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Got Bacon?: The Use of A Bioethics Advisory Board in Assessing The Future of Transgenic Animal Technology

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ABSTRACT

This article assesses the current state of the transgenic modification of animals and the law. It provides an introduction to the science behind transgenics as well as examples of transgenic livestock. This article discusses past federal level Ethics Advisory Boards, how these boards have impacted the development of controversial sciences, and how a new board can advance the use of transgenics. Bioethical arguments for and against the use of transgenics are evaluated. Finally, the article demonstrates how, if properly executed, an Ethics Advisory Board can help shape the national discourse on transgenics and provide a reasoned way forward for this new industry.

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INTRODUCTION

¶1 Would you feed your baby genetically modified human breast milk produced by a cow? What about genetically modified goat milk that combats diarrhea in children? Would your opinion change about these issues if this technology improves the world's access to quality nutrition or medical care? Humanity is at the beginning of exploring unprecedented ways in which we can alter the genes of other organisms.

¶2 After a long delay, in 2012 the Food and Drug Administration (FDA) stated that it is safe for the public to consume AquaBounty's transgenic AquaAdvantage Salmon and that these fish do not pose a threat to the environment.[1] Since that time, AquaBounty has been waiting for the FDA to initiate its final regulatory approval process. Transgenics[2] is a promising new technology that enables humans to genetically modify animals by combining character traits of other animals in order to produce a new trait.[3] Using AquaAdvantage's approval as a starting place, this article will prescribe the creation of an Ethics Advisory Board (EAB) or a bioethics council to assess how the United States can develop transgenics in a safe and reasoned way and subsequently what the United States can do to improve its regulatory review of transgenic animals.

¶3 First, Section I of this article will provide a short introduction to the science behind transgenics. Second, Section II of this article will provide examples of transgenic livestock to give the reader a sense of what this science can achieve and how the current political and social environment is stifling the development of transgenics. Third, Section III of this article will discuss past federal level Ethics Advisory Boards, how they have impacted the development of controversial sciences, and how a new board can advance the use of transgenics. Fourth, Section IV will assess the likely ethical arguments for and against transgenics. Finally, Section V of this article will demonstrate how, if properly executed, the Ethics Advisory Board can help shape the national discourse on transgenics and provide a reasoned way forward for this new industry.

I. UNDERSTANDING TRANSGENIC ENGINEERING

¶4 Humans have been modifying crops and selectively breeding animals since the beginning of humanity.[4] According to the FDA, "genetically engineered animals have

[1] AquaAdvantage Salmon Draft Environmental Assessment, U.S. FOOD AND DRUG. ADMIN. 2, 4 (May 4, 2012), http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf [https://perma.cc/H9ZE-2KCY] [hereafter "Draft Environmental Assessment"].

[2] Transgenics animals can also be described by the broader term, genetically modified organism (GMO).

[3] *Fact Sheet: Genetically Engineered Animals*, U.S. FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED. (2014), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113597.htm [https://perma.cc/9ZZU-NETG].

[4] BURT C. BUFFMAN, ARID AGRICULTURE: A HAND-BOOK FOR THE WESTERN *FARMER* AND STOCKMAN; *Genetic Engineering*, BRITANNICA,

been produced since the late 1970s and early 1980s."[5] The first successful production of transgenic mammals was carried out over two decades ago.[6] Since that time, many transgenic animals have been produced for scientific purposes both to improve livestock and to produce recombinant proteins.[7]

¶5 Perhaps due in part to its relatively brief history, the public is ill informed about the use of all forms of genetically modified organisms, not just transgenics.[8] A 2013 survey conducted by Rutgers University found that when asked, "How much do you know about genetically modified food" 54% of Americans say they know "very little" or "nothing at all."[9] 25% of the respondents said that they have never heard of genetically modified organisms (GMOs).[10] Even Jimmy Kimmel's famous television show highlighted how some members of the public who are opposed to consuming GMOs don't know what the acronym means.[11]

¶6 The science behind GMOs is complex which likely explains why so few average Americans understand it. Transgenic animals are animals that are altered using recombinant DNA (rDNA) technology to have certain traits from other animals.[12] A key advantage of transgenics is its ability to forgo crossbreeding and hybridizing by directly introducing modified DNA into the livestock.[13] This allows for geneticists to more precisely and quickly modify animals than humans have ever been able to in the past.[14]

¶7 The reasons for producing genetically engineered livestock are varied. According to the FDA, scientists develop transgenic animals for purposes such as: to produce pharmaceuticals to be used for other animals and humans; to serve as a source of cells, tissue, and organs closely matched to humans so that they may be transplanted into humans with a decreased risk of rejection; to produce high value materials such as those

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http://www.britannica.com/EBchecked/topic/228897/genetic-engineering (last visited Oct. 11, 2014) [https://perma.cc/6GZS-CD7U].

[5] Briefing Packet: AquaAdvantage Salmon, U.S. FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED. 1 (2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMateri%20%20als/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf [https://perma.cc/L5E2-3UF9].

[6] O.G. Maksimenko, A.V. Deykin, *Use of Transgenic Animals in Biotechnology: Prospects and Problems*, ActaNaturae (2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612824/ [https://perma.cc/N425-SPE8].

[7] *Id*.

[8] William K. Hallman, Cara L. Cutie, Xenia K. Morin, *Public Perceptions of Labeling Genetically Modified Foods*, RUTGERS SCHOOL OF ENVIRONMENTAL AND BIOLOGICAL SCIENCES 30 (2013), http://humeco.rutgers.edu/documents_PDF/news/GMlabelingperceptions.pdf [https://perma.cc/UWK9-LH37].

[9] *Id*.

[10] *Id*. at 3, 30.

[11] Jimmy Kimmel Live: What's a GMO?, YOUTUBE http://www.youtube.com/watch?v=EzEr23XJwFY (last visited Nov. 3, 2014) [https://perma.cc/P6CD-QCDN].

[12] Fact Sheet: Genetically Engineered Animals, U.S. FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED. (2014), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113597.htm [https://perma.cc/ZR3R-K8V8].

[13] Matthew B. Wheeler, *Transgenic Animals in Agriculture*, NATURE EDUCATION (2013), http://www.nature.com/scitable/knowledge/library/transgenic-animals-in-agriculture-105646080 [https://perma.cc/QL24-5PDL]

[14] *Id*.

used for surgical sutures; to provide more healthful and more efficiently produced food.[15] This is certainly not an exhaustive list as scientists are just beginning to discover the potential applications of transgenic livestock.[16]

II. CURRENT STATE OF TRANSGENIC LIVESTOCK

¶8 Scientists, universities, companies, and various special interest groups have already begun to delve into the research and development of transgenic animals. Pigs engineered to digest phosphorus more efficiently, goats that produce diarrhea-fighting milk, cows that produce hypoallergenic milk, and of course, fish, are all just some examples of how livestock are currently being genetically engineered.[17] Some of the animals that are typically candidates for genetic modification will be discussed below. Each will contain an assessment of where these animals are in their development process and how the currently political, social, and regulatory environment is impacting their ability to get to market.

