

WHATEVER HAPPENED TO THE “FRANKENFISH”?: THE FDA’S FOOT-DRAGGING ON TRANSGENIC SALMON

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WHATEVER HAPPENED TO THE “FRANKENFISH”?: THE FDA’S FOOT-DRAGGING ON TRANSGENIC SALMON

*Lars Noah**

I wonder where that fish has gone. –Monty Python¹

AquaBounty Technologies has genetically modified the Atlantic salmon through the introduction of a growth hormone gene from the Chinook salmon, which allows the fish to reach market size almost twice as quickly as its farmed counterparts. The research began more than two decades ago.² The company secured licenses for the patents that emerged out of this research,³ and its plans to commercialize the transgenic salmon (branded “AquAdvantage”) took shape more than a decade ago.⁴ In late 2010, the U.S. Food and Drug Administration (FDA) appeared to be on the verge of authorizing production,⁵ but, more than two years later, the company continues to await the agency’s blessing.

With AquaBounty facing bankruptcy,⁶ a group of biotechnology researchers and entrepreneurs wrote President Obama to denounce the political meddling that apparently had stalled the review process.⁷ Shortly thereafter, the FDA took a tentative further step toward approval, issuing a draft environmental assessment

* Professor of Law, University of Florida; author of *LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS* (3d ed. 2012). As a longstanding vegetarian, my interest in this subject is solely theoretical.

1. MONTY PYTHON’S *THE MEANING OF LIFE* (Universal Pictures 1983) (from “The Middle of the Film”).

2. See Tony Reichhardt, *Will Souped up Salmon Sink or Swim?*, 406 *NATURE* 10 (2000); Ross Anderson, *Controversy Surrounds “Supersalmon” Genetics: Some Hail Fast-Growing, Farm-Raised Fish as an Economic Miracle While Others Fear a “Frankenfish” Biological Disaster*, *PORTLAND PRESS HERALD*, Dec. 3, 1999, at 1A; *New Prospects for Gene-Altered Fish Raise Hope and Alarm*, *N.Y. TIMES*, Nov. 27, 1990, at C4.

3. See Matthew Perrone, *Fast-Growing Fish May Never Wind up on Your Plate*, *ASSOCIATED PRESS*, Dec. 4, 2012.

4. See Hannah Hoag, *Transgenic Salmon Still out in the Cold in United States*, 421 *NATURE* 304 (2003); Marc Kaufman, *“Frankenfish” or Tomorrow’s Dinner?; Biotech Salmon Face a Current of Environmental Worry*, *WASH. POST*, Oct. 17, 2000, at A1; Andrew Martin, *One Fish, Two Fish, Genetically New Fish: Firm Seeks OK for Altered Salmon*, *CHI. TRIB.*, Nov. 12, 2003, at 1; Carol Kaesuk Yoon, *Altered Salmon Leading Way to Dinner Plates, but Rules Lag*, *N.Y. TIMES*, May 1, 2000, at A1.

5. See Gautam Naik, *Gene-Altered Fish Close to Approval*, *WALL ST. J.*, Sept. 21, 2010, at A1; Andrew Pollack, *Panel Leans in Favor of Engineered Salmon*, *N.Y. TIMES*, Sept. 21, 2010, at B3.

6. See Andrew Pollack, *Betting on a Fish*, *N.Y. TIMES*, May 22, 2012, at B1; see also Adrienne Appel, *Caught in Troubled Waters: Firm’s Genetically Engineered Salmon Facing Fierce Opposition*, *BOSTON GLOBE*, Feb. 20, 2012, at B5 (reporting that “AquaBounty’s fiscal struggles are not unusual for a biotechnology start-up awaiting federal approval,” and adding that more than \$60 million has been invested in the company since its launch in 1991).

7. See Rosie Mestel, *FDA Too Slow to Approve Biotech Foods?; Products Made from Genetically Modified Animals Are Trapped in an Endless Logjam, Scientists Complain*, *L.A. TIMES*, Oct. 2, 2012, at A1.

(EA) at the end of 2012.⁸ In explaining why it would allow no more than sixty days for the submission of written comments, the agency noted that its draft EA differed little from the one that it had made available more than two years earlier,⁹ which makes one wonder what exactly it had done during the interim.¹⁰ If history is any guide, this next step in what has become a tortuous review process does not portend imminent approval: the FDA again will receive thousands of largely duplicative adverse public comments, and members of Congress representing constituents threatened economically by approval of the AquAdvantage salmon again will pressure the agency.¹¹ Will regulatory officials manage to ignore the static this time around when they seemed incapable of doing so just two years earlier?

I. MISPLACED CRITICISMS OF THE GE SALMON

In order to tell the tale of this fish, my Essay uses a pair of recent law review pieces on the subject as a foil. Patently silly mistakes that get published all too often find an uncritical audience that then may replicate the errors and distort the legal academic commentary on a particular subject.¹² Although I focus on flaws in a couple of recent student-authored articles,¹³ similar mistakes appear in the work

8. See FDA, Notice of Availability, Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon, 77 Fed. Reg. 76,050 (Dec. 26, 2012).

9. See *id.* (explaining that “the substance of this draft EA was made available to the public in advance of the Agency’s 2010 Veterinary Medicine Advisory Committee meeting”). Nonetheless, the agency later announced a two month extension. See FDA, Notice, Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon; Extension of Comment Period, 78 Fed. Reg. 10,620 (Feb. 14, 2013).

10. See Brady Dennis, *For Both Sides, Bigger Fish to Fry*, WASH. POST, Dec. 22, 2012, at A1 (“Friday’s determination echoes findings from two years ago Since then, the approval process for the fish has remained at a virtual standstill. But the public fight over it has churned on.”); Andrew Pollack, *Engineered Fish Moves Step Closer to Approval*, N.Y. TIMES, Dec. 22, 2012, at B1 (“The environmental assessment is dated May 4. It is unclear why it took until now for it to be released, but supporters of the salmon say they believe it is because the Obama administration was afraid of an unfavorable consumer reaction before the election in November.”); *id.* (“An article in Slate earlier this week said the White House had been delaying release of the environmental assessment for political reasons, violating the Obama administration’s pledge to make decisions based on science. The [EA] was released soon afterward.”).

11. See Dennis, *supra* note 10, at A1 (“Rep. Don Young (R-Alaska) . . . wants to force delays in any FDA approval. ‘If I can keep this up long enough, I can break that company,’ he said, referring to AquaBounty, ‘and I admit that’s what I’m trying to do.’”). This happened in spite of the apparently careful timing of the agency’s announcement. See Rosie Mestel, *Genetically Engineered Salmon Clears FDA Hurdle*, L.A. TIMES, Dec. 22, 2012, at AA1 (reporting that “the FDA’s actions—and the timing of its announcement, on the eve of a holiday weekend—drew outrage from consumer advocacy groups”); cf. Jacob E. Gersen & Anne Joseph O’Connell, *Hiding in Plain Sight? Timing and Transparency in the Administrative State*, 76 U. CHI. L. REV. 1157, 1158 & n.5, 1161-63, 1208-09 (2009) (discussing anecdotal evidence of this practice, but concluding that it is neither as frequent nor as effective as commonly assumed); Ed O’Keefe, *A Look at the “Holiday News Dump,”* WASH. POST, Jan. 4, 2012, at A15.

12. See, e.g., Lars Noah, *An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine*, 24 REV. LITIG. 369, 383 & n.50, 400-04 (2005).

13. On the undoubted difficulties of undertaking such work, see Andrew Yaphe, *Taking Note of Notes: Student Legal Scholarship in Theory and Practice*, 62 J. LEGAL EDUC. 259 (2012).

of more seasoned authors as well,¹⁴ but I will not take this occasion to repeat my previously published critiques of faculty articles related to genetically engineered (GE) fish and foods.¹⁵

A. Technological Misconceptions

The most recently published piece on the transgenic Atlantic salmon appeared one year ago in the *Minnesota Journal of International Law*, a Note by Katherine Wilinska that promised an analysis of the FDA's review of AquaBounty's application as contrasted with the European Union's handling of such matters.¹⁶ The first thing that is striking about this piece: fundamental misunderstandings about the underlying technology. Wilinska repeatedly asserted that the AquAdvantage enjoyed superior cold tolerance by virtue of an "antifreeze" gene inserted from the ocean pout.¹⁷ The only source that she cited for this claim—the briefing packet that the FDA had prepared in advance of the Veterinary Medicine Advisory Committee (VMAC) meeting—says nothing of the sort.¹⁸ The gene sequence from the ocean pout only serves as a promoter for the transgene from the Chinook salmon, resulting in growth hormone production even during colder months when the fish normally would not produce these proteins.

Wilinska also repeatedly asserted that the AquAdvantage would grow "several times bigger than" its wild cousins.¹⁹ If true, that would be quite a monstrosity!²⁰ The single source that she cited did reveal a dramatic size differential among

14. For a quasi-Marxist (and not terribly rigorous) analysis recently published by a pair of sociologists, see Rebecca Clausen & Stefano B. Longo, *The Tragedy of the Commodity and the Farce of AquAdvantage Salmon*, 43 DEV. & CHANGE 229, 233, 243-49 (2012); *id.* at 243 (calling it "a salmon without a 'soul'"); *id.* at 244 (noting "how the state's incomplete regulatory regime accommodates industry requests for minimal oversight"); *id.* ("The FDA . . . is failing to consider the full range of socio-ecological impacts that may result from this new invention."); *id.* at 246 ("In the case of AquAdvantage Salmon, a patented fish can displace traditional salmon fishers, with no hopes of extending the benefits to the millions of artisanal fishermen worldwide.").

15. See Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, ¶¶ 61-64, 67-71 (2006). Genetically modified (GM) is synonymous with GE or "transgenic."

