WHAT'S THE RUSH? AN EXAMINATION OF THE FDA'S PUSH TO INTRODUCE GENETICALLY ENGINEERED AND CLONED ANIMAL PRODUCTS INTO THE FOOD SUPPLY

Margie Alsbrook[*]

* Margaret L. "Margie" Alsbrook was the founding Editor-in-Chief of the *Journal of Food Law & Policy*. She is a graduate of Hendrix College and the University of Arkansas, where she attended law school, was a member of the *Arkansas Law Review*, and earned an LL.M. in agricultural law. Margie is currently an attorney at the Cottrell Law Office in Rogers, Arkansas, and would like to thank former professor Michael T. Roberts for his continued friendship and support.

I. INTRODUCTION

The majority of Americans will have eaten the progeny of a cloned or genetically engineered animal within the next five years.[1] The science is here,[2] development dollars are being invested,[3] product development research is ongoing,[4] and the United States Food and Drug Administration (FDA) is ready to ensure these products are ushered into the marketplace.[5]

What remains undetermined is whether policies and procedures will be in place to ensure the safety of these food products, and whether Americans will have any idea what they are eating. As of the publication of this article, the answer to both questions is no.

Currently, the FDA[6] has minimal plans to regulate food products made with cloned and genetically engineered animals or their progeny, and no plans to

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1. *See* GREGORY D. MILLER ET AL., HANDBOOK OF DAIRY FOODS AND NUTRITION 252 (2d ed. 2000) (estimating less than one percent of Americans completely avoid animals or animal products in their diet). *See also* Pallavi Gogoi, *Cloned Beef Burgers: "Delicious,"* BUSINESSWEEK, Jan. 11, 2007, http://www.businessweek.com/bwdaily/dnflash/content/jan 2007/db20070111_764946.htm (describing the introduction of cloned meat in the food supply).

2. *See, e.g.*, Jane Zhang, *FDA Plans Rules for Modified Food Animals*, WALL ST. J., Sept. 19, 2008, at A12 (giving examples of various genetically engineered animals currently pending approval by the FDA, and citing biotech industry speculation that two dozen variations will be commercially viable and awaiting marketplace approval by the end of 2008). *See also* Daniel Wüger, *The Many Faces of Modern Biotechnology*, *in* GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM 3, 3 (Daniel Wüger & Thomas Cottier eds., 2008) ("Today, the development of modern biotechnology is essentially irreversible.").

3. *See* Zhang, *supra* note 2. *See also* Wüger, *supra* note 2, at 3-8; Andrew Pollack, *Rules Near for Animals' Engineering*, N.Y. TIMES, Sept. 18, 2008, at C15 (quoting a biotechnology lobbyist welcoming FDA regulation of genetically engineered animals in the hope it will further increase investor confidence).

4. *See* Zhang, *supra* note 2. *See also* Wüger, *supra* note 2, at 3; Pollack, *supra* note 3; S. Brett Offutt, *Pardon Me, But Whose Genes are Those Anyway?: Examining Royalty Collection for 21st Century Livestock*, 10 SAN JOAQUIN AGRIC. L. REV. 153, 153 (2000).

5. *See, e.g.*, Press Release, U.S. Food & Drug Admin., FDA Issues Documents on the Safety of Food from Animal Clones (Jan. 15, 2008), *available at* http://www.fda.gov/bbs/topics/NEWS/ 2008/NEW01776.html [hereinafter FDA Issues Document on the Safety of Food from Animal Clones] (confirming the agency will not require any additional regulations or labels for food products made from cloned animals or their progeny); Press Release, U.S. Food & Drug Admin., FDA Issues Draft Guidance on Regulating Genetically Engineered Animals (Sept. 18, 2008), http://www.fda.gov/bbs/topics/news/2008/NEW01887.html (explaining the agency's proposed framework for genetically engineered animal product approval).

6. This article will focus on the FDA and its regulatory plans for products containing cloned and genetically modified animals. While several administrative agencies are currently

require these products be labeled at the point of sale.[7] The lack of regulation and labeling is especially disturbing given the FDA's rush to approve these products for the larger marketplace.[8] This article questions the wisdom of the FDA's haste and asks for more regulatory prudence.

II. HISTORICAL BACKGROUND

While the idea of cloning animals has been the subject of dreams and nightmares for over a century,[9] it was barely a decade ago that cloning animals for agricultural use became a realistic goal for science and industry.[10] The first animal cloned using the revolutionary somatic cell nuclear transfer (SCNT) method was introduced to the world in 1997,[11] when Dolly the Sheep became an instant international celebrity.[12] Dolly's creators bred her with the intention that she would revolutionize agriculture and modern industry.[13] Their new cloning technique solved many of the limitations that scientists had faced with previous

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charged with regulating the larger United States food supply, the FDA has been designated the lead agency in regulating food products and food additives using biotechnology. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304 (June 26, 1986). Although the United States Department of Agriculture is also charged with a secondary regulatory role related to food products, and a primary regulatory role related to animal health, as of September 2008, the agency had issued only one request for information related to genetically engineered animal products. *See* Genetically Engineered Animals, 73 Fed. Reg. 54,360, 54,361 (Sept. 19, 2008).

7. *See infra* Parts III.B, IV.D.

8. *See infra* Part IV.B.