A. Fish

¶9 In regards to the commercialization of transgenic animals, no organization has come as far as AquaBounty Technologies Inc.'s AquaAdvantage Salmon. AquaBounty first applied for FDA approval over 20 years ago.[18] In April of 2013, the FDA closed the public comment period on its December 2012 release of the "Draft Environmental Assessment" and "Preliminarily Finding of No Significant Impact."[19] The FDA concluded in those reports that the fish do not pose a threat to the environment and are "as a safe as food from conventional Atlantic salmon."[20] Since the comment period closed, AquaBounty remains today in a state of regulatory limbo as it awaits the FDA's next move.

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[15] Fact Sheet: Genetically Engineered Animals, U.S. FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED. (2014), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113597.htm [https://perma.cc/9ZZU-NETG].

[16] Wheeler, *supra* note 13 ("The potential applications of biotechnology in livestock production are endless. The utility of biotechnology in livestock production is limited only by our knowledge of the genes involved, gene function, and gene product interactions.").

[17] Rosie Mestel, *Scientists Fret Over FDA Slowness On Genetically Altered Animals: Approval of Foods From Genetically Modified Animals Is Unjustifiably Slow, Scientist Say; Some are Looking Abroad*, LA TIMES (Oct. 1, 2012), http://articles.latimes.com/2012/oct/01/science/la-sci-genetically-engineered-milk-20121002 [https://perma.cc/H8BY-LX87].

[18] *AquaBounty Technologies Supplies Statement on FDA Process for Approving Genetically Modified Food and Animals*, ENTERTAINMENT CLOSE-UP (Aug. 3, 2013), http://www.highbeam.com/doc/1G1-338543160.html (subscription required) [https://perma.cc/RD6D-62U7].

[19] *FDA Extends Comment Period on AquaAdvantage Salmon Documents*, U.S. FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED. (Feb. 13, 2013), http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm339270.htm [https://perma.cc/GAY8-XTHV].

[20] Draft Environmental Assessment, *supra* note 1, at 2.

¶10 When AquaBounty first sought FDA approval in 1995, the FDA had no guidelines for reviewing applications for transgenic animals.[21] It was not until 2005 when the FDA published its guidelines and AquaBounty was able to submit its studies.[22] As the word got out that AquaAdvantage Salmon was pending approval from the FDA, various interest groups began to vigorously debate whether or not the salmon should be commercialized. Critics cite concerns such as: a "Trojan gene" that would give the transgenic fish a mating advantage, the potential that the fish may escape into the environment and disrupt the natural ecosystem,[23] or that the genetically engineered salmon could be dangerous for human consumption.[24]

¶11 These are certainly serious concerns, but scientists who develop transgenic animals are addressing them. For example, the FDA has concluded that science has proven that AquaAdvantage Salmon poses no real threat to human or animal consumption.[25] Further, AquaBounty has taken great precautions to ensure that the salmon does not disturb the environment or biodiversity.[26] AquaBounty produces salmon so they cannot reproduce and they have added the precaution of growing the fish in landlocked tanks so they cannot escape.[27]

¶12 To make matters worse for AquaBounty, it must also contend with special interests that want to preserve the status quo. Congressman Don Young of Alaska — the most senior Republican in the U.S. House of Representatives — is deeply opposed to the competition AquaAdvantage Salmon could bring to the wild salmon industry in Alaska.[28] During a recent interview the Congressman stated, "You keep those damn fish out of my waters. It will ruin what I think is one of the finest products in the world."[29] He went on

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[21] Brendan Borrell, *Why Won't The Government Let You Eat Superfish*? BLOOMBERG BUSINESSWEEK: TECHNOLOGY (May 22, 2014), http://www.businessweek.com/articles/2014-05-22/aquadvantage-gm-salmon-are-slow-to-win-fda-approval#p3 [https://perma.cc/N76C-V42X].

[22] *Id*.

[23] *GE Fish & The Environment*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/309/ge-fish/ge-fish-and-the-environment (last visited Nov. 7, 2014) [https://perma.cc/8RCH-GMLP].

[24] *GE Fish & Human Health*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/309/ge-fish/ge-fish-and-the-environment (last visited Nov. 7, 2014) [https://perma.cc/6X3Z-QJX7].

[25] Briefing Packet: AquaAdvantage Salmon, U.S. FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED. 17 (2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMateri%20%20als/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf [https://perma.cc/Z6EW-52NZ] ("we have not identified any sequences that are likely to contain potential hazards to the target animal, humans, or animals consuming food from that animal, or the environment."); *see also* Andrew Pollack, *Modified Salmon is Safe*, F.D.A. Says, N.Y. Times, (Sep. 3, 2010), http://www.nytimes.com/2010/09/04/health/policy/04salmon.html?_r=1& [https://perma.cc/KW5Z-CZ3C].

[26] *Id*.

[27] *Id*. at 122 ("The probability that AquaAdvantage Salmon will escape... is extremely small"); *See also* Alison L. Van Eenennaam, William M. Muir, *Transgenic Salmon: A Final Leap to the Grocery Shelf?*, 29 Nature Biotech. 8, 706-09 (2011).

[28] *Congressman Don Young: Congressman for All Alaska*, UNITED STATES HOUSE OF REPRESENTATIVES, http://donyoung.house.gov/biography/ (last visited Nov. 9, 2014) [https://perma.cc/WY2G-25MD].

[29] Brady Dennis, *For Both Sides, Bigger Fish to Fry*, WASH. POST (Dec. 22, 2012), https://advance.lexis.com/document/?pdmfid=1000516&crid=e04929cf-c18c-4c08-9063-a8ed05e05b76&pdworkfolderid=88487131-a855-4fbe-8515-

to say, "If I can keep this up long enough, I can break [AquaBounty] and I admit that's what I'm trying to do."[30] It is notable that a leading Republican is using a federal administrative agency like the FDA as a mechanism for stifling a technologically innovative and entrepreneurial small business like AquaBounty as this is completely out of sync with the Republican Party's most recent national platform.[31] Alaska's former Democratic Senator, Mark Begich said, "the notion that consuming Frankenfish is safe for the public and our oceans is a joke."[32] The bi-partisan pushback AquaBounty is currently facing in Alaska has already been replicated in other states.[33] A decade ago, several states began to pass legislation limiting the use of transgenic fish.[34]

¶13 Controversy over GMO labeling and GMO products in general is raging across the country.[35] AquaAdvantage Salmon will likely continue to be subjected to political posturing until society wrestles with both the science-based and bioethical concerns associated with transgenics. Regardless of what happens with the FDA's approval of AquaAdvantage, other transgenic animal research in the United States has certainly been spooked.