16. See Katherine Wilinska, Note, *AquAdvantage Is Not Real Advantage: European Biotechnology Regulations and the United States' September 2010 FDA Review of Genetically Modified Salmon*, 21 MINN. J. INT'L L. 145 (2012).

17. See *id.* at 148, 149, 164.

18. FDA CTR. FOR VETERINARY. MED., BRIEFING PACKET FOR VMAC., AQUADVANTAGE SALMON 65, 66, 75 (2010) [hereinafter BRIEFING PACKET], available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>.

19. Wilinska, *supra* note 16, at 149; see also *id.* at 164, 172; Chad West, Note, *Economics and Ethics in the Genetic Engineering of Animals*, 19 HARV. J.L. & TECH. 413, 428 (2006) (crediting claims by an "activist group" that the transgenic salmon would grow to unusual sizes and suffer from grotesque abnormalities); *cf. id.* at 418 n.25 (noting that scientists discovered that the "antifreeze" transgene failed to improve cold tolerance).

20. *Cf.* Michael P. Vandenberg, Note, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529, 1529 & n.2 (1986) (alluding to a quip made by an EPA official). See generally HENRY I. MILLER & GREGORY CONKO, *THE FRANKENFOOD MYTH: HOW PROTEST AND POLITICS THREATEN THE BIOTECH REVOLUTION* (2004) (reacting to the unfounded horror stories spread by activists opposed to GE crops).

juvenile fish,²¹ but that unsurprising result simply demonstrated that the transgene worked as advertised. Nothing suggests that transgenic salmon would continue growing well beyond the normal size of mature Atlantic salmon.²²

These are not minor quibbles either. Wilinska’s assessment of the purportedly dire environmental consequences flowing from the possibility of escape depends centrally on assertions about the transgenic salmon outcompeting its wild counterparts.²³ The scientific literature on this question offers far more complex and cautious predictions about what might happen should the AquAdvantage get out,²⁴ avoiding exaggerations founded upon misconceptions about the animal’s greater cold tolerance and adult size.²⁵ Wilinska also made several references to

21. See BRIEFING PACKET, *supra* note 18, at 65-66. On these pages, the FDA discussed—and reproduced part of a table from—a study published in a peer-reviewed journal: Shao Jun Du et al., *Growth Enhancement in Transgenic Atlantic Salmon by the Use of an “All Fish” Chimeric Growth Hormone Gene Construct*, 10 NATURE BIOTECH. 176 (1992). This did show dramatic size differences between GE salmon (averaging over forty-seven grams) and non-GE salmon (averaging over nine grams) fourteen months after the injection of the gene construct into some of the eggs. See *id.* at 178 tbl.1. That converts to roughly 0.1 lbs. vs. 0.02 lbs. Farmed non-GE salmon reach a market size of approximately eight lbs. after almost three years; GE salmon do so in roughly half the time but do not continue growing beyond normal adult size. See Martin, *supra* note 4, at 1.

22. See Alice McCarthy, *Genetically Modified Salmon Vying for a Spot at the Dinner Table*, 18 CHEM. & BIO. 1, 1 (2011) (“It does not make the fish grow to larger sizes, just more quickly.”); Erik Stokstad, *Engineered Fish: Friend or Foe of the Environment?*, 297 SCIENCE 1797, 1799 (2002) (“Although the fish don’t end up larger than normal farmed Atlantic salmon, they reach market size up to a year sooner.”).

23. See Wilinska, *supra* note 16, at 150 (“[A] mere 25% size advantage is enough to push smaller fish away from feeding and mating grounds. Thus, one can presume that AAS [AquAdvantage Salmon], which has a significant size advantage over its natural cousin, could decimate the natural salmon population.” (footnote omitted)); see also *id.* at 172 (alluding to “the catastrophic and irreversible environmental consequences in case of escape or malicious release”); *id.* at 176 (“FDA approval of AAS will trigger developments that are inestimable and dangerous . . . [It] has an impact on the health of millions and on ecosystems around the world.”).

24. See Alison L. Van Eenennaam & William M. Muir, *Transgenic Salmon: A Final Leap to the Grocery Shelf?*, 29 NATURE BIOTECH. 706, 708-09 (2011). For a recent paper that canvasses much of the prior literature and suggests the complexities in predicting environmental effects, see Robert N.M. Ahrens & Robert H. Devlin, *Standing Genetic Variation and Compensatory Evolution in Transgenic Organisms: A Growth-Enhanced Salmon Simulation*, 20 TRANSGENIC RESEARCH 583 (2011) (focusing on Coho salmon). For papers that consider the full range of genetic modifications in aquaculture and include discussions of human health effects as well as environmental concerns, see Olivier le Curieux-Belfond et al., *Factors to Consider Before Production and Commercialization of Aquatic Genetically Modified Organisms: The Case of Transgenic Salmon*, 12 ENVTL. SCI. & POL’Y 170 (2009); and Rosalee S. Rasmussen & Michael T. Morrissey, *Biotechnology in Aquaculture: Transgenics and Polyploidy*, 6 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 2 (2007).

25. One decade ago, similar misconceptions greeted the arrival of the “GloFish,” zebra danios with a gene inserted from sea anemone, which gives them a red glow that becomes luminescent under black light. See Noah, *supra* note 15, ¶¶ 61-64 & n.229; see also *Int’l Ctr. Tech. Assessment v. Leavitt*, 468 F. Supp. 2d 200 (D.D.C. 2007) (rejecting a judicial challenge to the FDA’s decision against subjecting the GloFish to premarket review as a new animal drug). In 2012, after having sold millions of GloFish, Yorktown Technologies introduced the “Electric Green Tetra,” another freshwater aquarium fish genetically engineered to fluoresce, leading some environmentalists to voice concerns because tetra can survive in cooler water than zebra danios. See Adrienne Appel, *Neon-Bright Fish Slip Through Regulatory Net: Now What?*, WASH. POST, Sept. 4, 2012, at E1 (reporting that GE tetra might become invasive in places such as south Florida). I’d be more worried about the giant Burmese pythons that have established themselves down there! See Beth Kassab, *State Should Put Bounty on Pythons*,

fears about heightened allergenicity.²⁶ The FDA dismissed this concern in a conclusory fashion precisely because no one takes it seriously in this context. Anyone allergic to salmon will avoid all types of salmon, and nothing suggests that the somewhat elevated levels of growth hormone in the AquAdvantage will cause any greater reaction in sensitive consumers.²⁷

B. Regulatory Classification and Review

Wilinska's criticism of the FDA's review process also springs from a number of fairly grievous missteps. She repeatedly referred to the briefing packet that the FDA prepared for the advisory committee as if it represented the company's submission to the agency, faulting its relative brevity (a mere 180 pages in length) and conclusory nature.²⁸ Instead, of course, as it makes clear from the outset, that document amounts to a summary of the FDA's internal reviews of the company's far more voluminous submissions.²⁹ Wilinska also complained that, unlike its European counterpart, the agency fails to undertake independent reviews of applications.³⁰ True, the FDA conducts little in the way of intramural research,³¹ but that hardly means it only engages in passive reviews of drug approval applications.³² The advisory committee meeting further exposed the agency's

ORLANDO SENT., Aug. 16, 2012, at A1 (referencing the recent capture of a record-setting specimen that measured more than seventeen feet long and carried eighty-seven eggs, just one among the tens of thousands of these invasive constrictors living in south Florida).

26. See Wilinska, *supra* note 16, at 171-72.

27. See BRIEFING PACKET, *supra* note 18, at 75; see also *Stauber v. Shalala*, 895 F. Supp. 1178, 1184-85 (W.D. Wis. 1995) (discussing similar conclusions that the agency reached when it approved a recombinant growth hormone drug for dairy cows). In contrast, the FDA takes allergenicity issues quite seriously when GE foods might express proteins ordinarily not found in an item. See Noah, *supra* note 15, ¶ 39 & n.143.

28. See Wilinska, *supra* note 16, at 149, 154, 171.

29. See BRIEFING PACKET, *supra* note 18, at ii; Andrew Pollack, *Modified Salmon Is Safe*, *F.D.A. Says*, N.Y. TIMES, Sept. 4, 2010, at B1; see also 21 C.F.R. § 14.33(f) (2012) (specifying the materials that the agency must compile for members of advisory committees).

30. See Wilinska, *supra* note 16, at 157 & n.90, 164, 168; see also *id.* at 154 ("In approving GM foods, the FDA looks only at research information provided by the applicant and does not conduct its own independent research . . ."); *id.* at 172 (suggesting that the agency "set up its own research body to evaluate the scientific conclusions submitted in the application").

31. See Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 444 (2008); David Warsh, *Needed: Science Czar for the FDA*, BOSTON GLOBE, July 20, 1997, at F1.

32. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1765-66, 1776-84, 1797-99, 1852-53 (1996); Gardiner Harris, *Where Progress Is Rare, the Man Who Says No*, N.Y. TIMES, Sept. 16, 2009, at A1 (profiling Dr. Richard Pazdur, the FDA's chief (and often vilified) reviewer of cancer drugs); see also *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008) (explaining that the agency "spends an average of 1,200 hours reviewing" applications for device approval); *id.* at 343 (Ginsburg, J., dissenting) (noting that "the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices"); Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 390-92 (1998) (discussing FDA review of food additive petitions); *id.* at 401-21 (detailing three case studies).

decision-making process to external scrutiny,³³ and the transgenic salmon has gotten plenty of attention from other expert panels as well.³⁴

Wilinska also faulted the FDA for relying on its arguably inapt authority over animal drugs. First, she questioned the agency’s decision insofar as it failed to invoke more directly relevant authority,³⁵ not recognizing that the guidance document she cited lacks any binding effect.³⁶ Second, she wondered “[w]ould the definition apply to a human who consumes AAS flesh and the rDNA with it? . . . [I]f rDNA is considered a ‘drug,’ does it stop being a drug before ingestion by consumers?”³⁷ One could say the very same thing about any drug intended for use in livestock that leaves residues. The simple answer to this apparent regulatory inconsistency: the new animal drug has no intended therapeutic (or structure-or-function) use in humans who later may consume it.³⁸

Requiring new animal drug approval (NADA) for GE livestock does not amount to fitting a square peg into a round hole.³⁹ The FDA has a long (and

33. See FDA, Notice of Meeting, VMAC, 75 Fed. Reg. 52,605 (Aug. 26, 2010); see also Lars Noah, *Scientific “Republicanism”: Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1054 (2000) (discussing the FDA’s reliance on advisory committees).

