CITIZEN PETITION BEFORE THE
UNITED STATES FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY 660 Pennsylvania Ave, SE, Suite 302 Washington, DC 20003, *et al.*, Petitioners, v. ***Filed With:*** **ANDREW C. VON ESCHENBACH** Acting Commissioner Division of Dockets Management Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852 **MIKE LEAVITT** Secretary of Health and Human Services U.S. Department of Health and Human 200 Independence Avenue, S.W. Washington, D.C. 20201	Docket Number _____

PETITION SEEKING REGULATION OF CLONED ANIMALS

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,[1] the Administrative Procedure Act,[2] and

[1] "Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances." U.S. Const. amend. I. The right to "petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights." United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass'n, 389 U.S. 217, 222 (1967). It shares the "preferred place" accorded in our system of government to the First Amendment freedoms, and has "sanctity and a sanction not permitting dubious intrusions." Thomas v. Collins, 323 U.S. 516, 530 (1945). "[A]ny attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger." Id. The Supreme Court has recognized that

the Food and Drug Administration's ("FDA") implementing regulations,[3] petitioners respectfully request that the FDA regulate cloned animals as a "new animal drug" subject to the relevant requirements of the Federal Food Drug and Cosmetic Act ("FFDCA").[4] FDA's continued failure to regulate cloned animals is inconsistent with its regulatory authority and with its treatment of genetically engineered animals and other cloned products as drugs. This action is necessary to ensure that food from animal clones does not pose safety risks to consumers and that animal cloning does not pose new animal cruelty risks. In addition, this action requests that the ethical issues of animal cloning be thoroughly examined prior to any commercialization of any food products derived from cloned animals. Until a cloned animal, its products, or progeny have gone through a new animal drug process and the proper National Environmental Policy Act ("NEPA") review, FDA must impose a mandatory moratorium on the distribution of food or feed from cloned animals into the marketplace.

ACTIONS REQUESTED

Specifically, petitioner seeks the following:

1. Issuance of an interpretive rule requiring all producers of animal clones to comply with the Federal Food and Drug Cosmetic Act's new animal drug requirements and FDA's implementing regulations before permitting the sale of any cloned animals or cloned food products, including reviewing the health risks from consuming milk or meat products from the offspring of cloned animals.

2. Conversion of its voluntary moratorium on food or feed from cloned animals into a mandatory moratorium until each product of cloning completes the new animal drug process.

3. Preparation of an Environmental Impact Statement ("EIS") evaluating the environmental and health effects of each new animal drug petition.

4. Creation of an Advisory Committee to address the ethical issues of animal cloning by the Health and Human Services Department.

PETITIONER

Petitioner, **Center for Food Safety** (CFS), is a nonprofit based in Washington, DC that works to protect human health and the environment by curbing the proliferation of

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the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. United States v. Cruikshank, 92 U.S. 542, 552 (1875).

[2] 5 U.S.C. § 553(e).

[3] 21 C.F.R. §§ 10.20, 10.30.

[4] 21 U.S.C. § 360b.

harmful food production technologies and by promoting organic and other forms of sustainable agriculture.

Petitioner, **American Anti-Vivisection Society** (AAVS), is a non-profit animal advocacy and educational organization that unequivocally opposes and works to end experiments on animals, and opposes all forms of cruelty to animals. Founded in 1883, AAVS is the oldest organization in the United States devoted to ending the use of animals in research, testing, and education.[5]

Petitioner, **Center for Environmental Health** (CEH), is a non-profit organization that advocates for public health. CEH prevents pollution and protects the public from toxic chemicals and hazards in consumer products, promoting safe, sustainable food choices and other healthier products and practices.

Petitioner, **Consumer Federation of America** (CFA), is an alliance of over 300 organizations, whose combined membership exceeds 50 million people. CFA members are local, state, and national consumer advocacy organizations, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Founded in 1968, CFA employs research, education and advocacy to shape financial services, energy, health care, food, and international trade policies that serve the needs of American consumers. The organization's policy positions are established by vote of member group representatives. CFA's Food Policy Institute was created in 1999. The Institute staff works to create rational, equitable and responsible food and agricultural policies that will assure all have access to an adequate supply of safe and nutritious food.

Petitioner, **Food & Water Watch**, is a non-profit group based in Washington DC that challenges the economic and political forces promoting industrialized food production and the privatization of the oceans and fresh water resources on the local, national and international levels. Through research, public and policymaker education, media, and lobbying, we advocate the development of food systems that guarantee safe, wholesome food produced in a humane and sustainable manner; inform citizens about the dangers posed by industrialized agriculture and aquaculture; and protect people and the environment by preventing the shift of control of water resources including oceans, rivers and groundwater, from the public to private corporations.