9. *See, e.g.*, Stacy J. Ratner, Note, *Baa, Baa, Cloned Sheep, Have You Any Law? Legislative Responses to Animal Cloning in the European Union and United States*, 22 B.C. INT'L & COMP. L. REV. 141, 141 (1999) (explaining the origins of the word "clone" and noting that "Scientists and science fiction writers have long been captivated by the potential cloning holds for reengineering society.").

10. *See id*. at 142-46 (giving a very brief history of cloning and noting it was not plausible on a large scale before 1997).

11. *See, e.g.*, ANDREA L. BONNICKSEN, CRAFTING A CLONING POLICY: FROM DOLLY TO STEM CELLS 1-2 (2002).

12. *See, e.g.*, John Whitfield, *Obituary: Dolly the Sheep*, NATURE NEWS, Feb. 18, 2003, http://www.nature.com/news/1998/030217/full/news030217-6.html (describing Dolly as "the world's most famous sheep" and her death at age six due to progressive lung disease).

13. SARAH FRANKLIN, DOLLY MIXTURES: THE REMAKING OF GENEALOGY 21 (2007) (describing the grand dreams of Dolly's creators for her applications, which they hoped would be as significant to the modern industrial world as the invention of the steam engine, radio communications, and nuclear power).

cloning methods, and opened the door to a new era where cloned animals were a realistic investment for farmers and food companies.[14]

While many were quick to tout the potential economic advantages of cloning animals for human consumption, others were concerned about the ethical and health concerns of implementing large-scale cloning for agricultural purposes.[15] The FDA took a science-based approach, leaving the philosophical and ethical debates to others.[16] The agency determined it would view cloning as simply another form of the assisted reproductive technologies (ARTs) that were already used on a widespread basis in the agricultural community.[17]

A. *Cloned v. Genetically Engineered Animals*

The terms "cloning" and "genetic engineering" are often used interchangeably,[18] but there are significant technical differences that must be kept in mind in the context of food products. The FDA separates these two different types of technologies into two different regulatory schemes. Food products containing items from cloned animals are regulated as traditional food products,[19] while food products containing items from genetically engineered animals are likely to be regulated as animal drugs.[20]

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14. Linda Bren, *Cloning: Revolution or Evolution in Animal Production?*, FDA CONSUMER, May-June 2003 [hereinafter *Cloning: Revolution or Evolution in Animal Production?*] (describing the practical benefits livestock cloning has brought to the industry).

15. *Id*.

16. *See,* Linda Bren, *Animal Cloning and Food Safety*, FDA CONSUMER, Mar.-Apr. 2007 ("Although the FDA does not have the legal authority to address ethics surrounding cloning, we will continue to provide scientific expertise to interested parties working on these issues so that those discussions can be based on facts," according to the director of the FDA's Center for Veterinary Medicine).

17. *Cloning: Revolution or Evolution in Animal Production?*, *supra* note 14 ("Improving breeding practices in the hopes that offspring will be improved has been going on for thousands of years. Arab chieftains were using artificial insemination in horse breeding as early as the 14th century, according to historians."). *See also* K. Moore & W. W. Thatcher, *Major Advances Associated with the Reproduction in Dairy Cattle*, 89 J. DAIRY SCI. 1254, 1259-61 (2006) (giving examples of various ARTs including embryo transfer, in vitro fertilization, sexed semen, and cloning).

18. DESMOND S. T. NICHOLL, AN INTRODUCTION TO GENETIC ENGINEERING 1 (1994) (explaining that the term genetic engineering is often used to describe differing technologies including cloning, gene manipulation, recombinant DNA (rDNA) research and experiments, genetic modification, and other projects that involve manipulating genes).

19. *See infra* Part III.

20. *See infra* Part IV.

1. *Cloned Animals*

Cloned animals are created as exact genetic copies of their model animals, with no significant changes or alterations to their DNA strands.[21] On a molecular level the two animals are the same, although there may be differences in outward appearance and behavior.[22] For agricultural purposes, cloned animals will likely be used to ensure the animals that are best genetic specimens are bred the most, thus insuring increased production and increased profits. The cows that produce the best beef, the pigs that grow the largest, and the goats that create the most milk would all be replicated and bred so that only the most marketable genes are spread throughout the marketplace. The FDA has determined it will not implement any additional regulations or labeling requirements for food products from cloned animals or their progeny.[23]

2. *Genetically Engineered Animals*

Genetic engineering takes the cloning and cell-based ART concepts much farther. This technology manipulates rDNA, essentially altering an animal's DNA by inserting the DNA of another animal to form a new version of creature. For example, an Atlantic salmon was created to produce growth hormones year-round, so that it will reach market weight a full year faster than its non-engineered brethren.[24] Other animals have been engineered to be pharmaceutical in nature, such as cattle designed to produce human antibodies that are intended to fight disease or address a specific nutritional concern.[25] The FDA has not formalized how it will regulate genetically engineered animals, but its current regulatory proposal would provide little oversight of this new technology.[26]

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21. FRANKLIN, *supra* note 13, at 19 (explaining the word clone is "both a noun and a verb," and is often "synonymous with *copying*, its primary synonym").