B. Swine

¶14 Canadian scientists genetically engineered an "Enviropig" that produced less phosphorus in its manure[36] and was reportedly going to be considered next by the FDA following AquaBounty's salmon.[37] The Enviropig's reduction in phosphorus helps

8651bf31b71d&ecomp=4hcg&earg=88487131-a855-4fbe-8515-8651bf31b71d&prid=359f6f8e-09b3-4ae1-871a-883ae255dfeb [https://perma.cc/V6A5-5FBP].

[30] *Id*.

[31] *Republican Platform 2012: We Believe in America* 2, https://cdn.gop.com/docs/2012GOPPlatform.pdf [https://perma.cc/9LDX-K2YP] ("Small businesses are the leaders in the world's advances in technology and innovation, and we pledge to strengthen that role and foster small business entrepreneurship").

[32] Dennis, *supra* note 29.

[33] *See* Mischa Fisher, *The Republican Part Isn't Really the Anti-Science Party*, THE ATLANTIC (Nov. 11, 2013 12:36 PM), http://www.theatlantic.com/politics/archive/2013/11/the-republican-party-isnt-really-the-anti-science-party/281219/ [https://perma.cc/8FAU-AQBX] (discussing that the anti-GMO movement is largely a product of the political left and has reached high levels of delusion, paranoia, and anti-intellectualism).

[34] *See* Jane Kay, *"Frankenfish" Spawn Controversy/Debate Over Genetically Altered Salmon*, SFGate (Apr. 29, 2002, 4:00 AM), http://www.sfgate.com/news/article/Frankenfish-spawn-controversy-Debate-over-2843540.php [https://perma.cc/G6G4-XADZ] ("Maryland passed a law prohibiting transgenic fish any place that might connect with waterways. In Oregon, the law prohibits the release of transgenic fish into locations where they can mingle with wild populations").

[35] Ned Potter, *GMO Labeling: How to End the Fight*, FORBES (Nov. 7, 2014, 11:00 AM), http://www.forbes.com/sites/forbesleadershipforum/2014/11/07/gmo-labeling-how-to-end-the-fight/ [https://perma.cc/6MJ5-6VUY].

[36] *Enviropig*, UNIV. OF GUELPH, http://www.uoguelph.ca/enviropig/ (last visited Nov. 9, 2014) [https://perma.cc/3W44-GYME].

[37] *A Biotech Fish Story; Will An FDA nod to gene-spliced salmon lead to other transgenic animals?* CORPORATE COUNSEL (June 1, 2011), https://advance.lexis.com/document/?pdmfid=1000516&crid=93f1f033-d988-4b97-beb2-94e8d2e1481b&pddocfullpath=%2Fshared%2Fdocument%2Flegalnews%2Furn%3AcontentItem%3A5329-WH21-JBYY-24RB-00000-00&pddocid=urn%3AcontentItem%3A5329-WH21-JBYY-24RB-00000-

reduce the environmental impact pigs have on soil and water quality.[38] First developed in 1999, funding for the Enviropig recently dried up as it waited for years for approval from the FDA and from Health Canada.[39] In May of 2012 the pigs were euthanized after failing to find an industry partner to fund and commercialize the pigs.[40] Reportedly, the University of Guelph will cryogenically preserve the pig's genetic material so it could potentially be studied in the future.[41]

¶15 Enviropigs aside, scientists at the University of Edinburgh's Roslin Institute genetically modified a pig to make it immune to African Swine Fever,[42] a virus that can kill European pigs within 24 hours of infection.[43] Harvard Medical School researchers are also genetically modifying pigs by enriching them with omega-3 fatty acids to make them a healthier food choice.[44] As the science driving transgenics continues to advance, it is clear that there is a lot of potential to enhance pigs and significantly change the way this important source of food is produced. Despite the promise these genetically modified pigs offer, like AquaAdvantage salmon, these pigs have not been able to reach market. As with the salmon, many of the same concerns arise around the use of genetically modified pigs: political, bioethical, and societal.[45]

C. Cows and Goats

¶16 Cows and goats also have an enormous amount of potential as a source for transgenic livestock. Scientists working with the AgResearch Company in New Zealand have genetically modified a cow to produce milk without beta-lactoglobulin,[46] a milk-

00&pdcontentcomponentid=255422&ecomp=vhyg&earg=sr4&prid=cb18ec16-e171-429a-a5f1-b53a234ca5d1 [https://perma.cc/PDF6-H9VK].

[38] Rod Nicckel, *Death Knell May Sounds For Canada's GMO Pigs*, REUTERS: CANADA (Apr. 2, 2012 3:59 PM), http://ca.reuters.com/article/domesticNews/idCABRE83110320120402?sp=true, [https://perma.cc/F4UE-63VB]

[39] *Id.*

[40] Sarah Schmidt, *Genetically Engineered Pigs Killed After Funding Ends*, POSTMEDIA NEWS (June 22, 2012), http://www.canada.com/technology/Genetically+engineered+pigs+killed+after+funding+ends/6819844/story.html [https://perma.cc/7PKW-DU7G].

[41] Rebecca Boyle, *Enviropig, The Genetically Engineered Eco-Friendly Pork, Is Off The Table*, POPULAR SCIENCE (Apr. 3, 2012 3:06 PM), http://www.popsci.com/technology/article/2012-04/thats-all-folks-genetically-engineered-efficiently-pooping-pigs [https://perma.cc/H4BW-TCWR].

[42] The Roslin Institute also produced Dolly the sheep, the world's first cloned mammal. *See Dolly The Sheep*, THE UNIV. OF EDINBURGH: ROSLIN, http://www.roslin.ed.ac.uk/public-interest/dolly-the-sheep/a-life-of-dolly/ (last visited Nov. 9, 2014) [https://perma.cc/ND3X-XRPC].

[43] Nick Collins, *Pig born using new GM approach*, THE TELEGRAPH (Apr. 15, 2013, 7:50 PM), http://www.telegraph.co.uk/news/science/science-news/9995807/Pig-born-using-new-GM-approach.html [https://perma.cc/T67E-VXBE].

