Medical Colleges (AAVMC), where he has served since 2012. Prior to his appointment at the AAVMC, he served as a liaison at the Centers for Disease Control and Prevention (CDC), coordinating policies and programs between the CDC and the U.S. Food and Drug Administration. Dr. Maccabe was commissioned as a public health officer in the U.S. Air Force in 1988 and retired in 2017 following 24 years of active military and reserve officer service. His military career included domestic and international assignments in public health, preventive medicine, epidemiology, communicable disease control, risk assessment and health promotion. Dr. Maccabe earned his BS and DVM degrees from The Ohio State University. He also earned a Masters in Public Health degree from Harvard University and a Juris Doctor degree from the University of Arizona.

Dr. Clint Nesbitt

Biotechnology Innovation Organization



Dr. Nesbitt is the Senior Director of Science and Regulatory Affairs in the Food and Agriculture Section of the Biotechnology Innovation Organization (BIO). BIO is the world's largest trade

association representing more than 950 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 nations. Before joining BIO in late 2014, he worked for more than ten years as a regulator of agricultural biotechnology in the Biotechnology Regulatory Services of USDA's Animal and Plant Health Inspection Service (APHIS). Prior to this, he worked for Cornell University's Cooperative Extension Program, where he was director of a public outreach and education project on agricultural biotechnology. Dr. Nesbitt has a Ph.D. in plant breeding and plant molecular biology from Cornell University, where he studied tomato genetics.

Dr. Samantha Noll

Washington State University



Dr. Samantha Noll is an assistant professor in the School of Politics, Philosophy, and Public Affairs (PPPA) at Washington State University. She is also the bioethicist affiliated

with the Functional Genomics Initiative, which marshals genome editing to control disease in livestock and feed a growing population. Noll's research and teaching focuses on ethical and philosophical topics

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in food and agriculture. She publishes widely on topics such as how values impact consumer uptake of agricultural products, local food movements, and the application of genomics technology. Noll contributes to the fields of bioethics (ethics of biotechnology), philosophy of food, and environmental philosophy. She earned her BA in Philosophy from West Chester University and her PhD in Philosophy from Michigan State University, with interdisciplinary specializations in animal studies and gender, justice and environmental change.

Dr. Jon Oatley

Washington State University



Dr. Jon Oatley is the Director of the Center for Reproductive Biology and a professor in the School of Molecular Biosciences at Washington State University. Over the course of nearly two

decades, Dr. Oatley's research has focused on understanding how germ cells develop. Because they are the only cell type in the body that provides genetic information to the next generation, germ cells drive diversity and ensure continuity of all animals including humans. Dr. Oatley's research also focuses on engineering the genetics of farm animals to develop more efficient avenues for feeding the expanding global human population. Dr. Oatley has authored more than 70 scientific research papers, book chapters, and news articles on the areas of germ cell biology and animal genetic engineering. He earned a BS degree in Animal Sciences from the University of Nevada-Reno and MS and PhD degrees from Washington State University. He completed a Postdoctoral fellowship at the University of Pennsylvania, and has been a principal investigator since 2007.

Dr. Jeanne Perron

Covington & Burling



Jeanne Perron is a partner in Covington & Burling LLP's Food and Drug Practice Group. In addition to being an attorney, Dr. Perron also holds a degree in veterinary medicine and

has practiced as a veterinarian. Dr. Perron specializes in food and drug law, and advises clients in the regulation of dietary supplements, over-the-counter drugs, cosmetics for humans, and import and export of products regulated by the United States Food and Drug Administration as well as those having animal or microbially-derived ingredients regulated by USDA. The primary focus of Dr. Perron's practice, however, is all aspects of animal food and drug law, including pioneering animal drug approvals and defense, issues relating to veterinary biologics, approval or other clearance of animal feed and pet food ingredients, regulation of veterinary medical devices, review of claims for animal products, recalls of such products, and associated areas. Her work encompasses advising companies that manufacture feed, feed ingredients, drugs, biologics and medical devices for animals, as well as clients in related industries.