Petitioner, **Friends of the Earth** (FOE), is located at 1717 Massachusetts Avenue, NW, Suite 600, Washington, DC 20036. FOE is a non-profit organization that seeks to create a more healthy, just world. FOE is the U.S. voice of Friends of the Earth International, the world's largest federation of democratically elected grassroots environmental groups, located in 70 countries.

[5] AAVS emphasizes that the recommendations that follow aim to limit animal suffering and in no way endorse animal research.

Petitioner, **Humane Society of the United States** (HSUS), a non-profit charitable organization headquartered in Washington, D.C., is the largest animal protection organization in the United States, with nearly 10 million members and constituents. The HSUS protects all animals through education, investigation, litigation, legislation, advocacy and field work.

Petitioner, the **Religious Coalition for Reproductive Choice**, brings the moral power of religious communities to ensure reproductive choice through education and advocacy. The Coalition seeks to give clear voice to the reproductive issues of people of color, those living in poverty, and other underserved populations. Founded in 1973, the Religious Coalition comprises national organizations from major faiths and traditions, religiously affiliated and independent religious organizations, affiliates throughout the country, the national Clergy for Choice Network, Spiritual Youth for Reproductive Freedom chapters, The Black Church Initiative, and individuals who support reproductive choice and religious freedom.

STATEMENT OF GROUNDS

I. INTRODUCTION

Despite its preeminent role in protecting the nation's food supply, FDA's actions have failed to provide strict regulatory oversight over animal cloning. FDA has stated that it is examining the science to determine whether animal cloning endangers animals and our food supply.[6] Yet, there continues to be a paucity of published studies and publicly available data evaluating the food safety and animal welfare issues. The available science shows that cloning presents serious food safety risks, animal welfare concerns, and unresolved ethical issues that require strict agency oversight.

Currently, FDA has no mandatory rules prohibiting the sale of cloned animals or food products from cloned animals. In fact, FDA has failed to make a final determination on how it will regulate this technology. Instead, FDA is relying on industry to voluntarily keep cloned animals and its food products from the marketplace.[7] According to an FDA press release from 2003, "[u]ntil such time as FDA makes any final decisions on cloned animals, the agency will continue to request that producers withhold these products from the market, with the full expectation that firms will comply with this request as they have

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[6] *See, e.g.,* Linda Bren, *Cloning: Revolution or Evolution in Animal Production?*, 37 FDA CONSUMER, (May/June 2003), *available at* http://www.fda.gov/fdac/features/2003/303_clone.html.

[7] John C. Matheson, Senior Regulatory Review Scientist, Ctr. for Veterinary Med., U.S. FDA, Remarks at *Animal Cloning and the Production of Food Products: Perspectives from the Food Chain* Workshop (Sept. 26, 2002), summarized in Pew Initiative on Food and Biotechnology & Center for Veterinary Medicine of the FDA Workshop Proceedings at 26, *available at* http://pewagbiotech.org/events/0924/proceedings2.pdf [hereinafter "Animal Cloning-Pew"].

willingly done in the past."[8] However, since the moratorium is voluntary, there is no regulatory mechanism for FDA to monitor and enforce compliance.

Pursuant to its statutory duty to protect the food supply, FDA must regulate animal cloning and its constituent steps as a "new animal drug."[9] The new animal drug process, which requires a rigorous pre-market review to determine efficacy and ensure food, animal, and environmental safety, will help to address the wide-spread concerns about, and the potential risks and impacts from, animal cloning.[10] A recent survey conducted by the Pew Initiative on Food and Biotechnology reported that 66 percent of American consumers are uncomfortable with animal cloning and less than a quarter (23 percent) of consumers believe that animal cloning is safe.[11] Consistent with the public's concern with animal cloning, the best available science standard, and the agency's interpretation of the term "drug," FDA should require a science-based, pre-market review process for the approval of cloned animals through the new animal drug regulatory process.

While the agency fails to regulate cloned animals, research and production of cloned animals continues in a regulatory vacuum, and animal cloners are reportedly considering ignoring FDA's voluntary prohibition and touting the benefits of cloned animals for human consumption. For example, in 2005, the Associated Press reported that the cloning company ViaGen had cloned pigs and beef cattle "ready to efficiently produce juicier steaks and tastier chops."[12] In another example, on March 27, 2006, it was reported that pigs had been cloned and then genetically engineered to contain omega-3 fatty acid.[13] Announcements, like these, claim the success and benefits of cloning. Yet, there is no method to verify the veracity of these claims because cloning is not regulated by FDA and the scientific data from these experiments are not published or publicly analyzed. In fact, these announcements included actual suggestions of problems. For example, three of the six piglets that were born with the omega-3 gene had heart defects that required them to be killed.[14]

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[8] Press Release, FDA, FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning; Current Voluntary Moratorium on Releasing Animal Clones Remains in Effect (Oct. 31, 2003), *available at* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00968.html.