34. See WHITE HOUSE COUNCIL ON ENVTL. QUALITY (CEQ) & OFFICE OF SCI. & TECH. POL’Y (OSTP), GROWTH-ENHANCED SALMON, CASE STUDY NO. 1 (2001), available at http://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study2.pdf; see also Andrew Pollack, *Study Faults U.S. on Assessing Altered Fish*, N.Y. TIMES, Jan. 15, 2003, at A16 (discussing a report issued by the Pew Initiative on Food & Biotechnology, which echoed concerns of the National Research Council).

35. Wilinska, *supra* note 16, at 166–67.

36. See FDA, Notice of Availability, Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, 74 Fed. Reg. 3057 (Jan. 16, 2009); see also 21 U.S.C. § 371(h) (2006); 21 C.F.R. § 10.115(d) (2012); Lars Noah, *The FDA’s New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 119–20 (1997). The agency had made a draft available several months earlier and invited comments. See FDA, Notice of Availability, Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs, 73 Fed. Reg. 54,407 (Sept. 19, 2008); Jane Zhang, *FDA Plans Rules for Modified Food Animals—Guidelines to Focus on Safety Issues, Claims of Producers*, WALL ST. J., Sept. 19, 2008, at A12; see also Andrew Pollack, *Rules Near for Animals’ Engineering*, N.Y. TIMES, Sept. 18, 2008, at C15 (“The F.D.A. has been considering a policy for more than 15 years and its delay has irked both the industry and the critics of biotechnology.”).

37. Wilinska, *supra* note 16, at 165.

38. See Karen Kaplan & Thomas H. Maugh II, *For Genetically Modified Animals, Rules Are Ready: The FDA Unveils an Approval Process That Opens a Road from Farm to Market for the Creatures*, L.A. TIMES, Sept. 19, 2008, at A24 (“Technically, it is not the modified animals but the added DNA segments that are considered drugs. Realistically, however, the only way to regulate the property-changing DNA is to regulate the animal, said Eric Flamm, a policy advisor at the agency. . . . The new rules do not envision feeding the products to humans in the equivalent of clinical trials for drugs.”); cf. Noah, *supra* note 15, ¶ 58 & n.208 (discussing the genetic modification of animals to produce human drugs); Shankar Vedantam, *Drug Made in Milk of Altered Goats Is Approved*, WASH. POST, Feb. 7, 2009, at A5. One could, however, ask at exactly what point in the animal’s lifecycle does it stop qualifying as a drug: is it only upon death when harvested? Moreover, assuming a stable alteration of the germline (and that the transgenic animals manage to breed with one another in spite of efforts to prevent it), are the progeny also regulated as drugs?

39. See Graham M. Wilson, Note, *A Day on the Fish Farm: FDA and the Regulation of Aquaculture*, 23 VA. ENVTL. L.J. 351, 378 (2004) (“[T]he NADA process, with its safety, effectiveness and limited environmental impact requirements, may provide adequate pre-market review to evaluate most concerns regarding genetically modified animals. . . . [These will] undergo a much more intensive

sometimes controversial) history of creatively interpreting its statutory authority to regulate novel technologies.⁴⁰ Viewing a transgenic salmon's gene construct as analogous to an animal drug does not, however, seem particularly far-fetched: in theory, one could feed supplemental growth hormone to farmed Atlantic salmon.⁴¹ The transgene delivers the same protein more efficiently—and, to detractors of GE animals, it does so permanently (and perpetually into future generations).⁴²

Two decades ago, the licensing of a growth hormone product for injection into dairy cows created a similar stir. In 1993, after reviewing its safety and effectiveness, the FDA approved the new animal drug Posilac[®] (recombinant bovine somatotropin (rBST)).⁴³ Although critics focused their attacks on the use of genetic engineering to produce this drug, no one doubted that it would have to satisfy NADA requirements. Because the agency could detect no difference between milk from cows administered rBST and other milk, it did not require any special disclosure statement in labeling.⁴⁴

C. Demands for Disclosure

Wilinska, like other commentators before her, advocated consumer labeling to reveal that AquaBounty had genetically modified its salmon.⁴⁵ If allergenicity concerns had any merit, then the FDA would require some disclosure.⁴⁶ In the

screening process than comparable genetically engineered changes to plants.”). For a warning about regulatory tunnel-vision flowing from use of the NADA framework, see Martin D. Smith et al., *Genetically Modified Salmon and Full Impact Assessment*, 330 *SCIENCE* 1052, 1052 (2010) (“This approach fails to acknowledge that the new product’s attributes may affect total production and consumption of salmon. This potentially excludes major human health and environmental impacts, both benefits and risks.”); *id.* at 1053 (“This narrow focus may derive from FDA’s decision to treat GM fish as an animal drug rather than as a food; aggregate exposure to a drug is substantially shaped by disease incidence, whereas aggregate exposure to a food is driven more by market prices.”); *id.* (recognizing that the FDA could construe its authority more broadly to consider such factors).

40. See Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 *CORNELL L. REV.* 901, 917 (2008).

41. See Mark Fischetti, *A Feast of Gene-Splicing Down on the Fish Farm*, 253 *SCIENCE* 512 (1991) (reporting that efforts to feed synthetic growth hormone to farmed fish proved to be uneconomical).

42. See Jill U. Adams, *Biotech Animals: Scoping out a New Breed of Rules; Are Genetically Engineered Fish and Meat Coming Soon? We Examine the Food and Drug Administration’s Regulations*, *L.A. TIMES*, Jan. 26, 2009, at F1 (quoting Gregory Jaffe of the Center for Science in the Public Interest).

43. See 21 C.F.R. § 522.2112 (2012); see also FDA, Animal Drugs, Feeds, and Related Products; Sterile Somatotropin Zinc Suspension, 58 *Fed. Reg.* 59,946 (Nov. 12, 1993) (elaborating on this decision); *Stauber v. Shalala*, 895 F. Supp. 1178, 1191-92 (W.D. Wis. 1995) (rejecting a judicial challenge to the approval); Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 *COLUM. J. ENVTL. L.* 227 (1997) (defending the decision).

44. See FDA, Notice, Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Somatotropin, 59 *Fed. Reg.* 6279 (Feb. 10, 1994); see also *Stauber*, 895 F. Supp. at 1192-93 (rejecting challenge to the FDA’s decision against mandating rBST disclosure in labeling); Noah, *supra* note 15, ¶ 40 (elaborating); cf. *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 635-50 (6th Cir. 2010) (invalidating on First Amendment grounds one state’s prohibition on “rBST-free” labeling, but affirming in part a disclaimer requirement).

45. See Wilinska, *supra* note 16, at 169, 176; see also Wilson, *supra* note 39, at 387-94.

46. See FDA, GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RDNA CONSTRUCTS 15, 24 (2009), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndust>

absence of such concerns, however, what point would labeling serve other than an attempt to stigmatize the product in the minds of unsophisticated consumers?⁴⁷ Should farm-raised salmon also carry such labeling, so that buyers can understand the health and ecological consequences of their purchasing decisions,⁴⁸ and which way do those cut?⁴⁹ In light of currently unlabeled hazards associated with mercury and other pollutants in several types of seafood,⁵⁰ and outright fraud when identifying the species of fish for sale (which itself can pose health hazards due to unexpected exposures to *known* allergens and toxins),⁵¹ the fuss over labeling of GE salmon strikes me as seriously misplaced.⁵²

ry/UCM113903.pdf; *see also* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 178-79 & n.8 (D.D.C. 2000) (discussing similar FDA policy applicable to plant-derived foods).

47. *See* Amy Harmon & Andrew Pollack, *Battle Brewing over Labeling of Genetically Modified Food*, N.Y. TIMES, May 25, 2012, at A1. Arguably, it would do so in an entirely counterproductive fashion. *Cf.* Smith et al., *supra* note 39, at 1052 (“[T]he consequences of small differences in the nutritional and health profiles (if any) of one GM salmon compared with one non-GM salmon could be dwarfed by the public health benefits from substantial growth in the salmon market [because of reduced production costs] and from the eating of more salmon in place of other proteins such as beef.”); *id.* at 1052-53 (“[I]f GM salmon expands the aggregate salmon market, more consumers will eat more salmon and less of other proteins that are lower in omega-3 fatty acids, which would improve public health.”); Faye Flam, *Genetically Modified Salmon Could Be Sold in Two Years*, PHILA. INQUIRER, Oct. 4, 2010, at D1.

48. *See* Marian Burros, *Issues of Purity and Pollution Leave Farmed Salmon Looking Less Rosy*, N.Y. TIMES, May 28, 2003, at F1; Carolyn Butler, *It’s Good to Eat Fish, Especially If You Choose Where it Comes From*, WASH. POST, Nov. 20, 2012, at E4 (reporting concerns about drug residues, organic pollutants, and reduced nutritional value in farmed salmon and other fish, especially imports); Devra First, *Catch of the Day?: Wild Salmon Is Threatened, and the Farm-bred Alternative Raises Concerns*, BOSTON GLOBE, July 2, 2008, at E1. Sellers already must reveal that certain color additives are used in feed to make the salmon’s flesh pink. *See In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1173-74 (Cal. 2008).