Dr. Randall Prather

University of Missouri



Since 1982 Dr. Prather's research has focused on the early mammalian embryo. While at Wisconsin, he cloned the first pigs, and some of the first cattle, by

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nuclear transfer. His group at the University of Missouri created miniature pigs that have the alpha 1,3 galactosyl-transferase gene knocked out, thus paving the way for xenotransplantation. His group helped to develop pigs that have cystic fibrosis, thus providing the first whole-animal model that can be used to study the disease. His lab at Mizzou has made over 75 different genetic modifications for agriculture and medicine. He is the Director of the NIH-funded National Swine Resource and Research Center. In addition to his transgenic pig research, he and his collaborators have identified genes in the reproductive tissues of pigs and cattle that will help develop an understanding of the pattern of gene expression to reduce the 30% loss of pregnancies that naturally occurs in mammals. He is currently a Curators' Distinguished Professor in the Division of Animal Science at the University of Missouri. He obtained his BS and MS from Kansas State University, and PhD and Postdoc from the University of Wisconsin-Madison.

Dr. Pablo Ross

*Department of Animal Science,
University of California, Davis*



Dr. Pablo Juan Ross, DVM, MS, PhD, is an Associate Professor of Reproductive Biology in the Department of Animal Science at the University of California Davis. Dr. Ross

specializes in animal reproduction with emphasis on gametes, early embryos and embryonic stem cells. His studies are aimed at understanding the mechanisms of epigenetic remodeling and

transcriptional reprogramming that occur during preimplantation embryo development, somatic cell nuclear transfer and cellular reprogramming by induced pluripotency. His laboratory makes extensive use of next generation sequencing approaches and genome editing to determine transcriptome and epigenetic mechanisms operating in livestock embryos and to produce animal models for agriculture and biomedicine. Dr. Ross obtained a degree in veterinary medicine from La Plata National University (Argentina) and an MS degree in Animal Science from Mar del Plata National University (Argentina). He then moved to Michigan State University where he obtained his PhD in Animal Science in 2007.

Dr. Kurt Schrader

Member, United States Congress



Congressman Kurt Schrader is currently serving his sixth term in the United States House of Representatives. Before being elected to Congress in 2008, Schrader, a farmer and

veterinarian for more than thirty years, established and managed the Clackamas County Veterinary Clinic in Oregon City and operated a farm. In 1996, Congressman Schrader was elected to the Oregon State House of Representatives and in 2003, he was elected to the Oregon State Senate. Congressman Schrader currently serves as a member of the House Committee on Energy and Commerce (E&C), which oversees a wide portfolio of issues ranging from health care to the environment. Prior to joining E&C, Congressman Schrader served on

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the House Committee on Agriculture, where he served on the Farm Bill Conference Committee that successfully passed a five-year farm bill. In the 116th Congress, Congressman Schrader is serving on the Energy and Commerce Subcommittee on Health, the Subcommittee on Energy, and the Subcommittee on Communications and Technology. Congressman Schrader attended Cornell University where he received his BA in Government in 1973. He received his veterinary degree from the University of Illinois in 1977.

Dr. Bryan Slinker

Washington State University



Bryan K. Slinker is Professor and Dean in the College of Veterinary Medicine at Washington State University (WSU) in Pullman. Prior to assuming the position of

dean in November 2008, he served nearly 10 years as the chair of the Department of Veterinary and Comparative Anatomy, Pharmacology and Physiology (VCAPP). He has taught applied biomedical statistics, bioethics and responsible conduct of research, professionalism and ethics, as well as basic physiology and applied pharmacology to veterinary students. Dr. Slinker's NIH and American Heart Association-funded research focused on heart and cardiac muscle function and adaptation. In addition to his experimentally based research publications in cardiology, he has co-authored several biomedical statistics tutorials for biomedical journals as well as an intermediate statistics textbook, *Primer of Applied Regression and*

Analysis of Variance (3rd ed). He earned his BS in Zoology from the College of Idaho in 1976, and his DVM and PhD degrees from WSU in 1980 and 1982, respectively. He was a postdoctoral fellow at the Cardiovascular Research Institute of the University of California, San Francisco.