[9] 21 U.S.C. § 321(v).

[10] It is important to note that animal cloning may not survive the efficacy test under the new animal drug requirements. One scientist stated that "[i]f a drug for headaches worked only 2 percent of the time, the FDA wouldn't approve it. [But] that's where we're at [with cloning]." Sharon Cohen, *Cloning May Be Key in Animal Copies*, ASSOCIATED PRESS, July 13, 2001[hereinafter "Sharon Cohen"].

[11] *Pew Initiative Poll: Americans' Knowledge of GM Foods Remains Low* (Nov. 7, 2005), *available at* http://pewagbiotech.org/research/2005update/.

[12] Paul Elias, *21st Century BBQ: Juicier Beef from Cloned Cows*, ASSOCIATED PRESS, Oct. 7, 2005, *available at* http://www.livescience.com/othernews/ap_051007_cloned_food.html.

[13] David Biello, *Scientists Engineer Pigs with Heart-Healthy Meat*, Scientific American.com, Mar. 27, 2006, *available at* http://www.sciam.com/article.cfm?chanID=sa003&articleID=00095050-1EB7-1423-9EB783414B7F0000.

[14] *Id.*

Indeed, FDA's failure to regulate clones for food may already be a risk for consumers. Maryland farmer Greg Wiles has had two cloned dairy cows on his farm since 2001.[15] In 2002, Wiles stated that the clones were healthy animals and that he had used the clones to produce seven pregnancies.[16] Wiles acknowledged that he was "probably getting a little ahead of the FDA,"[17] and in 2005 he admitted that he often contemplates disregarding FDA's voluntary moratorium.[18] He also acknowledged that one of his two clones was suffering from unspecified health problems.[19]

Regulating cloned animals and their food products under the new animal drug provisions is a necessary step to protect the food supply and fits squarely within the FDA's regulatory authority. However, application of the new animal drug provisions should only be the first step in FDA's regulation of animal cloning. New animal drug provisions do not provide sufficient public transparency or opportunity for public participation. FDA must also prepare an EIS for each animal drug application because the NEPA categorical exclusions for New Animal Drug Applications will not apply.[20] In addition, consumers have a right to know if their food is a product of a cloned animal or progeny of an animal clone. FDA has no requirement for providing consumers with this information.

Moreover, in addition to looking at the food safety issues, the Department of Health and Human Services should develop an Advisory Committee on ethical analysis of cloning animals to work with the FDA and provide expertise on the difficult ethical issues raised by animal cloning. Cloning animals for commercial livestock production will increase animal cruelty because the process inherently involves needless suffering of surrogates and the deformed and sick offspring that often result from cloning. Animal cloning also is antithetical to some peoples' moral and religious beliefs. FDA should institute a mandatory moratorium on food or feed from cloned animals until full analysis of the ethical issues has occurred.

If FDA rescinds its voluntary moratorium without properly regulating cloned animals there will be uncertain and potentially detrimental effects on the food supply and a certain increase in animal suffering. FDA's failure to regulate would allow these effects to silently spread through the food supply, affect the welfare of animals, and place many in an unresolved ethical conundrum.[21]

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[15] Michelle Ranck, *Play it Again, Zita*, LANCASTER FARMING, March 24, 2001, at A1.
[16] Justin Gillis, *Cloned Food Products Near Reality*, WASHINGTON POST, September 16, 2002, at A1.
[17] *Id.*
[18] Frederick Frommer, *Dairy Industry Skeptical About Cloned Cows*, ASSOCIATED PRESS, July 11, 2005, *available at* http://www.usatoday.com/tech/science/genetics/2005-07-11-cloned-cow_x.htm.
[19] *Id.*
[20] *See* Sec. IV.F *infra*.
[21] At a minimum, if FDA were to lift its voluntary moratorium, it must prepare an environmental impact statement that would, *inter alia*, assess the health and environmental effects FDA's decision on public health as well as on the cloned animals, their birth surrogates, and on the progeny of clones.