49. *See* Elizabeth Cooney, *Fishing for Facts: Good for Your Health, or Toxic to You and the Environment: It’s Hard to Know What Fish to Eat*, BOSTON GLOBE, Dec. 14, 2009, at G6 (“There are good and bad ways to farm fish, just as there are good and bad ways to catch fish in the ocean.”); *see also* Claire S. Carroll, Comment, *What Does “Organic” Mean Now? Chickens and Wild Fish Are Undermining the Organic Foods Production Act of 1990*, 14 SAN JOAQUIN AGRIC. L. REV. 117, 138-39 (2004) (explaining why only farmed fish should qualify for organic labeling).

50. *See* *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 251-56 (3d Cir. 2008) (declining to find federal preemption of failure-to-warn claim where the FDA had failed to require mercury disclosures on tuna labels); Marian Burros, *More Testing of Seafood to Address Mercury Concerns*, N.Y. TIMES, Jan. 30, 2008, at F1.

51. *See* Beth Daley & Jenn Abelson, *From Sea to Sushi Bar, a System Open to Abuse*, BOSTON GLOBE, Oct. 24, 2011, at B1; Kim Severson, *Under Many Aliases, Mislabeled Foods Find Their Way to Dinner Tables*, N.Y. TIMES, Dec. 16, 2012, at A15; *see also* Kirk Johnson, *Survey Finds That Fish Are Often Not What Label Says*, N.Y. TIMES, Feb. 21, 2013, at A13 (“Almost two-thirds of the ‘wild’ salmon samples, for example, were found actually to be farmed Atlantic salmon, which is considered less healthy and environmentally sustainable.”).

52. For more on the agency’s general policies on the labeling of GE foods, *see* FDA, Notice of Availability, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 18, 2001); Carl R. Galant, Comment, *Labeling Limbo: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure*, 42 HOUS. L. REV. 125 (2005); Kelly A. Leggio, Comment, *Limitations on the Consumer’s Right to Know: Settling the Debate over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893, 948-50 (2001) (defending the FDA’s policy). California voters recently rejected an

D. Legislative Resistance: State and Federal

Wilinska cautioned, without any citation or further elaboration, that, “once the FDA allows it on the market, [AquAdvantage salmon] can be sold in each state regardless of the state’s residents’ opinion of GM foods.”⁵³ In fact, some states already have acted preemptively against transgenic fish: a few banned their use in aquaculture within state borders,⁵⁴ a few others required special permits for such uses,⁵⁵ and Alaska has mandated disclosures at retail.⁵⁶ Securing a federal license would not necessarily preempt the operation of such more restrictive state laws,⁵⁷ even if motivated primarily by protecting the economic interests of local fishermen.

Wilinska noted congressional resistance to the transgenic salmon, but she apparently failed to understand that unicameral passage of proposed legislation does not suffice.⁵⁸ Although House adoption of an appropriations rider may send a message to agency officials even if the Senate fails to concur, this signal emanated from the same deliberative body that kept pointlessly voting to repeal the health

initiative to require such labeling. See Andrew Pollack, *After Loss, the Fight to Label Modified Food Continues*, N.Y. TIMES, Nov. 8, 2012, at B4.

53. Wilinska, *supra* note 16, at 168-69. Although the failure to secure a required NADA would prevent retail sale of food derived from animals administered the drug, approval of an application does not amount to FDA licensure of the resulting food product; it simply removes the primary obstacle to its sale under federal law. An equally subtle distinction in this statute once befuddled members of the U.S. Supreme Court. See Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31, 54-55 & n.110 (2011).

54. See CAL. FISH & GAME CODE § 15007 (2012); WASH. ADMIN. CODE § 220-76-100 (2012) (“The use of transgenic fish . . . is prohibited.”); see also ALASKA STAT. § 16.40.100(d) (2012) (prohibiting the use of any Atlantic salmon in aquaculture); CAL. CODE REGS. tit. 14, §§ 671(c)(11), 671.1(a)(8) (2012) (determining that live transgenic aquatic animals pose a threat to native wildlife and cannot be imported or possessed without a permit issued by the Fish and Game Commission); Jane Kay, “*Frankenfish*” *Spawn Controversy: Debate over Genetically Altered Salmon*, S.F. CHRON., Apr. 29, 2002, at A4 (discussing initial legislative reaction in California and other states).

55. See MICH. COMP. LAWS ANN. §§ 286.874(9), 324.41305(a) (West 2012); MISS. CODE ANN. § 79-22-9(1)(d) (2012); see also OR. ADMIN. R. 635-007-0595 (2012) (barring “the release of transgenic fish into locations where such fish may gain access to wild fish populations”).

56. See ALASKA STAT. § 17.20.040(a)(14).

57. This question arose in connection with the FDA’s approval of the abortifacient drug previously known as RU-486, though state restrictions in that context would confront additional constitutional obstacles. See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 599-603 (2001); see also *Planned Parenthood v. Taft*, 444 F.3d 502 (6th Cir. 2006) (invalidating a state law that had attempted to prevent the off-label use of this drug at lower dosages or later in pregnancy).

58. See Wilinska, *supra* note 16, at 151 (“Congress voted in June 2011 to prohibit the FDA from approving GM salmon.”). House Amendment 449 to the “Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act” for Fiscal Year 2012, H.R. 2112, § 744, 112th Cong. (June 16, 2011), does not appear in the version enacted five months later, see Consolidated and Further Continuing Appropriations Act, 2012, Pub. L. No. 112-55, 125 Stat. 552 (2011), nor is the fate of the proposed rider mentioned in the accompanying conference report. Appropriations riders originating in House budget bills must secure concurrence by both the Senate and President. See Eenennaam & Muir, *supra* note 24, at 709 (“US legislation must be approved by both the House and the Senate for it to become law, and the Senate has not yet voted on this issue.”).

reform legislation.⁵⁹ The FDA probably took more seriously the correspondence that it had received from various members of both the House and Senate who expressed concerns about the agency’s review of AquaBounty’s NADA.⁶⁰ Conversely, in faulting the FDA for lacking the expertise to review environmental effects (and calling for legislation requiring that a different agency undertake such a task),⁶¹ Wilinska entirely failed to mention the fact that Congress had five years earlier (after satisfying requirements for bicameralism and presentment) already done so.⁶²

E. Supposed Procedural Irregularities

In a Note published in 2011, Michael Homer caught this admittedly minor statutory provision,⁶³ though he then proceeded to allege that the FDA had blatantly disregarded it, citing leaked e-mails from some civil servants accessed by a public interest group.⁶⁴ There is far less here than meets the eye,⁶⁵ and I

59. See Rosalind S. Helderman, *House Again Votes to Repeal Health-Care Law in Symbolic Gesture*, WASH. POST, July 12, 2012, at A4 (“It was the 33rd time that Republicans have moved to repeal all or parts of the legislation since the party took control of the House in January 2011.”).

60. See Wilinska, *supra* note 16, at 166; see also Debra M. Strauss, *The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply*, 48 IDAHO L. REV. 267, 298 (2012) (“[M]ore than forty members of Congress sent letters requesting the FDA halt approval [of AquaAdvantage.]”); *id.* at 297-99 (discussing House passage of the rider, and noting the introduction of a pair of bills in the Senate that failed to pass); Andrew Seidman, *Modified Salmon Faces Resistance: A Group of Senators Is Asking the FDA to Nix the Approval Process of the Genetically Altered Fish as Food*, L.A. TIMES, July 31, 2011, at A14; cf. Appel, *supra* note 6, at C5 (noting that three members of the congressional delegation from Massachusetts (home of AquaBounty) wrote the FDA Commissioner to urge that the agency press ahead). In the face of this congressional pressure, the USDA rescinded a \$500,000 grant that it had made to AquaBounty. See Pollack, *supra* note 6, at B1.

61. See Wilinska, *supra* note 16, at 164-65, 172-73.

62. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 1007, 121 Stat. 823, 969-70 (calling on the FDA to consult with the National Marine Fisheries Service (NMFS) in order “to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks”).

63. See Michael Bennett Homer, Note, *Frankenfish . . . It’s What’s for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & SOC. PROBS. 83, 112 (2011). In addition, as contrasted with Wilinska’s article, Homer showed a better understanding of the technology and its potential benefits, see *id.* at 107-09, offered a somewhat more nuanced account of the environmental threats, see *id.* at 110-12, 116, understood the nature of the briefing packet supplied to the advisory committee, see *id.* at 120, and recognized that FDA approval would not prevent states from imposing restrictions, see *id.* at 136, while his discussion of allergenicity and other suspected health risks, see *id.* at 124-29, struck me as even more over the top.

64. See *id.* at 114-15, 117-19; *id.* at 115 (“The e-mail describing this letter also suggested that the FDA had failed to consult with NMFS as required by Section 1007 of the FDAAA.”); *id.* at 114 n.234 (explaining that Food & Water Watch got these through a Freedom of Information Act request); see also *id.* at 86 (“The approval process has provoked fierce criticism from countless advocacy groups . . .”). Why would the FDA so blatantly disregard such a specific statutory requirement and invite judicial reversal of its decision?