[44] Jessica Marshall, *Transgenic Pigs Are Rich in Healthy Fats*, NEW SCIENTIST (Mar, 27, 2006, 2:52 PM), http://www.newscientist.com/article/dn8900-transgenic-pigs-are-rich-in-healthy-fats.html#.VDnktNTF8iF [https://perma.cc/XBT3-DDAG].

[45] Allan Chernoff, *Enviropig: the next transgenic food?*, CNN (Sept. 25, 2010, 12:00 AM https://cnneatocracy.wordpress.com/2010/09/25/enviropig-the-next-transgenic-food/ [https://perma.cc/2FFW-Y8MU].

[46] AgResearch is a Crown Research Institute which are companies owned by the New Zealand government. "AgResearch's purpose is to enhance the value, productivity and profitability of New

whey protein believed to be partially responsible for allergic reactions.[47] Chinese scientists have "successfully introduced human genes into 300 dairy cows to produce milk with the same properties as human breast milk… the scientists behind the research believe milk from herds of genetically modified cows could provide an alternative to human breast milk and formula milk for babies."[48] Professor James D. Murray of the University of California-Davis has pioneered transgenic technology that manipulates the mammary glands of goats to improve the properties of milk.[49] He is genetically modifying goats with a single human gene to enable the goat's milk to fight diarrhea in children.[50]

¶17 All of these examples of transgenic technology in goats and cows are indicative of the potential that genetic engineering has to not only improve the production of food, but also to save lives. However, none of this technology is reaching the American marketplace because the United States has yet to effectively assess how we will handle the development of transgenics.

III. A NATIONAL ETHICS ADVISORY BOARD IS A POSSIBLE SOLUTION TO OVERCOMING RESISTANCE TO ADVANCING TRANSGENICS

¶18 Past Presidents and Congressional leaders have employed the use of an Ethics Advisory Board (EAB) and other forms of independent counsel (i.e. committees, commissions, reports, etc.) to explore the science, theology, law, and social challenges surrounding controversial new technologies.[51] Using the history of research on embryos as an example this section will examine how a properly designed EAB can, through careful deliberation and public education, help resolve conflicts over the development of controversial sciences such as transgenics.

Zealand's pastoral, agri-food and agri-technology sector value chains to contribute to economic growth and beneficial environmental and social outcomes for New Zealand." *See AgResearch*, MINISTRY OF BUSINESS, INNOVATION, & EMPLOYMENT: SCIENCE + INNOVATION, http://www.agresearch.co.nz/about/statement-of-corporate-purpose/ (last visited Nov. 9, 2014) [https://perma.cc/NC5K-J8KX].

[47] Alexandra Sifferlin, *Researchers Genetically Modify a Cow to Produce Low-Allergy Milk*, TIME (Oct. 2, 2012), http://healthland.time.com/2012/10/02/researchers-genetically-modify-a-cow-to-produce-low-allergy-milk/ [https://perma.cc/NQ6V-AG4Y]; *see also*, Trevor Stokes, *Holy Cow! 'Daisy' Makes Hypoallergenic Milk*, LIVESCIENCE (Oct. 1, 2012), http://www.livescience.com/23615-transgenic-cow-hypoallergenic-milk-whey.html [https://perma.cc/Q2UN-H7FK].

[48] *Reminder: Genetically Modified Cows Produce 'Human' Milk*, FRACTURED PARADIGM (May 4, 2013), http://fracturedparadigm.com/2013/05/04/reminder-genetically-modified-cows-produce-human-milk/#axzz3FwwISB2K [https://perma.cc/JT4G-FPZA].

[49] *James D. Murray*, DEP'T OF ANIMAL SCIENCE, UC DAVIS, http://animalscience.ucdavis.edu/faculty/murray/ (last visited Oct. 12, 2014) [https://perma.cc/Y2C8-2K5D].

[50] Rachel Swaby, *Genetically Modified Goats Take On Child Killers*, PACIFIC STANDARD (May 24, 2012 9:03 AM), http://www.psmag.com/navigation/health-and-behavior/genetically-modified-goats-take-on-child-killers-42356/ [https://perma.cc/D9XY-454C].

[51] SOURCE BOOK IN BIOETHICS: A DOCUMENTARY HISTORY 88 (Robert M. Veatch et al., 1998).

A. Embryonic Stem Cell Research

¶19 In 1977 Congress created an EAB to decide how to best approach the then-controversial science of in vitro fertilization (IVF) and more broadly, Stem Cell research.[52] These sciences were and continue to be controversial as anti-abortion groups equate research on human embryos with abortion.[53] The 1977 EAB was comprised of 15 men and women, all of whom but three had a JD, MD, or Ph.D.[54] One member had a Doctor of Sacred Theology.[55] Ultimately, the EAB concluded that research on human embryos should be permitted.[56]

¶20 In 1980 President Reagan decided not to renew the EAB's charter.[57] President Reagan argued that the destruction of embryos did not differ from the destruction of fetuses.[58] Each President following Reagan employed the use of national ethics committees to study this science and weigh various ethical considerations.[59] Despite the diligent efforts of these national ethics committees, ethical concerns and abortion politics continued to stifle the development of Stem Cell research until 2009.[60] Finally, in 2009 President Obama signed an executive order lifting President Bush's ban on federal funding for embryonic stem cell research.[61]

¶21 What changed from 1978 to 2009? The answer is likely that scientists, industry leaders, and the public all became better educated and subsequently more comfortable with developing this science. For example, President Clinton's Human Embryo Research Panel (1993-1994) recommended that some embryonic research move forward.[62] This motivated a conservative Congress to pass the 1995 Dickey Amendment, which banned federally funded research of human embryos.[63] Each time an ethics committee issued its recommendations and the President and Congress responded, the public received more information about how embryonic research could be used.

¶22 While the national ethic committees addressing human embryo research did not have a consistent formula for membership or the same mission, each contributed to the

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[52] TEXTBOOK OF *IN VITRO* FERTILIZATION AND ASSISTED REPRODUCTION 661 (Peter R. Brinsden, 3d ed. 2005).

[53] GREGORY E. PENCE, CLASSIC CASES IN MEDICAL ETHICS 122 (McGraw Hill, 5th ed. 2008).

[54] Report and Conclusions: HEW Support of Research Involving Human *In Vitro* Fertilization and Embryo Transfer, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE: ETHICS ADVISORY BOARD 5 (1979), https://repository.library.georgetown.edu/bitstream/handle/10822/559350/HEW_IVF_report.pdf?sequence=1&isAllowed=y.

[55] *Id*.

[56] *Id.* at 104-14.

[57] Pence, *supra* note 53 at 122.

[58] *Id*.

[59] THOMAS F. BANCHOFF, EMBRYO POLITICS: ETHICS AND POLICY IN ATLANTIC DEMOCRACIES 71 (2011).