Dr. Paul Thompson

Michigan State University



Paul B. Thompson is the W.K. Kellogg Professor of Agricultural, Food and Community Ethics at Michigan State University. His career work has integrated the philosophy of technology

with environmental ethics through focusing on the role of agriculture and food systems in cultural and normative practices. He has served on advisory boards to the U.S. egg industry and to government agencies in the Netherlands, Canada and the United States. Thompson is the winner of numerous awards and honors including the Don Ihde Prize from Stony Brook University, the Richard P. Haynes Award for Career Achievement from the Agriculture, Food and Human Values Society, the William J. Beal Award for distinguished faculty achievement from Michigan State University and the Award for Excellence in Communication (twice) from the Agricultural and Applied Economics Association. From Field to Fork: Food Ethics for Everyone (Oxford) was the North American Society for Social Philosophy 2015 Book of the Year. *The Spirit of the Soil: Agriculture and Environmental Ethics* (Routledge) was released in a 2nd edition in 2018.

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Dr. Mark Walton

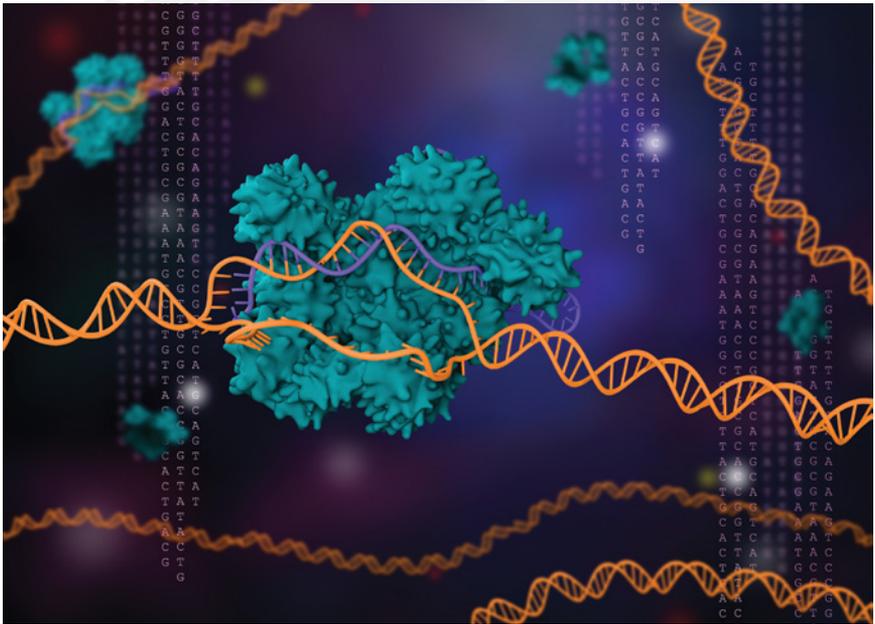
AquaBounty



Mark Walton was appointed Vice-President for R&D and Regulatory Affairs at AquaBounty in March 2019 and the Global Director of Regulatory Affairs in 2017. Before

joining AquaBounty, Dr. Walton held positions as President of ViaGen, a leading animal cloning company, Chief Business Officer for Recombinetics, the company that has developed Polled Holstein cattle using TALEN gene editing technology, and Executive Vice-President for Research and

Technology at RiceTec, a global hybrid rice seed company. He began his career in agriculture biotechnology in the 1980s and in 1990 started Linkage Genetics, the first DNA testing company to provide molecular marker services to plant and animal breeders. Mark is deeply involved in the on-going discussions between industry and governments on the regulation of genetically engineered livestock and played an active role in obtaining the Cloning Risk Assessment and the Guidance on Regulation of Genetically Engineered Animals from the U.S. Food and Drug Administration. He earned a PhD in Agronomy from the University of Nebraska – Lincoln.