22. *See* IAN WILMUT & ROGER HIGHFIELD, AFTER DOLLY: THE USES AND MISUSES OF HUMAN CLONING 40 (2006) (explaining that clones will never be exact copies of the original being because "Genes are in constant dialogue with their surroundings. . .which [are] in dialogue with other cells in the body, which in turn [are] in dialogue with the world at large. . . .Just as one can never really relive a moment, this dialogue can never be exactly reproduced."); Morris B. Hoffman, *Law and Biology*, 8 J. PHIL., SCI. & L. 1, 9 (May 2, 2008) ("There is a giant elephant in the living room of law and biology. . . : brains, not genes, cause behaviors.").

23. *See infra* Part III.

24. Ricardo Alanso-Zaldivar, *'Super Chicken' Might Be Next for Dinner*, IDAHO PRESS-TRIB., Sept. 19, 2008, at 8 (describing the salmon created by Aqua Bounty Technologies that was awaiting regulatory approval by the FDA, which contained the DNA of an eel-like fish that allowed the salmon to produce growth hormones all year long instead of just the summer months).

25. *Id.*

26. *See infra* Part IV.

B. *Regulatory Background*

The FDA was given the leading role in regulating food products containing cloned and genetically engineered animals in 1986.[27] For the first decade, most of the regulatory efforts surrounded genetically modified (GM) grains and plants.[28] In 2001, that focus shifted, and the FDA's Center for Veterinary Medicine (CVM) issued its *Update on Livestock Cloning*,[29] opening the door to cloned animal products in the food supply. Although the agency indicated it was aware of the heightened controversy and need for scientific research into cloned animals, it did not specifically prevent cloned animals or their progeny from becoming food products.[30] Instead, the FDA asked producers to voluntarily restrain from inserting cloned animals and their progeny into the food supply.[31] As a result of the FDA's erroneous assumption that producers would police themselves, several cloned animal specimens and their offspring were placed in food products well before the FDA officially declared they were safe for human consumption.[32]

Just as the agency fought against efforts to require labeling on food products containing genetically modified (GM) plants, the FDA also resisted labeling of food products containing cloned animals.[33] In 2002, the FDA issued a draft guidance for industry regarding the labeling of food products made with cloned animals in which the agency reiterated its continued opposition to mandatory labeling for all types of GM free foods.[34]

It is a common theme in the FDA's labeling regulations in the past decade. The language of the draft guidance indicated that the FDA was also contemplating preventing companies from labeling food "no genetically engineered material" or "GM free."[35] The agency has repeatedly refused to require mandatory labeling for food products made with GM grains or other controversial new technologies, while simultaneously preventing companies who do not use these con-

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27. Coordinated Framework for Regulation of Biotechnology, *supra* note 6, at 23,302.

28. *See generally id*. at 23,304-05.

29. Press Release, Ctr. for Veterinary Med., U.S. Food & Drug Admin., Update on Livestock Cloning (July 13, 2001), http://www.fda.gov/cvm/CVM_updates/clones.htm.

30. *Id*.

31. *Id*.

32. *See* Jane Zhang & Julie Jargon, *Animal Clones Offspring Are in Food Supply*, WALL ST. J., Sept. 2, 2008, at A3.

33. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4839-41 (Jan. 18, 2001) (giving the agency's history regarding the question of labeling biotech foods).

34. *See id*.

35. *Id*. at 4840.

troversial new technologies from advertising their comparative purity.[36] Rather than clarify this potential confusion, the FDA has repeatedly opted to give consumers less information than they desire.

C. *Recent Agency Controversy*

At the same time that the FDA is charged with determining whether cloned and genetically engineered animal products are safe for the populace, the agency is also defending itself against serious questions about its regulatory effectiveness.[37] Revelations of corruption in its regulatory approval processes[38] intermingle with reports showing that the agency is mismanaged and ineffective.[39] In the past decade, the FDA has faced fierce criticism from regulatory oversight agencies,[40] courts,[41] scientists,[42] consumer advocates,[43] and the general

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36. *See, e.g.*, Press Release, U.S. Food & Drug Admin., FDA Issues Draft Documents on the Safety of Animal Clones (Dec. 28, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01541.html [hereinafter FDA Issues Draft Documents on the Safety of Animal Clones].

37. *See, e.g.*, Editorial, *The F.D.A. in Crisis: It Needs More Money and Talent*, N.Y. TIMES, Feb. 3, 2008, at WK14 (describing concerns from industry and consumer groups that the FDA does not have enough money or staff, and stating that its scientific advisory board testified to Congress that the agency's food regulation units are in "a state of crisis").

38. *See* Shankar Vedantam, *FDA Moves to Try to Reduce Conflicts of Interest on Boards*, WASH. POST, Mar. 22, 2007, at A12 (explaining the FDA's proposal to reduce conflicts of interest, introduced after a "crescendo" of concern from Congress and the public). *See also* Press Release, Nat'l Research Ctr. for Women & Families, FDA Advisory Committee: Does Approval Mean Safety? (August 28, 2006), *available at* http://www.center4research.org/news/fda-app-safety.html (voicing concerns about voting members of FDA committees with substantial ties to regulated companies).

39. *See generally* U.S. GOV'T ACCOUNTABILITY OFFICE, IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE 2 (2008) (describing an agency plagued by chronic under-funding and understaffing, resulting in increased food safety risks for the population).