[60] DC Wertz, *Embryo and stem cell research in the United States: history and politics*, 9 GENE THERAPY 11, 674-75 (2002).

[61] Exec. Order No. 13,505 (2009).

[62] *Former Bioethics Commissions*, THE PRESIDENT'S COUNCIL ON BIOETHICS, https://bioethicsarchive.georgetown.edu/pcbe/reports/past_commissions/ (last visited Feb. 5, 2015) [https://perma.cc/X7XR-EZRT].

[63] Banchoff, *supra* note 59 at 71 (President Clinton agreed with Congress and signed the Dickey Amendment into law.).

public discourse on this technology.[64] Each commission weighed theological, political, practical, scientific, and moral concerns. The results of their intense deliberations sparked responses from Presidents and Congress. As political leaders sparred over how the government should handle recommendations, the public became more engaged, educated, and comfortable with this science.

B. Transgenics Needs Its Own Ethics Advisory Board

¶23 As with human embryo research, transgenics would benefit from a dedicated and focused ethics commission. Currently President Obama has a presidential commission on bioethics, but its mission is so broad that it cannot devote significant attention to assessing transgenics.[65] While this commission is certainly a step in the right direction its mandate requires it to consider so many advances in biotechnology that transgenics will not be able to adequately compete for attention.

¶24 The President or Congress should create a dedicated ethics advisory board to weigh the bioethical challenges to transgenic animals. However, in order to maximize legitimacy, the commission should be structured in a balanced way. From 2001 to 2005, President Bush appointed the conservative thinker, Dr. Leon Kass, to be Chair of his President's Council on Bioethics.[66] As Chair, Dr. Kass appointed other politically biased individuals who were hostile to biotechnology and to assisted reproduction.[67] In 2002 the media began to report on Dr. Kass and the political bent of President Bush's council.[68] The imbalanced nature of this panel inhibited its ability to be taken seriously by the public and industry.

¶25 A dedicated and balanced commission assigned to assess the future of transgenic biotechnology would allow for focused deliberation and subsequently public education about this new controversial science.[69] An ethics committee that tries to evaluate the facts about transgenics as fully as possible, talks with well-informed persons, invites all interested persons to contribute, argues in public, and tries to find where each committee member agrees and disagrees would surely provide an indispensable service to the public.[70] The council should also include representatives from other countries that are developing transgenic animals (i.e. New Zealand, Brazil, China, etc). This kind of focused attention to transgenics is utterly lacking in today's discourse regarding how our government and our society wants to employ this technology going forward.

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[64] *Former Bioethics Commissions*, THE PRESIDENT'S COUNCIL ON BIOETHICS, https://bioethicsarchive.georgetown.edu/pcbe/reports/past_commissions/ (last visited Feb. 5, 2015) [https://perma.cc/X7XR-EZRT].

[65] *Presidential Commission for the Study of Bioethical Issues: About the Commission*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., http://bioethics.gov/about (last visited Feb. 9, 2014) [https://perma.cc/EC88-W3NP].

[66] Pence, *supra* note 53 at 128.

[67] *Id.*

[68] Neil Boyce, *The President's Philosopher*, U.S NEWS AND WORLD REPORT (Feb. 11, 2002).

[69] Mary Darby, *Deliberation and Bioethics Education: A Case Study of Public Health Emergency Response*, blog.bioethics.gov (Nov. 6, 2014), http://blog.bioethics.gov/2014/11/06/deliberation-and-bioethics-education-a-case-study-of-public-health-emergency-response/ [https://perma.cc/82NM-NS78].

[70] *See* ALBERT R. JONSEN, THE BIRTH OF BIOETHICS 116-17 (1998).

¶26 As with the various commissions that studied human embryo research,[71] the results of an advisory board on transgenic animals would help the public to better understand the different dimensions of transgenics. The more the public is able to grapple with the risks and benefits of this technology the more our government leaders will have to take its development seriously.

IV. BIOETHICAL CHALLENGES TO TRANSGENIC LIVESTOCK

¶27 In order to realize the tremendous potential genetically engineered livestock have to improve the world's environment and quality of life, our society must evaluate serious bioethical concerns. Public discourse over animal biotechnology inevitably entails balancing the positive results gained by transgenesis against the risks and ethical problems the technology poses to society.[72] While there are most certainly many others, two of the most prevalent bioethical arguments against transgenesis are its affects on animal welfare and the fear that humans are "playing God."[73] Although grappling with these concerns is difficult, through careful consideration of all viewpoints and the acceptance of scientific knowledge, a positive way forward for transgenic livestock is possible.

A. Animal Welfare

¶28 Animal suffering is one of the most important ethical concerns for those against genetically engineered animals.[74] Jeremy Bentham, founded an important philosophical theory[75] which argues that the capacity for suffering is the key characteristic that entitles a being to equal consideration as humans.[76] Building off of Bentham's fundamental principle, modern animal rights activists argue that while we cannot directly feel a

[71] *Former Bioethics Commissions*, THE PRESIDENT'S COUNCIL ON BIOETHICS, https://bioethicsarchive.georgetown.edu/pcbe/reports/past_commissions/ (last visited Feb. 5, 2015) [https://perma.cc/X7XR-EZRT].

[72] HANDBOOK OF GENETICS AND SOCIETY: MAPPING THE NEW GENOMIC ERA 386 (Paul Atkinson et al., 2009).

[73] *Ethics Guide: Biotechnology*, BBC http://www.bbc.co.uk/ethics/animals/using/biotechnology_1.shtml (last visited Oct. 12, 2014) [https://perma.cc/M28Q-SSBG]; *See generally Enviropig: Societal and Ethical Issues*, UNIV. OF GUELPH, http://www.uoguelph.ca/enviropig/societal_issues.shtml (last visited Nov. 9, 2014) [https://perma.cc/XN7R-ZYNE].

[74] Harm and Suffering, NEW ENGLAND ANTI-VIVISECTION SOCIETY, http://www.neavs.org/research/harm-suffering (last visited Nov. 9, 2014); Katia Moskvitch, *Salmon Steak From GM Fish Could Soon Be On Your Plate*, BBC (Jan. 22, 2013 7:15 PM), http://www.bbc.com/news/technology-21078731 [https://perma.cc/K5LQ-WZTC] (Animal rights group PETA argues "that 'genetic modification only contributes to the cruelty already inflicting on animals raised for food and used in experimentation'").

[75] GREGORY E. PENCE, CLASSIC CASES IN MEDICAL ETHICS 199-236 (McGraw Hill, 5th ed. 2008).