65. An account of these documents published in a trade journal (the only published account that I could find) revealed that some lower-level employees at the Department of Interior’s Fish & Wildlife Service (FWS) complained about the FDA’s failure so far to consult with them as purportedly required under the Endangered Species Act, while the public interest group’s press release had alleged on this basis a failure to consult with NMFS. See Stephen Clapp, *Fish & Wildlife Service Officials Question*

previously have criticized authors and law journals for their growing willingness to depend on such unreliable source material.⁶⁶ Homer also cited surveys sponsored by these same public interest groups as demonstrating that “the American public overwhelmingly feels that the FDA should not introduce GE salmon to the marketplace.”⁶⁷ Similarly, we are told, the FDA received an avalanche of adverse public comments,⁶⁸ but this reflects nothing more than a letter-writing campaign orchestrated by these consumer advocacy organizations.⁶⁹

More generally, Homer offered an overly negative account of the NADA review.⁷⁰ For instance, he suggested that the FDA lacks the statutory authority to reject an application solely on environmental grounds,⁷¹ echoing an oft-repeated charge that has no basis in fact.⁷² Homer also questioned the failure to route the

GE Salmon Approval Process, FOOD CHEM. NEWS, Nov. 19, 2010, at 1. In any event, it eventually got around to getting the blessing of its sister agencies. See Pollack, *supra* note 10, at B1 (reporting that, in the draft EA it released at the end of 2012, the FDA concluded that the transgenic salmon “would have no effect on endangered species” and that NMFS and FWS “did not disagree”).

66. See, e.g., Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 882 n.181 (2009); see also Noah, *supra* note 15, ¶ 62 (noting that one author’s “basis for this assertion demonstrates nothing other than the fact that several self-anointed public interest groups stand ready to engage in scare mongering to suit their own purposes”). Historically, the FDA has been far more responsive to the griping by these groups than they care to admit. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2154-55 (2000) (“[H]ealth and safety agencies like the FDA have become more beholden to groups that purport to represent the public interest [C]onsumer groups have nothing to lose by aggressively pursuing their agenda and vocally criticizing the agency when they fail to prevail.”).

67. Homer, *supra* note 63, at 135 (adding that “most Americans have said they would not eat any seafood that had been genetically engineered”). But cf. Martin, *supra* note 4, at 1 (“45 percent of those surveyed [in 2002 by the Pew Initiative on Food & Biotechnology] thought that genetically modifying fish to reduce the cost was a good idea; 43 percent thought it was a bad idea”); Andrew Pollack, *Genetically Altered Salmon Set to Move Closer to Dinner Table*, N.Y. TIMES, June 26, 2010, at A1 (“How consumers will react is not entirely clear. Some public opinion surveys have shown that Americans are more wary about genetically engineered animals than about the genetically engineered crops now used in a huge number of foods. But other polls suggest that many Americans would accept the animals if they offered environmental or nutritional benefits.”).

68. See Homer, *supra* note 63, at 109.

69. See Stephen Clapp, *FDA Issues Final Guidance to Industry on Transgenic Animals*, FOOD CHEM. NEWS, Jan. 19, 2009, at 1. A pile of signed boilerplate postcards amounts to little more than a petition with a bunch of signatures. Cf. Marian Burros, *Chefs Join Campaign Against Altered Fish*, N.Y. TIMES, Sept. 18, 2002, at F1 (“The boycott [pledged by 200 chefs and grocers] is being led by the Center for Food Safety Other environmental groups have signed on to support the boycott, along with 42,000 individuals.”). For a more charitable take on this form of public participation in rulemaking, see Nina A. Mendelson, *Should Mass Comments Count?*, 2 MICH. J. ENVTL. & ADMIN. L. 173 (2012).

70. See Homer, *supra* note 63, at 86 (“The approval process has thus far been marred by secrecy and institutional incompetence by the FDA”); *id.* at 110 (“[T]he FDA’s handling of the approval process for AquAdvantage salmon has demonstrated the validity of the public’s concerns . . . [and] the flaws in the current regulatory scheme for GE animals.”); *id.* at 112 (“Critics of the approval process for GE animals worry that the FDA is not competent to adequately address these environmental risks.”); *id.* at 119 (“[T]he FDA is either incapable of evaluating—or unwilling to properly evaluate—the environmental risks associated with approving GE animals.”).

71. See *id.* at 105, 112, 114 n.232; see also Justin Gillis, *Old Laws, New Fish: Environmental Regulation of Gene-Altered Foods Is a Gray Area*, WASH. POST, Jan. 15, 2003, at E1.

72. See *Envtl. Defense Fund, Inc. v. Mathews*, 410 F. Supp. 336, 338 (D.D.C. 1976) (“NEPA provides FDA with supplementary authority to base its substantive decisions on all environmental

issue to the agency’s Center for Food Safety & Applied Nutrition (CFSAN), “the FDA center typically responsible for food safety evaluations.”⁷³ Evidently he failed to realize that the agency’s Center for Veterinary Medicine (CVM) has far more experience in dealing with food safety issues related to drug residues in livestock, perhaps imagining incorrectly that it just deals with drugs for pets.⁷⁴ Clearly, Homer did not recognize that CFSAN suffers from far more serious resource constraints than any other FDA division.⁷⁵ Indeed, one persistent critic of the agency’s tendency for overregulation—a scientist who had served as the founding director of the FDA’s Office of Biotechnology until stepping down in 1993—urged CFSAN review of the transgenic salmon precisely because this would have avoided the delays caused by the “onerous” NADA process.⁷⁶ Of course, calls for shifting primary responsibility to CFSAN at this late date aim solely to make matters worse rather than smooth the way for future applicants.⁷⁷

considerations including those not expressly identified in the FDCA and FDA’s other statutes.”); Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 314 n.83 (1994); Andrew C. Revkin, *F.D.A. Considers New Tests for Environmental Effects*, N.Y. TIMES, Mar. 14, 2002, at A20.

73. Homer, *supra* note 63, at 106 (“This is a curious regulatory fit for prospective GE animals intended for human consumption.”); *see also id.* at 130 (“Stripping the CVM of its jurisdiction and giving authority instead to . . . CFSAN would certainly be a logical improvement.”). *But see* Eenennaam & Muir, *supra* note 24, at 709 (calling such suggestions ironic because “[t]his is the very regulatory path that was eschewed after more than a decade of deliberations and numerous opportunities for public input”).

74. Cf. Mark Klock, *A Modest Proposal to Rename the FDA: Apologists for Carcinogens, Teratogens, and Adulterated Drugs*, 36 ARIZ. ST. L.J. 1161 (2004) (lambasting the agency for its failure to regulate drugs used with ornamental fish).

75. *See* Hutt, *supra* note 31, at 454 (explaining that CFSAN is “absolutely destitute”); *id.* at 459 (discussing CFSAN’s “disintegration”); Noah & Merrill, *supra* note 32, at 421-22 & n.409, 433 & n.458; William Neuman, *On Food Safety, a Long List but Little Money*, N.Y. TIMES, Aug. 23, 2011, at B1; *see also* Dina ElBoghdady, *Taking New Look at Food Inspection*, WASH. POST, Mar. 5, 2012, at A1; Monica Eng, *Who Tests the Safety of New Ingredients in Food?: Too Often, U.S. Lets Manufacturers Make the Call on Their Own Products, Critics Say*, CHI. TRIB., Aug. 26, 2012, at A1.

76. *See* Henry I. Miller, *The Use and Abuse of Science in Policymaking: The Regulation of Biotechnology Provides a Cautionary Tale of Politicized Science*, REGULATION, Summer 2012, at 26, 32-33; Henry I. Miller, Op-Ed., *Catch of the Day*, L.A. TIMES, Sept. 14, 2010, at A13 (“The FDA’s existing approach to [GE] foods should have been applied to genetically engineered animals. But characteristically, regulators chose the most risk-averse and burdensome approach.”); *see also* Justin Gillis, *Biotech Regulation Falls Short, Report Says: Pew Study Calls for Better Oversight*, WASH. POST, Apr. 1, 2004, at E3 (reporting that the FDA’s chief counsel at the time had balked at expansively construing the NADA provisions to cover GE animals, preferring the informal consultation approach used by the agency for biotech crops); Andrew Pollack, *Without U.S. Rules, Biotech Food Lacks Investors*, N.Y. TIMES, July 30, 2007, at A1 (reporting that similar sentiments stalled the issuance of guidelines to use the NADA rather than weaker food additive pathway).

77. Long after the close of the original comment period, public interest organizations filed a citizen petition that reiterated their objections and demanded FDA review under the process used for food additives. *See* Appel, *supra* note 6, at C5 (“On Feb. 7, [2012,] the Center for Food Safety and two other consumer advocacy groups petitioned the FDA to begin a new safety review. That set in motion a process that requires the FDA to respond to the request before it makes any decision about approving the fish.”). More than a decade earlier these same parties had filed a similar petition with the agency. *See* Andrew Pollack, *Groups Seek Moratorium on Alteration of Salmon*, N.Y. TIMES, May 9, 2001, at A25. Tardy involvement in licensing proceedings represents a tactic that such groups have used before in order to stall final FDA action. *See* Lars Noah, *Sham Petitioning as a Threat to the Integrity of the*

Homer credited criticisms that the public had received access to the briefing packet and other documents only two weeks ahead of the committee meeting, allegedly deviating from the two to three months typical before advisory committee meetings involving human drugs or devices.⁷⁸ Instead of taking Consumers Union's word for it, he should have consulted the *Code of Federal Regulations*, which plainly provides otherwise.⁷⁹ In fact, the FDA offered greater opportunities for public participation than normal in such licensing proceedings.⁸⁰ Homer also echoed complaints that the meeting took place on a weekend and in a "remote" location,⁸¹ failing to appreciate that most advisory committees meet adjacent to FDA headquarters just outside of Washington, D.C.⁸² By all accounts, and in spite of these purported obstacles to public participation, opponents had an ample

Regulatory Process, 74 N.C. L. REV. 1, 66-67 n.272, 68 & n.278 (1995); cf. Monica Eng, *Activists Taking Their Beefs Online: Battle Against "Pink Slime" Shows Growing Power of Social Media to Transform Nation's Food Policy*, ORLANDO SENT., Apr. 1, 2012, at A15 ("In the past, food activists relied almost solely on citizen petitions to the FDA, though these were rarely as high profile or effective as the latest campaigns.").