40. *See generally* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA'S MONITORING OF POSTMARKETING STUDY COMMITMENTS ii-iii (2006) (showing post-approval studies were intended for only forty-eight percent of the drugs the FDA approved for sale between 1990 and 2004; of those studies, seventy-four percent were clinical trials conducted on a small or limited scale instead of studies of the general population. The agency was open with the OIG that post-market monitoring is not a major concern, and over one-third of these studies were never completed or skipped entirely). *See* U.S. GOV'T ACCOUNTABILITY OFFICE, USDA AND FDA NEED TO BETTER ENSURE PROMPT AND COMPLETE RECALLS OF POTENTIALLY UNSAFE FOOD (2004) (chastising the FDA for its lax oversight of food recalls and ineffective use of its regulatory tools, and estimating that when a tainted food is finally recalled, less than forty percent is recovered from the food supply).

41. *See, e.g.*, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 76-77 (2d Cir. 1996) (Leval, J., dissenting) (listing several FDA regulatory failures and opining the public has good

public,[44] all of whom are concerned with the agency's ability to adequately police the food supply. Thus, the FDA is mired in a culture of diluted power, diluted effectiveness, and diluted credibility, even as it is charged with regulating the revolutionary idea of cloned and genetically engineered animals as food ingredients.

III. THE FDA'S PLANS FOR REGULATING FOOD PRODUCTS FROM CLONED ANIMALS

The FDA has made it clear that the agency does not plan to require additional regulatory measures for products from cloned animals. In spite of public concerns, the agency remains confident that cloning technology is safe and will produce no ill effects for the populace.

A. *The FDA's 2006 Proposal for Regulating Food Products from Cloned Animals*

On December 28, 2006, the FDA issued its *Draft Guidance for Industry #179: Use of Edible Products from Animal Clones or Their Progeny for Human Food or Animal Feed*.[45] While this was the most detailed regulatory document to

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reason not to trust the agency's opinions of a product's safety when those opinions are based on short-term studies that cannot foresee potential unknown side effects).

42. *See* Chris Mooney, *Bush and the Mad Scientists,* L.A. TIMES, Sept. 20, 2005, at B13 (describing increasing scientific criticism of the FDA). *See also* Alastair J.J. Wood et. al., *A Sad Day for Science at the FDA*, 353 NEW ENG. J. MED. 1197, 1199 (2005) ("The recent actions of the FDA leadership have made a mockery of the process of evaluating scientific evidence, disillusioned many of the participating scientists both inside and outside the agency, squandered the public trust, and tarnished the agency's image."). *See generally* Phil B. Fontanarosa et. al., *Postmarketing Surveillance—Lack of Vigilance, Lack of Trust*, 292 JAMA 2647, 2647 (2004).

43. *See* Press Release, Sarah Klein, Staff Attorney, Ctr. for Sci. in the Pub. Interest, FDA Inaction to Blame for Salmonella Outbreak (June 10, 2008), *available at* http://www.cspinet.org/new/200806101_print.html (chastising the FDA's reliance on voluntary programs instead of regulatory actions in regulating food safety); Press Release, Consumers Union, Consumers Union Says FDA Action Overdue on Mad Cow Risk (Nov. 18, 2004), *available at* http://www.consumersunion.org/pub/2004/11/001652print.html (accusing the agency of failing to protect the public from the dangers of mad cow disease).

44. *See* Press Release, Harvard Sch. of Pub. Health, Even Before Tomato Warning, a Substantial Proportion of Americans Lacked Confidence in the System for Protecting Food Safety (June 12, 2008) (revealing a poll showing over half of Americans have low confidence in the nation's food inspection system).

45. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY #179: USE OF EDIBLE PRODUCTS FROM ANIMAL CLONES OR THEIR PROGENY FOR HUMAN FOOD OR ANIMAL FEED (2006), *available at* http://www.fda.gov/cvm/guidance/guide179.pdf.

date regarding the agency's plans to address food products made from cloned animals and their progeny, it did not reveal any new regulatory positions for the FDA.[46] The 2006 draft guidance essentially elaborated on the FDA's previous positions on biotechnology developments.[47] The agency stated it planned to regulate food products containing cloned animals and their progeny like traditional food products, with no additional precautions or labeling requirements.[48] The rationalization was that since cloned animals were molecularly identical to non-cloned members of their species, they were the same and no additional regulatory action was needed.[49]

1. *Public Reactions*

The public reaction to the Draft Guidance was strong. Consumer groups and traditional agricultural stakeholders were concerned about the safety and the viability of the new technology.[50]

Consumers, in particular, remained skeptical of the idea of eating clones. Many had an instant negative reaction that researchers termed the "yuck factor."[51] Consumers voiced strong aversions to all types of cloned foods in a number of recent studies. For example, a 2005 study by the International Food Information Council showed that sixty-three percent of Americans would be unlikely to buy meat, milk, and eggs from cloned animals even if the FDA determined they were safe.[52] These types of statistics caused considerable industry concern, particular-

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46. *See* discussion *supra* Part II.B.

47. *See* CTR. FOR VETERINARY MED., *supra* note 45, at 2-3.

48. FDA Issues Draft Documents on the Safety of Animal Clones, *supra* note 36 (stating that the "FDA does not recommend any special measures relating to human food use of offspring of clones of any species.").

49. *Id*.

50. *See* Stephen Clapp, *Dairy Industry Wary of Milk from Cloned Cows*, FOOD CHEMICAL NEWS, Aug. 1, 2005, at 8, 8-9 [hereinafter Clapp, *Dairy Industry Wary of Milk from Cloned Cows*].