[76] PETER SINGER, PRACTICAL ETHICS 57 (Cambridge Univ. Press, 2d ed., 1993).

chicken's suffering when we slaughter it, this does not mean that the chicken does not suffer.[77]

¶29 If one accepts the premise that animals have the capacity to suffer, as many scientists do,[78] then moral decency compels us to study how genetic modifications to animals will impact their welfare. Certainly there are horrifying stories of genetic modification gone wrong – the broiler chicken is a famous example.[79] However, it is possible that genetic engineering could enhance livestock welfare through: increasing resistance to diseases or parasites, decreasing response to ingestion of toxic plants, eliminating horns on cattle, or producing hens that only bear female offspring.[80] Of course, it is likely that market forces will ultimately reconcile how far the industry will go in balancing the maximization of profit with preserving animal welfare.[81]

B. Humans As God

¶30 One of the most common arguments against genetically engineering animals is that humans are "playing God."[82] The direct genetic manipulation of animal DNA is argued to be fundamentally different than using God's existing structure.[83] Essentially, this premise argues that humans go from using God's blueprint to becoming the architect.[84]

¶31 While this argument resonates with many, it does not adequately reconcile the long history humans have with genetically modifying animals that was not controversial.[85] Furthermore, if one argues that genetically modifying animals is playing God, then certainly genetically modifying plants or even more simple organisms is as well. The Pew

[77] *Id*. at 69 ("Animals in pain behave much in the same way humans do, and their behaviour is sufficient justification for the belief that they feel pain").

[78] Philip Low, *The Cambridge Declaration on Consciousness*, UNIV. OF CAMBRIDGE (July 7, 2012), http://fcmconference.org/img/CambridgeDeclarationOnConsciousness.pdf [https://perma.cc/R3HA-HA4F] ("The weight of the evidence indicated that humans are not unique in possessing the neurological substrates that generate consciousness").

[79] While not transgenically engineered, these chickens were genetically modified to produce more meat. The chickens often develop severe deformities and metabolic diseases. *See Poultry Health and Disease Fact Sheet*, GOV'T OF SASKATCHEWAN (2007), http://www.agriculture.gov.sk.ca/Poultry_Health_Disease [https://perma.cc/X5SK-Z3HD].

[80] COMMITTEE ON DEFINING SCIENCE-BASED CONCERNS ASSOCIATED WITH PRODUCTS OF ANIMAL BIOTECHNOLOGY, ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS 105-06 (2002) http://www.nap.edu/openbook.php?record_id=10418&page=105 [https://perma.cc/H9MN-2668].

[81] Michael Greger, *Transgenesis in Animal Agriculture: Addressing Animal Health and Welfare Concerns*, 24 J. ARGIC. ENV'T ETHICS 451 (2011) ("Selective farm breeding has historically been undertaken for purposes of economic advantage, even when at the expense of animal welfare, and research remains geared towards profitability"); *See also* P.B. Thompson, *Animal Biotechnology: How Not to Presume*, 8 AM. JOURNAL OF BIOETHICS 6, 49–50 (2008).

[82] LEON R. KASS & JAMES Q. WILSON, THE ETHICS OF HUMAN CLONING 19 (1998).

[83] MAURA A. RYAN, ETHICS AND ECONOMICS OF ASSISTED REPRODUCTION: THE COST OF LONGING 92 (1998) ("Genetic engineering is a significant 'enlargement of human power over life,' perhaps 'the most advanced form of technics every conceived'").

[84] *See* Autumn Fiester, *Justifying a Presumption of Restraint in Animal Biotechnology Research*, UNIV. OF PENN. CTR. FOR BIOETHICS 3 (2008) http://repository.upenn.edu/cgi/viewcontent.cgi?article=1068&context=bioethics_papers [https://perma.cc/GU8R-7FYS].

[85] *See* Buffman, supra note 4.

Research Center found that 57% of those polled decided that producing organs for human transplant was a good reason to genetically alter animals.[86] To adopt the principle that humans should not "play God" would effectively inhibit all GMO research.

¶32 Not all ethicists see the genetic modification of animals as playing God. Gary Comstock, a well-known evangelical Protestant, argues that "God wants human beings to pursue science… it isn't playing God; it's doing what God has given researchers the mental gifts to do."[87] Despite the difficulty in determining what God's will is, at least one thing is clear: no one fully agrees on what God's will is as no one knows what the ultimate expression of God is. A better framework would be to try and identify principles of bioethical behavior that scientists from all over the world can work off of as we continue to further develop this technology.

C. How a Bioethics Commission Can Reconcile The Need to Respect Nature and Promote Science

¶33 There is no one accepted way of establishing an ethical framework that simultaneously ensures that nature receives the respect our universe demands while enabling humans to take advantage of scientific progress, nor will there likely ever be.[88] Philosophy and the field of bioethics do offer some strategies for how the bioethics commission could approach assessing the value of transgenics.

¶34 One approach uses a two-step matrix that first utilizes the ethical theory of principlism[89] to establish core values that then are assessed against how the genetic modification of the animal will affect the values described in the matrix.[90] Another approach argues for the use of a theory called "Presumption of Restraint" which constitutes a justificatory process setting out the criteria for permitting or rejecting individual transgenic animal projects.[91] Both of these approaches have merit and can provide insight into how we can better ethically regulate the genetic modification of all manner of organisms in the future.

¶35 However, while these approaches can help inform a bioethics council, the council does not need to come up with a solution that would resolve all of the potential problems this technology may pose. The value of an ethics advisory board dedicated to transgenics lies in its ability to flush out the concerns of scientists, philosophers, lawyers, doctors, laypersons, and others. Through their deliberation and any conclusions they may draw, a bioethics commission will help guide society, government leaders, and regulatory decision-makers.

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[86] Fiester, *supra* note 84 at 7-8 (citing Pew Research Center's Initiative on Food and Biotechnology).

[87] Id. at 9.

[88] Greger, *supra* note 81.

[89] *See* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (7th ed. 2012).

[90] M. Kaiser, *Assessing Ethics and Animal Welfare In Animal Biotechnology for Farm Production*, 24 REVIEW SCI. TECH. OFFICE INT'L EPIZOOTIES 1, 83-85 (2005) http://www.oie.int/doc/ged/d1682.pdf [https://perma.cc/69LW-D56F].

[91] Fiester, *supra* note 84 at 2.