78. See Homer, *supra* note 63, at 121; see also *id.* at 122 n.283 (claiming that announcements of advisory committee meetings in the *Federal Register* normally give at least two months advance notice); Andrew Zajac, *FDA Panel to Vote on Modified Salmon: It Grows Faster, Eats Less and Has Spawned Debate About Altering Animals Used for Food*, L.A. TIMES, Sept. 19, 2010, at A22 ("The FDA's apparent readiness to approve the AquaBounty salmon has inflamed a coalition of consumer, environmental, animal welfare and fishing groups, which accuse the agency of basing its judgment on data compiled from small samples supplied by the company, rushing the public portion of the review process and disclosing insufficient information about the fish.").

79. See 21 C.F.R. § 14.20(a) (2012) (providing for notice "at least 15 days in advance of a meeting" and suggesting typically no more than one month).

80. See Eenennaam & Muir, *supra* note 24, at 707 (calling it "an unprecedented move toward increased transparency"); Andrew Zajac, *No Agreement Near on Salmon Labeling; FDA Hearing Is Split over Who Should Alert Consumers That a Fish Is Genetically Altered*, L.A. TIMES, Sept. 22, 2010, at A20. It held a public hearing in tandem with the advisory committee meeting to address labeling questions. See FDA, Notice of Public Hearing, Labeling of Food Made from AquAdvantage Salmon, 75 Fed. Reg. 52,602 (Aug. 26, 2010); Andrew Pollack, *F.D.A. Hearing Focuses on the Labeling of Genetically Engineered Salmon*, N.Y. TIMES, Sept. 22, 2010, at B3.

81. See Homer, *supra* note 63, at 121-22. He also echoed a common objection about fragmented statutory authority, citing my biotech article solely for this proposition, see *id.* at 101 & n.133, evidently not noticing that I had in that very paragraph taken pains to refute this common complaint, see Noah, *supra* note 15, ¶ 9.

82. See 21 C.F.R. § 14.22(b) ("All advisory committee meetings will be held in Washington, DC, or Rockville, MD, or the immediate vicinity, unless the Commissioner receives and approves [under specified criteria] a written request from the advisory committee for a different location."); cf. Noah, *Rewarding Regulatory Compliance*, *supra* note 66, at 2150 ("Now let us leave the comforting confines of the Beltway to discover how drug labeling is regulated in the heartland."). Technically, Rockville lies just outside of the Beltway, but it hardly qualifies as a remote location, while the suggestion to hold hearings at sites near fishing interests very well might be far off the beaten path. On rare occasions, the FDA has held public hearings or town hall meetings at locations around the country. See, e.g., Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 756-57 (2003) (describing public hearings about GE crops that the FDA took on the road during 1999); Marlene Cimons, *New U.S. Seafood Safety Rules Expected to Be Unveiled*, L.A. TIMES, Jan. 21, 1994, at A18 ("The FDA plans to hold a series of public meetings in nine cities, including Los Angeles, during the next two months to discuss the proposals.").

opportunity to put in their two cents worth.⁸³

Finally, Homer objected to the composition of the advisory committee that reviewed the transgenic salmon, alleging a lack of expertise and conflicts of interest on the basis of a single blog posting and letter from a public interest group.⁸⁴ As he conceded, however, the committee hardly rubber-stamped the agency’s tentative conclusions.⁸⁵ Nonetheless, Homer exaggerated the significance of stray remarks made by individual members,⁸⁶ evidently failing to notice that the official report issued by the committee shortly thereafter largely had endorsed the FDA’s position.⁸⁷

83. See Mary Clare Jalonick, *Genetically Modified Salmon Engineered Food Fight: FDA Panel Says Fast-Growing Fish Safe, but Opponents Want Approval Put on Ice*, HOUS. CHRON., Sept. 21, 2010, at A1; Lyndsey Layton, *Fears over Modified Salmon Voiced*, WASH. POST, Sept. 21, 2010, at A4.

84. See Homer, *supra* note 63, at 123-24; see also *id.* at 130-31 (crediting this group’s interpretation of the 2009 guidance document as a direct outgrowth of heavy lobbying by the biotech industry). He also relied on this same public interest group’s criticism of the health effects data. See *id.* at 125-27. For a pointed rebuttal by a pair of scientists with no apparent axe to grind (apart from their obvious distaste for the “alarming” and “frightening” food safety claims made by these consumer advocates), see Eenennaam & Muir, *supra* note 24, at 707-08; *id.* at 708 (“[T]he AquAdvantage salmon food safety studies do not suggest that the fastgrowth phenotype is associated with any food safety concerns.”); see also Miller, *The Use and Abuse of Science in Policymaking*, *supra* note 76, at 30 (objecting that the media “consistently len[t] exaggerated credibility and ink to the alarmist claims of anti-biotech activists”). As it happens, the consumer advocate who served on the advisory committee, Greg Jaffe of the Center for Science in the Public Interest, “saw no cause for alarm based on the data he reviewed.” Mestel, *supra* note 7, at A1. But see Homer, *supra* note 63, at 123 & n.294 (dismissing Jaffe as a lawyer who previously had expressed support for biotechnology in agriculture).

85. See Homer, *supra* note 63, at 124 (“Despite the questionable composition of the Committee, the VMAC still found ample reason to criticize the NADA, as well as the FDA’s review of the application.”); *id.* at 128 (“Despite the VMAC’s stacked membership . . . , [it] nonetheless concluded that the FDA should pursue a more rigorous analysis of the GE salmon’s possible health effects and environmental risks before granting approval.”); Andrew Zajac et al., *Panel Tackles Salmon Engineering: One Member Says FDA Will Likely OK Genetically Modified Fish, but Not Soon*, CHI. TRIB., Sept. 21, 2010, at A13.

86. See Eenennaam & Muir, *supra* note 24, at 709 (objecting to the fact that advocacy groups who wrote the FDA Commissioner to demand the preparation of an EIS were “selecting excerpts from the public meetings to support their contention,” adding that “it has been suggested that NEPA requirements are being used by some environmental groups (for example, the Center for Food Safety) as a legal approach to slow or prevent regulatory approvals of products to which they are opposed”); cf. Noah, *supra* note 66, at 871 & n.135 (criticizing a federal appellate court for giving “exaggerated significance to the comments of the advisory committee, disregarding the fact that the FDA had undertaken a lengthy internal review (and had no obligation to abide by the committee’s recommendations) and that the committee had in the end recommended approval,” thereby “turn[ing] a complex risk-utility judgment, using data from less than ideal clinical trials, into a no-brainer by allowing the jury to conclude that the drug was totally ineffective”).

87. See David Senior, *VMAC Meeting: September 20, 2010, Chairman’s Report* (Oct. 14, 2010), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicine/AdvisoryCommittee/UCM230467.pdf>. For instance, on the question of food safety, “[t]he committee deemed the studies selected to evaluate this question to be overall appropriate and a large number of test results established similarities and equivalence between AquAdvantage Salmon and Atlantic salmon.” *Id.* at 2. As for environmental concerns, “[a]lthough the committee recognized that the risk of escape from either facility could never be zero, the multiple barriers to escape at both the PEI [Prince Edward Island] and Panama facilities were extensive [I]t is the committee’s understanding that both facilities will be regulated as ‘drug manufacturing’ locations, which carries a high level of FDA

F. Exaggerated Environmental Concerns

More than anything else, critics fear that transgenic salmon would manage to escape. To be sure, non-GE farmed fish routinely get out from aquaculture net pens in the open water,⁸⁸ and their selective breeding may threaten native salmon.⁸⁹ Wild populations of Atlantic salmon face all manner of threats already,⁹⁰ and some attempted fixes for dwindling salmon are environmentally irresponsible.⁹¹ In what way would transgenic salmon make things any worse? Critics routinely invoke the “Trojan gene” hypothesis, which suggests that GE fish might enjoy a mating advantage but otherwise lack fitness in the wild, resulting after several generations

scrutiny.” *Id.* at 3; *see also* Jeffrey L. Fox, *Transgenic Salmon Inches Toward Finish Line*, 28 NATURE BIOTECH. 1141, 1142 (2010); Pollack, *supra* note 6, at B1 (“[A] committee of outside advisers, while finding various faults with the F.D.A. analysis, more or less endorsed its conclusion that the fish would be safe for consumers and the environment.”). Homer cited this document only twice (far less often than the transcript of the meeting), and only for purposes of highlighting caveats or suggestions for possible avenues of future research, *see* Homer, *supra* note 63, at 125 & n.308 (noting a suggested need for an environmental impact statement if the sponsor planned on using additional facilities, failing to include in his quotation from page 3 of the *Chairman’s Report* the fact that only “certain committee members raised” this concern), and then completely exaggerating the point, *see id.* at 128 & n.326 (claiming that it wanted “a more rigorous analysis of the GE salmon’s possible health effects and environmental risks *before granting approval*” (emphasis added)).