II. STATEMENT OF LAW

Administrative Procedure Act, 5 U.S.C. § 551, *et seq*.
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*

III. PROCEDURAL HISTORY AND STATEMENT OF FACTS

The cloning at issue in this petition, somatic cell nuclear transfer ("SCNT" or "cloning"), first produced a mammal clone on July 5, 1996 when Dolly, the cloned sheep, was born.[22] At five and a half years, Dolly prematurely developed arthritis. A year later, at the age of six and half Dolly was euthanized because she suffered from progressive lung disease and arthritis in the hind joint leg. Sheep typically live to be eleven or twelve years of age.[23] Since Dolly, dairy cows and beef cattle, poultry, hogs, and other livestock have been cloned. However, much of the information about the health of these clones and their surrogate mothers is not publicly available.

In 1999, FDA met with a cattle cloning company called Infigen, Inc. to discuss its business plans and the nature of its technology. Since then, FDA has talked to other cloning researchers and "encouraged them to develop and openly publish their safety data."[24] In October 2000, FDA commissioned the National Academy of Science ("NAS") report on animal biotechnology.

In 2001, FDA requested that industry engage in a voluntary moratorium on bringing cloned food and feed to the marketplace.[25] The NAS report was released in August 2002. The NAS acknowledged the lack of scientific evidence related to food safety and the paucity of data on the safety of food from cloned animals, stating "[t]here are to date no published comparative analytical data assessing the composition of meat and milk products of somatic cell clones, their offspring, and conventionally bred individuals."[26]

In 2003, FDA announced that it was looking at the science to determine whether animal cloning endangers animals and our food supply.[27] In late October 2003, FDA released a draft assessment of the safety of food from clones or their progeny relying on just a single study of milk from cloned animals, and no data at all on cloned meat. The FDA concluded based on limited evidence, that there did not appear to be a food safety risk. This conclusion is premature; further study is needed because existing reviews are too limited to provide clear scientific evidence on safety. The agency itself acknowledged the scientific uncertainty cautioning that "[a]dditional data on the health status of

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[22] *Dolly the Sheep Clone Dies Young*, BBC NEWS, February 14, 2003.
[23] *Id.* (quoting Dr. Harry Griffin of the Roslin Institute which created Dolly)
[24] Animal Cloning-Pew, *supra* note 7, at 26.
[25] *Id.*
[26] NATIONAL ACADEMY OF SCIENCES, ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS, BOARD ON AGRICULTURE AND NATURAL RESOURCES, 65 (2002), *available at* http://www.nap.edu/books/0309084393/html/ [hereinafter "NAS 2002 study"]; *See also id.* at 8-9, 64-5.
[27] Bren, *supra* note 6.

progeny, and composition of milk and meat from clones and their progeny would serve to further increase the confidence in these conclusions."[28] The agency recognized that it must continue to assess additional data.[29] FDA Veterinary Medicine Advisory Committee met in November 2003 and reviewed the draft assessment; a majority of the committee members believed that more data should be developed to adequately identify the hazards and characterize the risks relating to food consumption.[30] Currently, it is largely unknown whether eating cloned animal products is safe because there have been few studies and no long-term evidence demonstrating the safety.[31]

The science also shows that animal cloning has low success rates and results in extreme suffering for the animals involved. Well over 99 percent of all cloning attempts still fail.[32] Even when nuclear transfers produce embryos that are successfully implanted in surrogates, only 3% to 5% of these pregnancies produce offspring that live to adulthood.[33] These few cloned animals that do survive are likely to suffer a wide range of health problems. In late 2004, the New England Journal of Medicine reported that "given the available evidence, it may be exceedingly difficult, if not impossible, to generate healthy cloned animals or humans."[34] Many cloned animals die within the first 24 hours of birth due to "respiratory distress, increased birth weight and major cardiovascular abnormalities . . . ."[35] Surviving clones often have compromised immune systems and if used in intense animal confinement settings may consistently require the use of antibiotics.[36] This potential for increased use of antibiotics represents yet another food safety issue which FDA must address in considering whether to approve the employment of this technology.

The suffering experienced by surrogate mothers is another concern. Surrogate animals are subjected to repeated surgical operations to implant the cloned embryos and extract the cloned fetuses. Most cloned animals exhibit a condition known as "large-offspring syndrome," which results in overly stressful deliveries for the surrogate mothers.[37]