»»» LETTER TO THE FDA FROM MEMBERS OF CONGRESS



Part of the impetus for convening this symposium was a letter sent by 23 Members of Congress to the leadership of the Food & Drug Administration requesting they develop a more science and risk-based approach to regulating animal biotechnology. Our hope is that this symposium will assist them in that process.



▶▶▶ LETTER TO THE FDA FROM MEMBERS OF CONGRESS

Congress of the United States
Washington, DC 20515

July 26, 2019

The Honorable Norman E. Sharpless
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless,

In recent years advances in animal genetics have provided significant breakthroughs that can help to address some of society's most difficult challenges. These technologies can treat and protect animals from illness; limit the transmission of dangerous diseases, like African swine fever or avian influenza; curb the use of antibiotics in agriculture; address hunger and insect-borne disease in developing nations; improve animal welfare; among many other benefits. However, we are concerned that the current regulatory approach may unintentionally set the United States up to limit domestic access to these innovations by farmers, consumers, and public health officials. Equally concerning, this approach is driving research and first access to these advances into the hands of foreign competitors. U.S.-based companies are already turning to foreign markets for development and marketing of animal innovations. We encourage you to work with other relevant agencies and stakeholders to develop a revised regulatory approach for animal biotechnology that is science and risk-based, provides a viable pathway to market, and ensures the safety of these products for humans, animals, and our environment.

Under the Food, Drug & Cosmetic Act, the U.S. Food & Drug Administration (FDA) currently regulates the DNA of all intentionally altered animals and all of their offspring as an "animal drug" – even if alterations could have happened naturally or through conventional breeding. This regulatory process, which can take years, if not decades to complete, also carries enormous regulatory costs. This burden is deterring many academics and developers from conducting research and will likely consolidate the industry to only the largest companies. In fact, in the agency's nearly 25 years of regulating these animals, only one animal intended for food has ever been approved, delaying many important innovations.

We are worried that there may be many unintended consequences with FDA's approach as well. For example, many U.S.-produced animals are currently bound for international commerce. Suggesting that U.S.-raised animals contain a "drug" invites foreign competitors to impose non-tariff trade barriers on U.S. goods. Foreign governments are also implementing their own regulatory systems to attract U.S. researchers who feel stymied. Argentina recently completed review of a gene edited animal in less than a year – an effort that may take a decade under FDA's existing approach. Brazil, Canada, China, and others are undergoing similar efforts. To maintain competitiveness, it is critical that the U.S. reconsider its current approach.

While we think a robust conversation should be had on the best way to provide transparency to consumers and users on the nature of these animals, that discussion will be moot if our nation's regulatory system prevents these animals from coming to market. We again urge you to work

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LETTER TO THE FDA FROM MEMBERS OF CONGRESS

with other relevant agencies and stakeholder communities to develop a more appropriate, workable approach that will provide sufficient safeguards, while allowing U.S. farmers, consumers, and public health officials access to animal innovations.

Sincerely,



KURT SCHRADER
Member of Congress



DAVID LOEBSACK
Member of Congress



ANN KUSTER
Member of Congress



MARC VEASEY
Member of Congress



BOBBY RUSH
Member of Congress



G.K. BUTTERFIELD
Member of Congress



LISA BLUNT ROCHESTER
Member of Congress



JOHN SHIMKUS
Member of Congress



MORGAN GRIFFITH
Member of Congress



BILLY LONG
Member of Congress



GUS BILIRAKIS
Member of Congress



GREG GIANFORTE
Member of Congress



BILL FLORES
Member of Congress



BUDDY CARTER
Member of Congress

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TOM O'HALLERAN
Member of Congress



TONY CARDENAS
Member of Congress



BILL JOHNSON
Member of Congress



SUSAN BROOKS
Member of Congress



MARKWAYNE MULLIN
Member of Congress



FRED UPTON
Member of Congress



TIM WALBERG
Member of Congress



ADAM KINZINGER
Member of Congress



CATHY McMORRIS RODGERS
Members of Congress





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