88. In 2000, a storm allowed more than 100,000 salmon to escape a fish farm in Maine. *See* Stokstad, *supra* note 22, at 1797; *see also* U.S. Pub. Interest Research Grp. v. Atlantic Salmon of Me., LLC, 257 F. Supp. 2d 407, 412, 420-22, 434, 435-36 (D. Me.) (holding that farmed salmon threatened native populations upon escape and qualified as a “pollutant” under the Clean Water Act, and granting a permanent injunction against the stocking of net pens with non-native salmon), *aff’d*, 339 F.3d 23, 28-30, 33 (1st Cir. 2003); *id.* at 421-22, 428 n.17 (discussing the prospect of future escapes of transgenic salmon); Homer, *supra* note 63, at 118 n.262 (“[G]rowing GE salmon in ocean net-pens in Maine was banned by the FWS and NMFS in order to ‘eliminate the potentially adverse disease and ecological risks posed by the use of transgenic salmonids in aquaculture.’”). Imagine what a weather event with a more menacing name could do. *See* Yamiche Alcindor & Doyle Rice, *East Coast Braces for “Frankenstorm,”* USA TODAY, Oct. 26, 2012, at 3A.

89. *See* Eenennaam & Muir, *supra* note 24, at 709 (“In principle, there is no difference between the types of concerns and potential magnitude of the environmental risks associated with the escape of GE fish and those related to the annual escape of the millions of fish that are genetically divergent from native populations in other ways”); *see also* William K. Hershberger et al., *Genetic Changes in the Growth of Coho Salmon (Oncorhynchus kisutch) in Marine Net-Pens, Produced by Ten Years of Selection*, 85 AQUACULTURE 187, 195 (1990) (finding “a large increase in growth,” comparable to other selective breeding efforts that reported growth gains of, for instance, “30% per generation for Atlantic salmon”); Stokstad, *supra* note 22, at 1797 (“Farmed salmon are big, hungry, and aggressive.”); Alexei Barrionuevo, *Virus Kills Chile’s Salmon and Indicts Its Fishing Methods*, N.Y. TIMES, Mar. 27, 2008, at A6.

90. *See* 50 C.F.R. §§ 17.11(h), 224.101(a) (2012); *see also* Endangered and Threatened Species: Final Endangered Status for a Distinct Population Segment of Anadromous Atlantic Salmon (*Salmo salar*) in the Gulf of Maine, 65 Fed. Reg. 69,459 (Nov. 17, 2000) (setting forth the basis for this listing), *amended*, 74 Fed. Reg. 29,344, 29,385 (June 19, 2009); Joan Nathan, *Don’t Look for Nova in Nova Scotia*, N.Y. TIMES, Sept. 12, 2012, at D3 (reporting that, in the vicinity of Nova Scotia, “Atlantic salmon were fished out 30 years ago,” and that, in New York markets, “salmon today comes mostly from farms off the coasts of Norway, Chile, Scotland and Canada”).

91. *See* Henry Fountain, *A Rogue Climate Experiment Has Ocean Experts Outraged*, N.Y. TIMES, Oct. 19, 2012, at A1 (reporting the unauthorized and roundly criticized dumping of 100 tons of iron dust into the north Pacific Ocean done partly to help the local salmon population recover by triggering a plankton bloom).

in the extinction of the native species.⁹² These critics generally fail to mention that the scientist who originally proposed this idea had testified before the VMAC to explain its inapplicability to the transgenic salmon under review.⁹³

Indeed, transgenic salmon may offer distinct ecological advantages over current fish farming. AquaBounty planned to use landlocked containment facilities distant from potential tributaries.⁹⁴ Critics made much of the fact that the company eventually hoped to sell eggs for other aquaculture firms to raise, which would differ from the facilities specified in its application.⁹⁵ The sponsor would, however, first have to secure supplemental approval from the FDA.⁹⁶ Are we to assume that AquaBounty plans to violate the limited terms of its requested license—in that case, why would it not already have proceeded with its plans using those non-U.S. facilities even in the absence of any FDA approval?⁹⁷ Moving toward domestic production in the future would help to reduce its carbon footprint,⁹⁸ and careful selection of sites for inland tanks—not Portland (on either coast), but Tulsa or Omaha for example—would minimize ecological risks in the event of any escape.

AquaBounty also proposed to adopt mechanisms of “biological containment” by creating only female fish and inducing sterility through triploidy,⁹⁹ though these would offer no guarantee against the risk of interbreeding in the event of escape.¹⁰⁰

92. See, e.g., Homer, *supra* note 63, at 111.

93. See Eenennaam & Muir, *supra* note 24, at 708-09; *id.* at 709 (explaining that this testimony “appears to have been largely ignored”); Peter Fimrite, *Activists Resist Bioengineered Salmon*, S.F. CHRON., Dec. 27, 2010, at A1; see also Homer, *supra* note 63, at 111 n.211 (noting this testimony).

94. See Eenennaam & Muir, *supra* note 24, at 707 (AquaAdvantage salmon would be “produced at a single facility in Canada, and grown out in a fresh water, land-based culture facility in Panama. Both locations were inspected by FDA and featured simultaneous, multiple and redundant physical and geographical containment measures, effectively precluding concerns about the possibility of transgenic fish escape.”); *id.* at 708 (concluding that the risk of escape “was seen to be extremely small” in light of “land-based production with physical confinement barriers (screens)” and “thermally lethal lake and stream temperatures downstream from the proposed production facility in Panama—and high salinity of waters surrounding the Canadian location”).

95. See Homer, *supra* note 63, at 108, 118; Wilinska, *supra* note 16, at 163, 171.

96. See Pollack, *supra* note 10, at B1 (“[O]ther facilities for growing the salmon would require separate approvals.”).

97. Cf. Kaufman, *supra* note 4, at A1 (“Because of a loophole in the rules governing the importing of animal drugs, engineered salmon raised abroad could . . . be imported if the FDA finds them to be safe for human consumption before tackling the more complex and time-consuming process of determining environmental safety.”). If one believes the critics, then the supposed ambiguity over the agency’s jurisdiction suggests that the folks at AquaBounty were chumps to ask for a NADA in the first place. Cf. Gillis, *supra* note 71, at E1 (explaining the company’s tactical choice); Pollack, *supra* note 34, at A16 (same).

98. See Clausen & Longo, *supra* note 14, at 245 (“[T]he zigzag transport from Canada to Panama to the US adds tremendous food miles to an already energy-intensive production scheme.”).

99. See Eenennaam & Muir, *supra* note 24, at 707 (“[A]s an extra precaution, additional levels of biological containment were proposed, including the production of 100% female fish and triploidy induction with an average success rate of 99.8% (98.9-100%). All-female fish are unable to interbreed with each other, and triploidy results in sterility.”); see also Andrew Pollack, *No Foolproof Way Is Seen to Contain Altered Genes*, N.Y. TIMES, Jan. 21, 2004, at A10. Producing only females also happens to help AquaBounty guard against unlicensed reproduction of its GE salmon.

100. See Homer, *supra* note 63, at 118 (quoting a 5% failure rate); Wilinska, *supra* note 16, at 150, 164, 172 (same).

As compared to traditionally farmed salmon, however, the transgenic salmon should pose less of a threat: inland tanks raise costs, but the efficiencies promised by the AquaAdvantage (in speed to market and improved feed conversion) would offset these, offering the possibility that they could outcompete in the marketplace farmed salmon raised in net pens, displacing that far more deleterious method of production.¹⁰¹ If nothing else, the availability of fast growing and ultimately cheaper transgenics may counterbalance overfishing and the depletion of native stocks,¹⁰² more than offsetting any speculative risk of escapees intermingling with their wild relatives.

Calling some of the published commentary incompetent and unduly alarmist hardly means that we have nothing to learn or fear from transgenic salmon. Indeed, while AquaBounty's NADA poses relatively straightforward questions, other GE animals under development very well could confound regulatory officials in the future.¹⁰³ Although transgenic livestock should not present the same sorts of

101. See Kaufman, *supra* note 4, at A1 (“Even some critics of genetically modified salmon acknowledge that [a shift to inland tanks] could protect wild salmon from damage being done by fish farming.”); Pollack, *supra* note 10, at B1 (“AquaBounty has argued that the faster growth of its fish makes it feasible to rear them in inland tanks rather than ocean pens, reducing the environmental impact.”); Andrew Zajac, *Is Engineered “Frankenfish” Coming to the Nation’s Table?: AquaBounty Seeks Approval for Salmon That Reaches Market Weight in Half the Usual Time*, L.A. TIMES, Aug. 14, 2010, at B1 (AquaBounty “hopes to avoid the pollution, disease and other problems associated with saltwater fish farms by having its salmon raised in inland facilities.”). Then again, if transgenic salmon reduce production costs and increase market demand, this might magnify the adverse effects from expanded aquaculture operations and threaten to deplete wild stocks of fatty fish used to produce fish oil for salmon feed. See Smith et al., *supra* note 39, at 1053. If, however, that reduces consumption of beef, see *id.* at 1052-53, the net environmental effects may well remain favorable. Tissue engineers have begun serious work on the real solution. See Scott Canon, *Meat from a Petri Dish: Credible or Inedible? Proponents See Ecological, Ethical, Financial Benefits*, CHI. TRIB., Sept. 19, 2011, at A14; Tiffany Hsu, *Burger Made of Lab-Grown Meat Is in the Works*, L.A. TIMES, Feb. 21, 2012, at B4. No doubt the luddites and livestock lobbies will rail against such advances as well.

102. See Eenennaam & Muir, *supra* note 24, at 709 (“Wild-caught fish deplete the oceanic stocks and do not present a long-term, ecologically sustainable solution to rising global fish demand. One of the benefits associated with the development of GE fish for aquaculture may well be in helping to reduce recognized pressure on wild fish populations.”); Rasmussen & Morrissey, *supra* note 24, at 3 (“Use of biotechnology in aquaculture has the potential to alleviate these predicted fish shortages and price increases by enhancing production efficiency”); Devra First, *Tipping the Scales Genetically: To Its Critics, Fast-growing Modified Salmon Is a Threat; To Its Mass. Creators, It Is a Fix to Shortages and Overfishing*, BOSTON GLOBE, Sept. 23, 2010, at B1. Because transgenic salmon reach market size using less feed, they also could reduce pressures on wild populations of the smaller fish used to produce their feed. See Kenneth R. Weiss, *It Came from the Gene Lab: Faster-growing Salmon? Aquarium Fish That Glow in the Dark? Regulators Are at a Crossroads over Bioengineered Animals*, L.A. TIMES, May 14, 2003, at A1 (“Raising salmon on less food is an important advance. It now takes about 2½ pounds of wild fish ground into meal to produce one pound of farmed salmon. For that reason, feeding salmon on those proliferating farms contributes to the overfishing that is rapidly depleting the world’s oceans.”).