51. Carly Weeks, *Clone Appetit*, GLOBE AND MAIL, Jan. 16, 2008, at L1 (quoting Joseph Heath, University of Toronto philosophy professor).

52. Stephen Clapp, *Most Consumers Would Reject Food from Cloned Animals: IFIC Survey*, FOOD CHEMICAL NEWS, Aug. 1, 2005, at 7, 7 ("63% of American consumers would be unlikely to buy meat, milk and eggs from cloned animals even if FDA determined they were safe. If the products came from conventionally bred animals whose parents were clones, most consumers (57%) would still reject them."). Similarly, a study by the Pew Initiative on Food and Biotechnology indicated that forty-three percent of Americans thought that food from cloned animals was likely to be unsafe, and sixty-six percent said that the idea of eating cloned animals made them uncomfortable. Justin Gillis, *Shoppers Uneasy About Cloning*, WASH. POST, Nov. 16, 2005, at D1.

ly from the dairy industry, which was still recovering from the bovine growth hormone controversies of the 1990s.[53]

Farmers and agricultural industry trade groups, on the other hand, were more concerned about the possibilities that this new technology would be prohibitively expensive as well as unprofitable.[54] This is particularly true of beef and dairy farmers, who have felt the flames of an angry public in the past and were not anxious to take on another public controversy without proven financial rewards.[55] In an era when farming was becoming an increasingly expensive profession, the idea of investing millions of dollars into technology[56] that could prove to be unpalatable with consumers made farmers wary.[57]

Consumer concerns about cloned animals in the food supply were amplified by the FDA's proposal that foods containing cloned animals and their progeny would not be labeled.[58] Consumers worried about unstable technology, the lack of long term studies,[59] and the erosion of choice. There were also unans-

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53. Clapp, *Dairy Industry Wary of Cloned Cows*, *supra* note 50, at 8 (quoting the National Milk Producers Federation statement that it "does not at this time support milk from cloned cows entering the marketplace until FDA determines that milk from cloned cows is the same as milk from conventionally-bred animals"). *See generally* Int'l Dairy Foods Ass'n. v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (detailing the saga of public protest over the use of recombinant bovine growth hormone, which made its way into the food supply through cows and milk products. In response to public concern, Vermont passed a law stating that such products should be labeled. Several industry trade groups sued the state challenging whether the statute was constitutional. The groups convinced the Court that the labeling law violated the First Amendment of the U.S. Constitution, a decision that the dissent decried as "stand[ing] the First Amendment on its ear" by allowing consumers to be deceived by industry looking to implement new and untested technology at the potential expense of public safety.).

54. Susanne Quick, *A Breed Apart: Cloning's Next Step*, MILWAUKEE J. SENTINEL, March 28, 2005, at A1.

55. Frederic J. Frommer, *Dairy Industry Skeptical about Cloned Cows*, CHARLESTON GAZETTE, July 11, 2005, at 8A (quoting the spokesperson for the International Dairy Foods Association as saying, "[t]here's a strong general feeling among our members that consumers are not receptive to milk from cloned cows. . . . This seems to be one of the things where technology seems to drop something in the lap of the food companies. . . . It's not driven by the market or any benefit to the consumer.").

56. *Compare id*. (stating a cloned cow will usually cost $20,000), *with* Jonathan D. Rockoff, *FDA Nears OK of Cloned Cow Products*, BALT. SUN, Oct. 2, 2005, at A3 (quoting a biotech industry source saying a cloned cow will cost $15,000).

57. *Guidance May Signal No FDA Regulation of Food from Cloned Animals*, FDA WEEK, Sept. 16, 2005 ("The dairy industry had worried that FDA would lift the voluntary ban when it releases the draft guidance, causing sales of dairy products to plummet.").

58. *See* Press Release, Consumers Union, Consumers Union Calls on Congress to Require Tracking and Labeling of Clones for Milk and Meat (Jan. 17, 2008), http://www.consumersunion.org/pub/core_food_safety/005362.html.

59. *See id*.

wered questions about clones and their increased vulnerability to large offspring syndrome (LOS), a deadly disease.[60]

The FDA's reassurances of safety did nothing to soothe consumers' panic. Meanwhile, biotechnology lobbyists further concerned consumers by arguing that clone free labels would be confusing to the average food buyer.[61] In the alternative, the lobbyists argued that clone free labels should not be allowed because they would imply that foods from cloned animals were different or dangerous.[62]

The FDA received approximately 30,500 comments during the Draft Guidance comment period.[63] Many of the comments were consumers concerned about the labeling issue. The FDA dismissed most of the comments for being non-substantive, and determined none of the comments were persuasive enough to convince the agency to change its labeling stance.[64]

2. *"Or Their Progeny" Explained*

The reason the phrase "or their progeny" is important when discussing the regulation of food products from cloned animals is the FDA insists it is unlikely that many actual clones will enter the food supply. The agency argues that, because of the expense involved in creating a cloned animal, most food products are likely to consist of the children of cloned animals.[65] The FDA envisions that clones will be created and then used as breeding stock.[66] So when products from

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60. *See* George E. Seidel, Jr., *Genetic and Phenotypic Similarity among Members of Mammalian Clonal Sets*, *in* PRINCIPLES OF CLONING 219-20 (Jose Cibelli et al. eds., 2002) (describing the syndrome and explaining how it is not fully understood).