V. AN ETHICS ADVISORY BOARD CAN HELP CREATE A STRONGER TRANSGENIC LIVESTOCK INDUSTRY IN THE UNITED STATES

¶36 As previously discussed, the genetic modification of livestock is moving at a rapid pace.[92] While the United States engages in a heated public discourse over whether or not it is appropriate to label GMO products,[93] (much less encourage the development of transgenic animals) the rest of the world is leaving America in the dust.[94] Since the 1980's China and other countries have been moving forward with transgenic livestock.[95] If the United States is to lead the world in regulating and developing this controversial technology, then the public needs to be educated about the science behind genetically engineered animals. Our government leaders need to commit to serious regulatory reform that incorporates the bioethical concerns associated with this science. If the United States fails to properly assess transgenics then it will not be able to adequately participate in the global development of this industry and it risks falling behind in providing high quality medical care.

A. A Bioethics Commission Fosters Public Discourse Informed By Scientific Knowledge

¶37 History provides countless examples of the fear people associate with a new technology. The advent of telegraph created fears that the wires were affecting the weather, trains were blamed for nervous disorders, and the mobile cell phone was thought to make planes fall from the sky.[96] We are at a similar place with GMOs in general.[97] Nowhere is this clearer than in the current debate raging over the labeling of GMOs.[98] The public needs to know that consuming transgenically modified animals such as AquaAdvantage Salmon or the Enviropig would have not be any less safe for human consumption or for the environment than traditionally reared salmon and swine.[99]

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[92] *See infra*, Part II.

[93] Luke Runyon, *No Matter How Colorado Votes, GMO Labeling Debate Far From Over*, PBS (Oct. 8, 2014, 6:12 PM), http://www.pbs.org/newshour/rundown/matter-colorado-votes-gmo-labeling-debate-far-finished/ [https://perma.cc/RF53-YJ8Z].

[94] *See* Potter, *supra* note 35.

[95] *See* Zhang-Liang Chen and Li-Jia Qu, The Status of Agriculture Biotechnology in China, Address at Peking University, Beijing.

[96] *Fear of technology: The Shock of the New*, THE ECONOMIST (Mar. 23, 2005), http://www.economist.com/node/3789466 [https://perma.cc/Z9BZ-WPMA].

[97] Jon Entine, *Frankenfood: A Metaphor That Has Cursed GMOs*, GENETIC LITERACY PROJECT (Nov. 7, 2014), http://www.geneticliteracyproject.org/2014/11/07/frankenfood-the-metaphor-that-has-cursed-gmos/ [https://perma.cc/C6PM-RAH8].

[98] Andrea Rock, *Where GMOs Hide In Your Food*, CONSUMERREPORTS.ORG (Oct. 2014), http://consumerreports.org/cro/2014/10/where-gmos-hide-in-your-food/index.htm [https://perma.cc/E3M5-NM7F].

[99] Draft Environmental Assessment at 2 (FDA says AquaAdvantage salmon are as safe as to eat traditional salmon); *Enviropig: Societal and Ethical Issues*, UNIV. OF GUELPH, http://www.uoguelph.ca/enviropig/societal_issues.shtml (last visited Nov. 9, 2014) [https://perma.cc/FTA7-29W3] (the Enviropig has all the same attributes as conventional pigs).

Scientists in Europe and the United States have not found any negative affects associated with consuming current GMO's on the market.[100]

¶38 The GMO industry as a whole is facing a crisis of knowledge. There is an enormous amount of fear and confusion surrounding this industry.[101] The source of this fear is difficult to pinpoint because disparate interest groups are propagating it across the country. For example, the Center for Food Safety is staunchly opposed to farm biotechnology and went on record to argue that AquaAdvantage Salmon "has no socially redeeming value."[102] Given what the broader scientific community has said about AquaAdvantage Salmon, statements such as this one are clearly extreme.

¶39 Aside from the interest groups diluting the public's ability to assess the merits of transgenics itself, there is increasing evidence that the public is distrustful of science in general. Recently the Pew Research Center, in collaboration with the American Association for the Advancement of Science, polled the public and scientists to see whether the consider U.S. scientific achievements to be either the best or among the world's best.[103] Only 54% of the public said, "yes," compared to 92% of the scientists.[104] This disparity is alarming because it indicates that the public is becoming less committed to demanding sound science policy from our government and less committed to scientific progress.

¶40 Alan Leshner, the Chief Executive Officer of the American Association for the Advancement of Science, argues that in order to bridge the increasing divide between the public and scientists we need respectful bidirectional communication.[105] An ethics advisory board dedicated to assessing transgenic technology would be an important mechanism for contributing to the kind of bidirectional communication advocated for by Mr. Leshner. If the public knows that a diverse group of individuals has assessed the merits of transgenic research then society may be more comfortable accepting the science.

¶41 Restricting the conversation about transgenics to scientists alone in a non-public forum will be viewed by the layperson as an elitist move and serve only to foster mistrust of the science. Moreover, if the United States lets ideology trump science then it will fail to realize real economic, environmental, and social welfare benefits for its populace. Transgenics has tremendous potential to help humanity and a public bioethics advisory board would go a long way in helping people better understand this science and others.

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[100] Jason Kashdan, *Consumer Reports Looks At Heated Debate Over GMO Foods*, CBS NEWS (Oct. 7, 2014 3:05 PM), http://www.cbsnews.com/news/consumer-reports-gmo-food-label-study-on-american-products/ [https://perma.cc/Z94X-QR88].

[101] Brooke Borel, *Core Truths*: 10 Common GMO Claims Debunked, Popular Science (July, 11, 2014, 10:00 AM), http://www.popsci.com/article/science/core-truths-10-common-gmo-claims-debunked [https://perma.cc/KJ8U-JSR4].

[102] Andrew Pollack, *Engineered Fish Moves A Step Closer To Approval*, N.Y. TIMES (Dec. 21, 2012), http://www.nytimes.com/2012/12/22/business/gene-altered-fish-moves-closer-to-federal-approval.html?pagewanted=all&_r=0 [https://perma.cc/EDB7-CY6K].

[103] Cary Funk and Lee Rainie, *Public and Scientists' Views on Science and Society*, PEW RESEARCH CENTER (Jan. 29, 2015), http://www.pewinternet.org/2015/01/29/public-and-scientists-views-on-science-and-society/ [https://perma.cc/YX87-8E6K].

[104] *Id.*

[105] Alan I. Leshner, *Bridging the opinion gap*, 347 SCIENCE 459 (2015), http://www.sciencemag.org/content/347/6221/459 (subscription required) [https://perma.cc/U8A2-3AYM].