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[28] Food & Drug Admin., *Animal Cloning: A Risk Assessment, Draft Executive Summary* 11 (Oct. 21, 2003), *available at* http://www.fda.gov/cvm/Documents/CLRAES.pdf [hereinafter "Animal Cloning Risk Assessment"].
[29] *Id.*
[30] FDA Veterinary Medicine Advisory Committee meeting, November 4, 2003, Transcript at 206-216, *available at* http://www.fda.gov/cvm/Documents/03VMACTrans.doc.
[31] Center for Food Safety, *Initial Comments Concerning FDA's Animal Cloning Risk Assessment*, (Nov. 4, 2003) *available at* http://www.centerforfoodsafety.org/pubs/ClonedAnimalCommentFDANov2003.pdf (citing paucity of scientific testing on effects of long-term consumption of cloned animal products).
[32] James C. Cross, *Factors Affecting the Developmental Potential of Cloned Mammalian Embryos*, 98 PROC. NAT'L ACADEMY OF SCIENCES 5949 (May 22, 2001) [hereinafter "2001 NAS"].
[33] Rick Weiss, *Human Cloning Bid Stirs Experts' Anger; Problems in Animal Cases Noted*, WASH. POST, Mar. 7, 2001, at A1.
[34] Rudolf Jaenisch, *Human Cloning – The Science and Ethics of Nuclear Transplantation*, 351 NEW ENG. J. MED. 2787 (Dec. 2004).
[35] I. Wilmut et al., *Somatic Cell Nuclear Transfer*, 419 NATURE 583 (Oct. 2002).
[36] Initial Comments Concerning FDA's Animal Cloning Risk Assessment, *supra* note 31.
[37] *Id.*

Even FDA's own Director for the Center for Biologics Evaluation and Research stated during her 2001 Congressional testimony that "the [animal cloning] success rate remains low and numerous abnormalities in the offspring and safety risks to the mother have been observed."[38] The scientific evidence consistently shows that there are severe risks to animals resulting from cloning.

IV. ARGUMENT

FDA SHOULD REGULATE ANIMAL CLONING UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT'S NEW ANIMAL DRUG REQUIREMENTS

At a minimum, FDA should regulate SCNT in animals as a "new animal drug" because: (1) animal cloning and its respective parts fits within FDA's broad definition and interpretation of the term "drug," (2) the scientific evidence shows that there is no consensus among the scientific community that animal cloning is generally recognized as safe and effective for animals or consumers; moreover, the paucity of scientific evidence makes any determination regarding a consensus in the scientific community premature and inappropriate, and (3) animal cloning has not been used for a material extent or time. By regulating the products of animal cloning as a "new animal drug," producers of animal clones will be required to go through a rigorous science based animal and food safety pre-market review.

A. Somatic Cell Nuclear Transfer and Its Respective Components Are Each a "Drug."

FDA interprets the definition of drug "based upon their functional claims rather than their chemical structure or manufacturing source."[39] FDA has repeatedly interpreted this term broadly. An FDA Newsletter article explains that

> some transgenic animals will be regulated, in certain respects as a drug, under the animal drug provisions of the FFDCA. Most of the transgenic animal experiments conducted to date involve the introduction of the genetic material into the germ line or somatic cells. When the genetic material is introduced into somatic or germ cells to produce phenotypic change that meets the definition of a drug in the animal or its offspring,

[38] Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Statement on Issues Raised by Human Cloning Research before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States Representatives (Mar. 28, 2001), *available at* http://energycommerce.house.gov/107/hearings/03282001Hearing141/Zoon205.htm [hereinafter "Zoon testimony"].

[39] *Regulatory Issues in Agricultural Biotechnology,* 13 FDA NEWSL. (1998), *available at* http://www.fda.gov/cvm/january98.htm.

the expressed drug product would be considered to be a new animal drug.[40]

Somatic cell nuclear transfer as whole and its respective components fits within the FFDCA's definition of "drug" and FDA's broad interpretation of this term. Under the FFDCA, the term "drug" means "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[41] In addition, "articles intended for use as a component of any article specified in clause (A), (B), or (C) [of sec. 321(g)(1)]" are defined as a drug.[42] The courts have also interpreted the term "drug" broadly.[43]

(1) <u>The constituent steps Somatic Cell Nuclear Transfer each meet the FFDCA's definition of a drug.</u>

FDA should find that each of the three steps of somatic cell nuclear transfer meets the FFDCA's definition of drug.[44] The three component steps of SCNT are:

i. Enucleation: scientists remove the nucleus (containing the DNA or genetic material) from a cell of an unfertilized egg
ii. Fusion: using an electrical stimulus, they fuse that enucleated cell with the nucleus obtained from a somatic cell (any cell in the body other than the reproductive cells). The product of this fusion is a reprogrammed cell.
iii. Implantation: the reprogrammed egg cell is implanted into a surrogate mother.

The resulting phenotype is allegedly identical to the nucleus donor and cannot be achieved through traditional breeding because SCNT attempts to take genetic material from solely one animal.[45] The product of each of these cell manipulations constitute a drug because each is intended to affect the "function or structure" of an animal.