103. See Homer, *supra* note 63, at 91 (“[D]ozens of other GE animals are in development. One such animal is ‘Enviropig,’ a pig engineered to better digest phosphates, making it more environmentally friendly and less expensive to feed. Livestock such as cows, chicken, pigs, and goats, and numerous varieties of farmed fish, are being genetically engineered to enhance disease resistance and other qualities.” (footnotes omitted)); *id.* at 91-92 (“For example, researchers are currently developing dairy cows resistant to mastitis, cows resistant to bovine spongiform encephalopathy, or ‘mad cow disease,’ and chickens resistant to avian flu. Other food animals are being developed with enhanced nutritional

environmental concerns,¹⁰⁴ they might pose more difficult food safety questions.

II. LICENSING HELD HOSTAGE TO POLITICS

More than two years have elapsed since the FDA held its advisory committee meeting to review its tentative conclusions favoring approval of the transgenic salmon. That unquestionably amounts to an unusual delay,¹⁰⁵ which may discourage other innovation in the field.¹⁰⁶ In the case of transgenic salmon, the agency may have taken the advisory committee’s feedback seriously and decided to revisit issues that it previously had viewed as nearly settled. More likely, it took seriously the pressure emanating from members of Congress who had—hook, line, and sinker—bought into the charges leveled by opponents,¹⁰⁷ and consumer

values for humans, such as hens genetically engineered to lay low-cholesterol eggs.” (footnotes omitted); Mestel, *supra* note 7, at A1 (providing updates on some of these and other efforts).

104. Cf. Jackson Landers, *Are Wild Pigs Headed for the Beltway?*, WASH. POST, Nov. 13, 2012, at E1 (“It takes generations in the wild for domestic pigs to revert to a wild-type body. These pigs can have a hard time becoming established in the face of predators such as bobcats and coyotes and direct competition from deer for food.”); *id.* (reporting that thirty-six states have wild pigs, with Texas harboring the largest population at 3.4 million, and that they cause an estimated \$1.5 billion in damage annually in addition to threatening native wildlife); Andrew Pollack, *F.D.A. Says Food Supply May Contain Altered Pigs*, N.Y. TIMES, Feb. 6, 2003, at A26.

105. See Dennis, *supra* note 10, at A1 (“How long [after the release of the agency’s draft EA at the end of 2012] a final approval might take is anyone’s guess. AquaBounty first applied for permission to sell its genetically altered fish in 1995, and even by FDA standards, its application has moved at a glacial pace in recent years.”); Mestel, *supra* note 7, at A1 (describing the process as “a hopeless logjam,” with the transgenic salmon stuck “in regulatory limbo”).

106. See Greg Cima, *Salmon Could Show Path for Transgenic Animals*, 237 J. AM. VETERINARY MED. ASS’N 1113 (2011); Eenennaam & Muir, *supra* note 24, at 709 (“The abuse of good-faith attempts to increase transparency and enable public participation in the GE animal regulatory process, coupled with political efforts to prohibit the FDA from regulating GE AquAdvantage salmon as it approaches the close of its protracted regulatory journey, are unlikely to have reassured potential investors.”); Mestel, *supra* note 7, at A1 (“[T]he slow pace of progress on AquaBounty’s application has had a chilling effect on animal biotech efforts—which are conducted in academic laboratories and small companies, not by the multinational corporations that develop genetically modified plants. Efforts have been foundering for lack of funding, or moving overseas.”); see also Noah & Merrill, *supra* note 32, at 426 n.433, 428-29 & n.445.

107. See Eenennaam & Muir, *supra* note 24, at 709; Miller, *The Use and Abuse of Science in Policymaking*, *supra* note 76, at 31-33. The company certainly saw it that way, as explained in a brief update published by its CEO:

[T]he activist community essentially ignored the released data and persisted in inflammatory and unsubstantiated attacks upon both AquaBounty and the FDA. Additional opposition also emerged from some in the capture fisheries industry, who view the AquaBounty technology as an economic threat. Congressional representatives from Alaska, California, Washington, and Oregon have introduced bills in Congress to ban or label AquAdvantage salmon. The rhetoric from these individuals has not been based on their economic concerns, but rather seized upon the inflammatory rhetoric and fear mongering of the antitechnology groups, ignoring the FDA and other independent scientific reviews.

Ronald Stotish, *AquAdvantage Salmon: Pioneer or Pyrrhic Victory*, 21 TRANSGENIC RESEARCH 913, 914 (2012); see also Editorial, *Science and Salmon*, L.A. TIMES, Aug. 2, 2011, at A10 (“[E]ight senators from salmon-fishing states are warning the [FDA] that they will pursue legislation—already passed in the House—to keep the FDA from using any of its funding to study whether genetically modified salmon are safe for the environment and consumers.”).

activists kept up their pressure by filing a citizen petition long after the public comment period had closed.¹⁰⁸ Once it sensed that the question had become unduly politicized, the FDA apparently got spooked and lost the courage to act on its original convictions.¹⁰⁹ The publication of its draft EA at the end of 2012 renewed hope that the agency might soon reach a final decision on AquaBounty's NADA,¹¹⁰ but, in light of what has happened to this point, I wouldn't bet the (fish) farm on it.

Politics have intruded into FDA licensing decisions in the past.¹¹¹ The most visible recent example involved efforts to switch the emergency contraceptive product (marketed as "Plan B") to nonprescription status. Notwithstanding internal and external recommendations to do so, the agency repeatedly stalled and then only grudgingly authorized partial over-the-counter (OTC) marketing.¹¹² After exhaustively cataloguing various shenanigans that had occurred during the review process, a federal court ordered the FDA to revisit the age-restriction that it had imposed.¹¹³ Even with the transition to the Obama administration, political considerations continued to intrude upon scientific judgments: immediately after the new FDA Commissioner announced plans to approve unrestricted OTC access, the Secretary of Health and Human Services (HHS) overrode her subordinate.¹¹⁴

Even if politics play a legitimate role in agency rulemaking, such extraneous influences generally should have no place in adjudicatory proceedings.¹¹⁵ If the FDA has changed its view of the merits (even if solely at the direction of higher ups in the Executive branch), then it should reject AquaBounty's application

108. See *supra* note 77.

109. See Mestel, *supra* note 7, at A1 ("[M]any animal geneticists said they suspected the regulatory stalling on the AquaBounty case had more to do with politics than an inefficient or overly fastidious FDA Some scientists say they suspect the roadblock is higher up in the Department of Health and Human Services or even the White House.").

110. See *supra* notes 8-11 and accompanying text.

111. See, e.g., Noah, *supra* note 57, at 572-74, 583-85, 591-93 (discussing the abortifacient mifepristone); Lyndsey Layton, *FDA Reports Political Pressure over Implant: Approved Knee Device Will Be Reviewed*, WASH. POST, Sept. 25, 2009, at A21 (discussing controversy over a premarket clearance granted to Regen Biologics).

112. See Susan F. Wood, *The Role of Science in Health Policy Decision-Making: The Case of Emergency Contraception*, 17 HEALTH MATRIX 273, 280-88 (2007); Rob Stein, *Plan B Use Surges, and So Does Controversy*, WASH. POST, July 13, 2007, at A1.

113. See *Tummino v. Torti*, 603 F. Supp. 2d 519, 526-38, 544-50 (E.D.N.Y. 2009). Remarkably, conservative public interest groups also had challenged the partial OTC switch. See *Ass'n Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4 (D.D.C. 2008) (holding that the plaintiffs lacked standing and had failed to exhaust administrative remedies); *id.* at 11 (noting that they too alleged that the FDA had been "improperly influenced by political pressure").

114. See Rob Stein, *Wider Access to Plan B Is Rejected: HHS Overrides FDA's Decision*, WASH. POST, Dec. 9, 2011, at A1; see also Alastair J.J. Wood et al., *The Politics of Emergency Contraception*, 366 NEW ENG. J. MED. 101 (2011); Gardiner Harris, *White House and the F.D.A. Often at Odds*, N.Y. TIMES, Apr. 3, 2012, at A1. A federal court recently invalidated this decision as tainted by politics. See *Tummino v. Hamburg*, No. 12-CV-763 (ERK)(VVP), 2013 WL 1348656 (E.D.N.Y. Apr. 5, 2013); see also Pam Belluck, *Judge Overturns Age Limit to Buy a Contraceptive*, N.Y. TIMES, Apr. 6, 2013, at A1 (noting that the "acidly worded" opinion "accused the Obama administration of putting politics ahead of science").

115. See Nina A. Mendelson, *Disclosing "Political" Oversight of Agency Decision Making*, 108 MICH. L. REV. 1127, 1141 & n.68, 1143 (2010); Kathryn A. Watts, *Proposing a Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 8 n.14, 48 & n.215 (2009); see also Noah, *supra* note 77, at 58-59, 64-70 (discussing the need for restrictions on rights of public participation).

forthrightly and defend that judgment—while a formal judicial challenge seems unlikely, and those in the public interest community will declare victory, the agency can expect a skeptical response from the scientific community. Stalling in the hopes that the problem will simply go away on its own (by bankrupting the sponsor) demonstrates a pathetic lack of courage.