61. *See* Press Release, Biotechnology Indus. Org., BIO Says Proposed 'Cloned Food Labeling Act' Will Mislead Consumers (Jan. 26, 2007), http://www.bio.org/news/pressreleases/newsitem.asp?id=2007_0129_01.

62. *See id*. *See also* Rick Weiss, *Can Food from Cloned Animals Be Called Organic?*, WASH. POST, Jan. 29, 2007, at A6 (discussing BIO's arguments that organically-raised cloned animals should bear the organic label and resulting protests from consumer groups).

63. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., FDA's RESPONSE TO PUBLIC COMMENT ON THE ANIMAL CLONING RISK ASSESSMENT, RISK MANAGEMENT PLAN, AND GUIDANCE FOR INDUSTRY (DOCKET NO. 2003N-0573), http://www.fda.gov/cvm/CloningRA_FDAResponse.htm.

64. *Id.*

65. *See* Gogoi, *supra* note 1 ("Since it costs upwards of $16,000 to produce a clone, it's unlikely that any cloned animals themselves will be used for meat or milk.").

66. *See, e.g.*, FDA Issues Draft Documents on the Safety of Animal Clones, *supra* note 36 ("Because clones will be used primarily for breeding, almost all of the food that comes from the cloning process is expected to be from sexually-reproduced offspring and descendents of clones, and not the clones themselves."); Biotechnology Indus. Org., *supra* note 61 (quoting BIO's Presi-

cloned or genetically engineered animals are introduced into the marketplace, they will likely be made from the offspring of these expensive animals. On a practical level, however, not every clone will be perfect or capable of breeding, and many of these culled clone animals will likely end up in the food supply.[67] This is the reason all regulations related to products containing materials from cloned animals need to address both the clones and their progeny.

B. *The FDA's Current Plans for Regulating Food Products Related to Cloned Animals*

After two years of study and consideration, the FDA released its final determinations regarding the safety of food products derived from cloned animals and their progeny on January 15, 2008.[68] The series of documents confirmed the FDA would not be initiating any specific regulatory efforts to oversee cloned animals, their progeny, or the products containing particles from these animals. It also confirmed it would not be requiring any specific labels to identify these products to consumers.

Along with the guidance, the FDA issued a 968-page risk assessment report[69] filled with scientific data on cloned animals and their progeny. The report relied on FDA research, research from biotech companies, and a separate report from the National Academy of Sciences, all of which proclaimed they did not foresee any health problems related to the progeny of cloned animals in the food supply.[70] While the FDA noted there were some lingering animal health con-

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dent, Jim Greenwood, saying, "The likelihood that consumers will eat products from an animal clone is small; animal clones will be primarily used as breeding stock . . . . ").

67. *See, e.g.*, NAT'L RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 66 (2002) (explaining that cloned animals that are failures would likely be sent to slaughterhouses along with other meat, and the "safety of food products from such animals that were culled from transgenic lines might present concerns").

68. U.S. FOOD & DRUG ADMIN., *supra* note 45 ("we do not believe that meat or milk from cattle, swine, and goat clones would require any additional controls compared with meat or milk from cattle, swine, or goats currently entering the food supply today"). The agency also announced it would ask industry to continue to exercise a voluntary ban on cloned sheep or other animals that were not cattle, swine, or goats due to a lack of data. *See* Animal Cloning Risk Assessment; Risk Management Plan; Guidance for Industry; Availability, 73 Fed. Reg. 2923 (Jan. 16, 2008).

69. *See* CTR. FOR VETERINARY MED, U.S. FOOD & DRUG ADMIN., ANIMAL CLONING: A RISK ASSESSMENT (2008), *available at* http://www.fda.gov/cvm/documents/cloningrisk assessment_final.pdf.

70. *See* NAT'L RESEARCH COUNCIL, *supra* note 67, at 65.

cerns related to animals produced through cloning,[71] it expressed confidence that these anomalies would be worked out as the "clones approach puberty."[72]

IV. THE FDA'S PROPOSAL FOR REGULATING GENETICALLY ENGINEERED ANIMALS

In September 2008, the FDA announced plans to introduce genetically engineered animals into the food supply by regulating them as animal drugs.[73] Genetically engineered animals are significantly different than cloned animals, [74] as genetically engineered animals are creatures whose DNA has been modified by recombinant DNA (rDNA) techniques.[75] By proposing that genetically modified animals be regulated as animal drugs,[76] the Draft Guidance appeared to propose stricter safeguards for food products containing these new types of animals. A close read of the document, however, indicates that the FDA's proposal is more focused on swiftly moving these products into the marketplace rather than on ensuring consumer safety.

A. *Six Anticipated Uses for Genetically Engineered Animals*

In issuing the Draft Guidance, the FDA described six proposed categories of genetically engineered animals, based on the purpose for which the animals are created.[77] The first are animals that are bred to "enhance food quality or

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71. *See* CTR. FOR VETERINARY MED, *supra* note 69, at 9 (noting that cloned cows and sheep continue to experience higher rates of large offspring syndrome (LOS) and post-birth morbidity rates than animals produced through other ARTs).

72. *See id*. at 10.

73. *See* Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs; Availability, 73 Fed. Reg. 54,407, 54,407 (Sept. 19, 2008) (outlining the FDA's proposal for regulating food products derived from genetically engineered animals). The same day the FDA issued its Draft Guidance, the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) issued a call for comments on the issue, and announced its intentions to collaborate with the FDA's determinations. *See* Genetically Engineered Animals, *supra* note 6.