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[40] *Id.*
[41] 21 U.S.C. § 321(g)(1)(C).
[42] *Id.* § 321(g)(1)(D).
[43] S*ee*, *e.g.*, *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969) (recognizing the definition of "drug" in the FFDCA should be construed broadly, as FFDCA is a remedial statute with the purpose of protecting public health); *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688 (2d Cir. 1975) (explaining that protection of public health dictates that the definition of "drug" under the FFDCA be construed liberally); *United States v. Article Consisting of 36 Boxes, etc.*, 284 F. Supp. 107 (D. Del.1968), *aff'd,* 415 F.2d 369 (3d Cir. 1969).
[44] 21 U.S.C. § 321(g)(1).
[45] Clones produced by SCNT are not identical to the organism who donated the nucleus. Mitochondrial DNA from the egg cell can contribute to the genetic make-up of the clone, resulting in an organism which is not a genetic duplicate of the original donor. The significance of these genetic differences is unknown. *See* Yong-Hua Sun et al., *Cytoplasmic Impact on Cross-Genus Cloned Fish Derived from Transgenic Common Carp* (Cyprinus carpio) *Nuclei and Goldfish* (Carassius auratus) *Enucleated Eggs,* 72 BIOLOGY REPROD. 510 (2005), *available at*: http://www.biolreprod.org/cgi/content/full/72/3/510 (noting that the skeletal structure of the fish clone shared characteristics with that of the egg donor, rather than the nucleus donor); Takashi Kohda et al., *Variation in gene expression and aberrantly regulated chromosome regions in cloned mice*, 73 BIOLOGY REPROD. 1302 (2005) (finding "large epigenetic diversity in neonatal cloned mice, despite their normal appearance and genetic identity"); Joanna Somers et al., *Gene expression*

Enucleation qualifies as a drug because it attempts to eliminate all of the genetic material of the cell; its purpose is to affect both the function and structure of the cell which will be manufactured into an animal. Enucleation removes the genetic material of a nucleus (containing the egg's genes) from an unfertilized egg or oocyte. The ability to eliminate all the genetic material of the oocyte is important to facilitate nuclear transfer efficiency. The enucleation creates the platform for inserting a new set of genetic material in the cell. It affects the cell's structure because the product of enucleation is elimination of existing genetic material changing the very nature of the cell and its future animal. Enucleation also meets the definition of drug because it is intended for use as component of SNCT;[46] the product of SCNT, the cloned animal, is a drug. *See infra* IV.A.(2).

The product of the next step in SCNT, the fusion of the somatic cell with the enucleated oocyte qualifies as a drug because the product of the fusion is a cell transformed in its structure and function which will specifically dictate the desired "identical" genetic makeup of the animal which is bred. After being harvested from the animal to be cloned, a somantic cell is fused into the enucleated egg. The fusion is stimulated by an electrical pulse and produces an embryo. The phenotypic change occurs when genetic material from the parent's somatic cell is introduced into the oocyte. The cell structure is changed because it receives new genetic material. The cell is literally reprogrammed. The function of the cell is to be a biological clone of the somatic cell rather than an egg in the sexual reproductive process of the animal from which the egg was harvested. The cellular fusion process also meets the definition of drug it is intended for use as component of SNCT;[47] the product of SCNT, the cloned animal, is a drug. *See infra* IV.A.(2).

Additionally, the implantation of the fused oocyte into the surrogate mother qualifies as a drug because the implantation of the oocyte affects the function and structure of the surrogate mother. The implantation causes the mother to become pregnant asexually. In addition to triggering the reproductive process in the surrogate mother, the implantation and the subsequent growth of the fetus causes the surrogate mother biological changes and health issues that occur more frequently than with sexual reproduction. The scientific research shows that surrogate hosts can experience significant pain.[48] *See infra* IV.B.(1). The harm to surrogate mothers demonstrates that animal cloning creates great risks to the animals used in animal cloning. Thereby, the implantation affects the function of the

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profiling of individual bovine nuclear transfer blastocysts, 131 REPROD. 1073 (2006) (found over 2% of profiled bovine blastocyst genes showed differed expression in NT produced embryos when compared with *in vitro* embryos). *See generally* David Humpherys et al., *Abnormal gene expression in cloned mice derived from embryonic stem cell and cumulus cell nuclei*, 99 DEVELOPMENTAL BIOLOGY 12889 (2002) (finding that nuclear transfer is the cloning technology which results in the most frequent abnormal genetic expressions); Hiroshi Suemizu et al., *Expression Profiling of Placentomegaly Associated with Nuclear Transplantation of Mouse ES Cells*, 253 DEVELOPMENTAL BIOLOGY 36 (2003) (exploring the extent and type of genetic changes and reporting five principal genetic abberant events).