B. A Bioethics Advisory Board Can Help Foster Regulatory Reform And National Legislation For Transgenics In The United States

¶42 Not only would a bioethics council help guide the public on this new science, it would help government leaders and regulators as well. The tremendous struggle AquaBounty has faced with getting its transgenic salmon approved by the FDA is a clear indication that the FDA is having difficulty with how it should handle transgenics. Currently GMOs are regulated under the Coordinated Framework for Regulation of Biotechnology, published in 1986.[106] Under this framework, at least twelve different statutes and five different agencies or services govern transgenic animals.[107] The two primary agencies are the FDA and the U.S. Department of Agriculture (USDA). It is worth noting that the Environmental Protection Agency (EPA) "does not regulate the environmental or potential impacts of genetically engineered animals."[108]

¶43 The FDA asserts jurisdiction over genetically engineered animals, pursuant to its authority to regulate 'new animal drugs' (NADs) under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, NADs are deemed generally unsafe unless the FDA has approved a New Animal Drug Application for the particular use of the drug (or in our case, animal).[109] It is the apparent politicization of this process that has scholars worried that sound science behind transgenic animals is being stifled by special interests.[110]

¶44 The USDA's role in approving transgenic animals is limited to utilizing its Food Safety and Inspection Service (FSIS) to ensure the safety of food products prepared from domestic livestock.[111] This suggests that FSIS has the regulatory authority over genetically modified livestock and poultry.[112] Given the scope of authority that the USDA and FSIS have over genetically engineered animals, it is unlikely that the USDA would block livestock like AquaAdvantage Salmon. However, it is possible that other forms transgenic livestock may pose a greater threat.[113]

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[106] *Restrictions on Genetically Modified Organisms: United States*, LIBRARY OF CONGRESS, http://www.loc.gov/law/help/restrictions-on-gmos/usa.php (last visited Nov. 9, 2014) [https://perma.cc/QM77-HBN8].

[107] Gregory N. Mandel, *Gaps Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2167 (2004).

[108] Gregory N. Mandel, *Toward Rational Regulation of Genetically Modified Food*, 4 Santa Clara J. Int'l L. 21, 30 (2006).

[109] Draft Environmental Assessment at 2.

[110] Lars Noah, *Whatever Happened to the "Frankenfish"?: The FDA's Foot-Dragging On Transgenic Salmon*, 65 Me. L. Rev. 605, 623 (2013).

[111] Mandel, *supra* note 107; 9 C.F.R. §§ 300.1, 300.2, 300.3 (2003) (establishing FSIS with the USDA); 21 U.S.C. §§ 451, 601, 1031 (2003) (granting the FSIS administrator the authority to regulate the safety of domestic livestock, poultry, and poultry products).

[112] *Id*.

[113] Noah, *supra* note 110 at 622 ("While [AquaAdvantage Salmon] poses relatively straightforward questions, other GE animals under development very well could confound regulatory officials in the future"); [need to find some old guy's FDA reform argument].

¶45 The relatively limited role of the USDA in the approval process for transgenic animals suggests that the FDA needs the most guidance for how to handle this technology. The United States does not have any federal legislation that is specific to genetically modified animals or GMOs in general.[114] Without any legislation or presidential directive, the FDA lacks an assessment of transgenic technology from an independent entity, which leads stagnation within the FDA. A bioethics advisory board that was chartered by either the President or Congress would help fill that void until Congress or the Executive Branch is prepared to offer clear direction to the FDA. A bioethics council would give the FDA at least some sense of how it should approach this technology. This would also give investors a better idea of what to expect from the government when they consider investing in this technology.

¶46 Additionally, a properly structured bioethics council would simultaneously provide public policy feedback to the President and Congress, and give recommendations on how to handle bioethical concerns like playing God or animal welfare. For example, a council dedicated to reasoning through transgenics could influence Congressional legislation as the previous bioethics commissions on embryo research did.[115] A bioethics advisory board offers tremendous potential in its ability to help government direct and develop regulations for the oversight of transgenics.

C. Global Development Of Transgenic Technology Necessitates The Creation Of A Transgenics Bioethics Advisory Board

¶47 Given the recalcitrant attitude of the American public towards the genetic engineering of animals, it is amazing to observe how fast other nations are progressing. The Chinese government has invested over $800 million in public-private research into transgenic animals.[116] Since the early 1980's Chinese scientists have been transgenically modifying carp[117] and have successfully modified cows to produce human breast milk.[118] As previously discussed, nations such as Brazil, New Zealand, Cuba, and others have already begun developing transgenic livestock.[119]

¶48 As countries around the world continue to develop transgenic animals for their various purposes, the United States needs to grapple with how it will handle importing these genetically modified organisms. Our government will need to ensure that we protect the environment, the animals themselves, and human health.[120] A bioethics

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[114] Potter, *supra* note 35.

[115] Banchoff, *supra* note 59 at 71.

[116] Entine, *supra* note 97.

[117] Gang Wu, Yonghua Sun, Zuoyan Zhu, *Growth Hormone Gene Transfer In Common Carp*, 16 AQUATIC LIVING RES. 416, 419 (2003), https://www.researchgate.net/publication/248858528_Growth_hormone_gene_transfer_in_common_carp [https://perma.cc/KT97-4V8J].

[118] Henry Blodget, *China Genetically Modifies Cows To Produce Human Breast Milk*, BUSINESS INSIDER (Jun. 10, 2011, 7:34 AM), http://www.businessinsider.com/china-genetically-modifies-cows-to-produce-human-breast-milk-2011-6 [https://perma.cc/C9MM-LJXF].

[119] *See infra*, Part II; Entine, *supra* note 97.

[120] Debra Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution Into The U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 168 (2006)("In the international community, heated debates have focused on the public health, safety, and environmental issues of

council on transgenics would serve as an excellent venue for assessing how the United States will need to respond to the use of this technology in other countries. As was discussed above, a committee member representing scientists in another country who are developing transgenics could be a valuable source for the advisory board. Without seriously considering what other nations are doing to develop this technology, the United States cannot develop a holistic response to the development of this technology.

CONCLUSION

¶49 Transgenic animals such as AquaAdvantage Salmon represent a new era of technological progress. Scientists like Professor James Murphy of the University of California-Davis are poised to make significant advancements for our economy, our environment, and for human health.[121] The creation of a bioethics advisory board dedicated to assessing transgenics would help our society, politicians, and government regulators better understand the potential risks and benefits of this new technology. While it remains to be seen what a commission such as the one proposed here would say about transgenic animals, what is most important is that there is a properly structured commission to assess the technology in a public manner so that we may all learn more about this technology.

¶50 The development of transgenic animals should not be stifled before we are able to have a reasoned debate about what this technology can offer. As the global population continues to increase and natural resources dwindle, humanity will need higher quality medical care and more efficient nutrition. AquaAdvantage salmon represents a new era of human technological achievement. We must not silence its potential before we are able to assess this new science.

introduced genes, particularly, allergenicity, antibiotic resistance, gastrointestinal problems, potential gene flow to other organisms, and destruction of biodiversity").

[121] Sifferlin, *supra* note 47.