74. *See supra* Part II.A (explaining the difference between cloned and genetically engineered animals).

75. Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs; Availability, *supra* note 73, at 54,408.

76. *See* USDA, FDA Issues Documents on the Safety of Food from Animal Clones, *supra* note 5 (explaining that genetic engineering alters the structure of animals, so all animals that have undergone this process will need to be reviewed under the FDA's animal drug regulations).

77. U.S. Food & Drug Admin., Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs (Guideline #187) (Sept. 18, 2008), http://www.fda.gov/cvm/guidance/guide187.htm [hereinafter Guideline #187].

agronomic traits," such as salmon that grow to market weight faster or pigs bred to produce less animal waste.[78] The second are animals that are bred to "improve animal health," such as cows that are resistant to bovine spongiform encephalopathy (BSE, commonly known as "mad cow disease").[79] The third are animals that are bred to be biopharm animals, such as pigs that produce human insulin.[80] The fourth are animals that are bred to address issues with human-animal companion relationships, such as hypoallergenic pets.[81] The fifth are animals that are bred to be research animals, such as mice that are genetically programmed to be more susceptible to cancer or addictions.[82] The sixth are animals that are bred for xenotransplant purposes, such as pigs that grow organs for harvest and transplant into human bodies.[83]

B. *ADUFA*

The FDA plans to regulate new animal drug applications under the Animal Drug User Fee Act (ADUFA).[84] The goal of ADUFA is to increase the speed and efficiency with which the FDA reviews proposed new animal drugs, and also to increase the revenue for the agency by charging applicants "user

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78. *Id*.; Zaldivar, *supra* note 24.

79. Guideline #187, *supra* note 77; Roger Highfield, *Scientists Engineer Cattle Immune to BSE*, TELEGRAPH (London), Jan. 3, 2007, *available at* http://www.telegraph.co.uk/scienceand technology/science/sciencenews/3350198/Scientists-engineer-cattle-immune-to-BSE.html (describing cows bred without prion protein, and noting the recent developments of cows created to help fight bioterrorism weapons such as anthrax).

80. Guideline #187, *supra* note 77. *See* Mitchell Hall, *Clinical Trials Could See Billion Dollar Pig Industry Rival Dairying*, NAT'L BUS. REV. (New Zealand), Sept. 22, 2008, *available at* http://www.nbr.co.nz/article/clinical-trials-could-see-billion-dollar-pig-industry-rival-dairying-35506 (describing genetically engineered pig pancreas cells as a potential new boom industry, as they can be used to treat diabetes in humans).

81. *See, e.g.*, Lifestyle Pets, http://www.lifestylepets.com (last visited Dec. 3, 2008) (offering hypoallergenic kittens for sale with prices ranging from $7,950 to $37,000 and dogs for $15,000).

82. *See, e.g.*, Paul Elias, *Genetically Engineered Mice Provide Research Progress*, USA TODAY, Aug. 7, 2005 (describing various laboratory mice that are created to study the effects of diseases and addictions).

83. *See* FDA Releases Draft Guidance on Regulation of Genetically Engineered Animals, FDA Consumer Health Information (U.S. Food & Drug Admin.), Sept. 18, 2008, at 2, http://www.fda.gov/consumer/updates/ge_animals091808.html ("Pigs are being engineered so that their cells, tissues, or organs could be transplanted into humans with a reduced risk of immune rejection.").

84. Animal Drug User Fee Act; Public Meeting; Request for Comments, 73 Fed. Reg. 9571, 9572 (Feb. 21, 2008). ADUFA was created in 2003 as an amendment to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 (2008).

fees."[85] The increased revenue is intended to provide the FDA with more resources, which in turn helps meet the goal of increasing the speed of regulatory reviews.[86]

ADUFA mandates a one hundred and eighty day deadline for the FDA, starting from the point when an application for a new animal drug is submitted.[87] At that point, the agency may approve the product or item that is being reviewed or give the company whose product is under review a detailed list of what needs to change in order for the product to be approved.[88] The agency may extend that time at its discretion, but the Act makes it clear that these extensions should be rare.[89]

User fee statutes are controversial, as critics charge that raising revenue for the FDA through user fees makes the FDA monetarily dependent on the companies it regulates.[90] Critics of user fees argue that the fees create an inherent conflict of interest while diluting the regulatory power of the agency.[91] In choosing to regulate genetically engineered animals under the ADUFA, the FDA may increase its revenue and speed of decisions but it will not increase confidence in its approval decisions.

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85. *Id.*

86. *Id.*

87. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., FY 2006 PERFORMANCE REPORT TO CONGRESS FOR THE ANIMAL DRUG USER FEE ACT 4 (2006), http://www.fda.gov/cvm/documents/2006perfrpt/.

88. *Id.* at 3-4 (listing the FDA's goals related to ADUFA, all of which relate to the speed with which applications will be reviewed and approved for sale). ADUFA underwent several revisions in 2008 designed to increase the FDA's revenue from the program and increase the agency's speed in reviewing animal drug applications. *Compare* Animal Drug User Fee Act; Public Meeting; Request for Comments, *supra* note 84, at 9571 (discussing the FDA's proposed recommendations for ADUFA), *with* Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2009, 73 Fed. Reg. 53,254 (Sept. 15, 2008) (discussing the FDA's payment procedures for ADUFA).