[46] 21 U.S.C. § 321(g)(1)(D).

[47] *Id.*

[48] *See* NAS 2002 study, *supra* note 26, at 94.

surrogate. The artificial implantation also meets the definition of drug because it is intended for use as component of SNCT;[49] the product of SCNT, the cloned animal, is a drug. *See infra* IV.A.(2).

(2) <u>Moreover, the Cloned Animal Product of Somatic Cell Nuclear Transfer Is a Drug.</u>

Somatic cell nuclear transfer meets the FFDCA's definition of "drug" because it affects both the function and structure of animal by designing a genetically specific animal. SCNT does not

> result in an exact replica of an individual animal, although the progeny are very similar to each other and to their donor cell parent. Any genetic dissimilarity is likely due to the cytoplasmic inheritance of mitiochondria from the donor egg, which possesses its own DNA, and to other cytoplasmic factors, which seem to have the potential to influence the subsequent 'reprogramming' of the transferred somatic cell genome in such a way that spatial and temporal patterns of gene expression in the embryo are affected as it develops.[50]

The cloned animal with all of its genetic similarity and any residual dissimilarity is the expressed product that should be defined as a drug.

SCNT affects both the functional and structure of the cloned animal. The intent of SCNT is to replicate specific genetic traits in the cloned animal, thereby affecting its fundamental function and structure. For example, a prized dairy cow would be cloned with the intent of producing identical prized dairy cows that can similarly produce milk at a high rate. Moreover, the three constituent steps of SCNT each meet the definition of "drug." FDA should find that animal cloning fits within FDA's broad definition and interpretation of the term "drug." In addition, resulting clones are often used as the stud or parent of new offspring of higher value cows when used that way the clone is designed to affect the structure and function of offspring animals. This production also falls within the scope of the "drug" definition.[51]

B. Somatic Cell Nuclear Transfer in Animals Is a New Animal Drug Because It Is Not Generally Recognized as Safe or Effective.

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[49] 21 U.S.C. § 321(g)(1)(D).

[50] NAS 2002 study, *supra* note 26, at 18.

[51] To conclude otherwise, USDA will be acting contrary to the evidence before the agency. *See, e.g. Motor Vehicle Mfrs., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) (stating that the APA requires that agencies "articulate a satisfactory explanation for [their] actions including a rational connection between the facts found and the choice made") (internal quotation marks and cite omitted); *Nat'l Cable & Telecommc'ns Ass'n v. Brand X Internet Servs.*, 125 S.Ct. 2688, 2699 (2005) (explaining that unexplained agency inconsistency is a "reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act").

Based upon the limited amount of scientific evidence, FDA should find that animal cloning cannot be generally recognized among the scientific community as safe. Therefore, SCNT should be regulated as a "new animal drug."[52]

After determining that product of SCNT and the products of SCNT's constituent steps meet the statutory definition of "drug," FDA should find that the product of animal cloning is a "new animal drug." A drug used in animals is a "new animal drug," and falls within FDA's regulatory regime, unless it has been "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective" and has "been used to a material extent or for a material time."[53] The FFDCA defines "new animal drug" as

> any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, —
> (1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
> (2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.[54]

The general recognition exemption from "new animal drug" status is a narrow one.[55] When there is either a dispute concerning the safety and effectiveness of the drug or an unawareness of the drug among experts, the general recognition requirement for new animal drugs is not met.[56] To overcome the hurdle of general recognition, there is a two step process. First, there must be a consensus among experts that the product is safe and

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[52] 21 U.S.C. § 321(v).
[53] *Id.*
[54] *Id.*
[55] *See Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 802 (2d Cir. 1980). (states "Congress' exclusion of 'generally recognized' drug products from the definition of a 'new drug' is a very narrow one, which is not intended to permit a pharmaceutical manufacturer to substitute its opinion regarding the safety or effectiveness of a drug for that of the FDA, the publicly recognized repository of expertise in such matters, or to require the court to develop its own body of scientific knowledge in substitution for that of the FDA").
[56] *U.S. v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin Suspension*, 675 F.2d 994, 1000 (8th Cir. 1982).

effective.[57] Second, this expert consensus must be based upon "substantial evidence."[58] This includes adequate and well-controlled investigations and substantial support in scientific literature.[59]

In this case, somatic cell nuclear transfer falls within the "new animal drug" status because there is no general consensus among scientific experts and no long term studies demonstrating that animal cloning is safe and effective for animals or consumers. Research studies repeatedly show severe animal health risks and high failure rates. Additionally, there are only limited studies, providing no long term data, regarding the human health risks associated with consumption of dairy and meat products from clones and their offspring. Based upon the substantial scientific evidence showing that animal cloning is neither safe nor effective, FDA should regulate the product of somatic cell nuclear transfer in animals, i.e. the cloned animal, as a "new animal drug."