89. CTR. FOR VETERINARY MED., *supra* note 87, at A3.

90. *See* Richard A. Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. AM. BOARD FAM. PRAC. 142, 146 (2004). *See also* Letter from Am. Ass'n of Meat Processors et al. to U.S. Representative Jim Nussle (Feb. 15, 2006), *available at* http://www.sheepusa.org/?page=site/text& nav_id=991639bef061728dffddc686cdc61dca ("Food safety 'user fees' would also create the perception of conflict of interest between inspectors and the industries they are supposed to regulate, which could erode public and international confidence in the U.S. food safety inspection programs.").

91. Under the 2009 ADUFA schedule, the application fee for an animal drug is $246,300. This is in addition to the $59,450 annual establishment fee, $4,925 annual product fee, and $52,700 annual sponsor fee. All ADUFA fees may be paid using check, money order, wire transfer, or by submissions via www.pay.gov. Animal Drug User Fee Rate and Payment Procedures for Fiscal Year 2009, *supra* note 88, at 53,254, 53,257. *See also* Deyo, *supra* note 90.

C. *No Human Trials*

Even though products made from genetically engineered animals will be treated as animal drug products for the purposes of approval, the FDA does not plan to test the effects of consuming genetically engineered animals on human subjects before approving them for wide-scale introduction into the marketplace.[92] The FDA also does not plan on monitoring the safety or adverse effects of genetically engineered animals after they are approved for release into the food supply.[93]

D. *Limited Labeling Requirements for Food Products from Genetically Engineered Animals*

The Draft Guidance makes it clear the FDA does not intend to require labeling for the majority of food products made of bioengineered animals or their progeny.[94] No special labels will be required for products containing animals that have simply undergone modifications to their genetic code that changes their size, rate of growth,[95] or agricultural efficiency; and products containing other animals may not be clearly labeled as genetically engineered.

Instead, those labels may simply advertise the intended health benefits of the genetic engineering process. The FDA has often used the example of pork enhanced with omega-3 fatty acids as a genetically engineered food product that will likely be on the market once genetically engineered animals are formally approved for consumption.[96] The FDA has also stated this type of food would bear a label identifying it to the public, since animals bred to be nutriceuticals would have different nutritional values than non-genetically engineered animals of this nature.[97] It should not be assumed, however, that the FDA intends those

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92. Zhang, *supra* note 2 ("Regulators said they won't require human trials to test the safety of eating genetically modified animals.").

93. *See* Guideline #187, *supra* note 77 (reserving post-market review for "non-food" animals).

94. *See id*.

95. *See* Alanso-Zaldivar, *supra* note 24 (reserving labeling only for food that has been changed in terms of the final product).

96. *See, e.g.*, Karen Kaplan & Thomas H. Maugh II, *FDA Proposes Approval Process for Genetically Modified Animals*, L.A. TIMES, Sept. 19, 2008, at 24 (explaining the FDA's example of pigs created with increased omega-3 fatty acids).

97. *See, e.g.*, Julia Moskin, *Superfood or Monster from the Deep?*, N.Y. TIMES, Sept. 17, 2008, at F1 (describing the increased use of nutraceuticals in modern food products, and giving various examples such as Tropicana Healthy Heart orange juice which is fortified with fish from Peru and quoting a former FDA commissioner concerned about the trend of using nutraceuticals because products that are "both food and drugs" can easily "slip through the cracks, and the indus-

labels to clearly indicate omega-3 enhanced pork is genetically engineered. Instead, it seems the FDA may allow food companies to advertise the enhanced nutritional benefits of this meat under the agency's modified health claims regulations.[98]

E. *Recall Authority*

The FDA's proposal to loosely regulate food products made from genetically engineered animals takes on added significance when viewed in the context of the agency's lack of mandatory recall authority. Despite the potentially deadly threat of contaminated foods,[99] the FDA does not have the legal authority to force food producers to pull tainted or dangerous foods off the market.[100] Instead, the FDA must rely on pressure techniques[101] and hope the company producing or distributing the contaminated food will voluntarily pull it from the marketplace. The lack of recall authority is especially disturbing in light of the untested technologies that will be present in genetically engineered foods.

V. CONCLUSION

Producing cloned and genetically engineered animals on a large scale and releasing them into the food supply is a serious decision that should not be made lightly or with excessive haste. To date, the FDA has been more concerned with approving new technologies than with the safety and palatability of its proposals. This trend needs to end with genetically engineered animals, as the health and safety stakes have never been higher and rushing these products to the dinner table is a mistake.

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try is always ahead of the agency."). *See* Alanso-Zaldivar, *supra* note 24 (indicating that the FDA requires labeling for food that has been changed in terms of final product).

98. *See, e.g.*, Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 J. FOOD L. & POL'Y 187, 206-07 (2005) (describing the history of the FDA's regulation of omega-3 fatty acids and noting the agency discouraged consuming more than three ounces of them each day).

99. *See, e.g.*, Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563, 565 (2004) (estimating approximately 5,000 people die each year from food-induced illnesses, in addition to over 76 million cases of non-fatal illness).

100. *See, e.g., id*. at 567.

101. *Compare id*. at 567-68 (describing the various regulatory, legal, and marketing pressures that can be employed to force a company to recall tainted food), *with id*. at 572-75 (giving numerous examples of when these pressures did not work in a timely manner, or in some cases did not work at all).