(1) <u>Animal Cloning Is Not Generally Recognized as Safe for Animals.</u>

There is a considerable amount of scientific evidence identifying the severe harm and suffering to animals involved in the cloning process. Specifically, the science shows that cloning causes harm to surrogate mothers and often creates deformed and/or unhealthy animal clones. These health risks are far different from traditional breeding. Based upon this evidence, FDA should find that animal cloning creates severe health risks for animals and thus, is not generally recognized as safe.[60]

The implantation of a cloned cell in a surrogate can cause harm to the surrogate mothers. Surrogate animals are subjected to repeated surgical operations to implant the cloned embryos and extract the cloned fetuses. Most cloned animals exhibit a condition known as "large-offspring syndrome," which results in overly stressful deliveries for the surrogate mothers. Because of their large size, a higher than normal percentage of clones are delivered via cesarean section.[61] In one documented cattle cloning project, three out of 12 surrogate mothers died during pregnancy.[62]

The cloned animals that survive from birth are likely to suffer a wide range of health problems. In late 2004, the New England Journal of Medicine reported that "given the available evidence, it may be exceedingly difficult, if not impossible, to generate healthy

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[57] *United States v. Atropine Sulfate 1.0 MG (Article of Drug) Dey-Dose*, 843 F.2d 860, 862 (5th Cir. 1988).
[58] *Id.*
[59] 21 U.S.C. § 360b(d)(3).
[60] In the draft assessment, FDA states that animal clones "can pose an increased frequency of health risks to animals involved in the cloning process, but these do not differ qualitatively from those observed in other ARTs or natural breeding." Petitioner disagrees with FDA's conclusion and directs the agency to review the scientific discussed in this section. Animal Cloning Risk Assessment, *supra* note 28 at 1.
[61] NAS 2002 Study, *supra* note 26, at 12, 95-6.
[62] JACKY TURNER, COMPASSION IN WORLD FARMING TRUST, THE GENE AND THE STABLE DOOR: A REPORT FOR THE COMPASSION IN WORLD FARMING TRUST 5 (2002), *available at* http://www.ciwf.org.uk/publications/reports/the_gene_and_the_stable_door_2002.pdf.

cloned animals or humans."[63] Many cloned animals die within the first 24 hours of birth due to "respiratory distress, increased birth weight and major cardiovascular abnormalities."[64]

The scientific evidence shows that cloned animals that manage to survive birth often require more care than those sexually reproduced. Cloned calves for example have required neonatal glucose infusions to treat hypoglycemia or oxygen treatments to offset hypoxia.[65] Jonathan Hill, who has worked on cattle cloning at Cornell University, suspects that 25% to 50% of clones are born having been deprived of normal levels of oxygen. The neonatal condition of most clones is so poor, according to Rebecca Krisher, an animal reproduction specialist at Purdue University, that "[a]lmost all of these animals, if born on a farm without a vet hospital, . . . probably wouldn't survive."[66]

Another example of a clone with health problems is a sheep cloned by Ian Wilmut and his team, the same group who brought Dolly into the world. This much less heralded sheep, born not long after Dolly, had a malformed respiratory tract and was soon euthanized.[67] In fact, such abnormalities are common. Late in 2002, scientists at the New Zealand government's AgResearch reported that 24% of the cloned calves born at the facility died between birth and weaning. This compares to a 5% mortality rate for non-cloned calves. Another 5% of cloned calves died after weaning, compared to 3% of sexually reproduced calves.[68] One review of scientific literature, authored by executives at the commercial cloning lab Advanced Cell Technology, found that nearly 25% of cow, sheep, swine, and mouse clones showed severe developmental problems soon after birth. However, the vast majority of the studies considered for this review had follow-up periods of only a few weeks or months.[69] Many later-developing health problems would not be reflected. In sum, in light of the serious animal welfare problems experienced by cloned animals that differ widely from traditionally bred animals, FDA should find that animal cloning is not generally recognized as safe for animals.

(2) <u>Animal Cloning Is Not Generally Recognized as Safe for Consumers.</u>

There is very little scientific data and no long term studies showing that eating food products derived from clones are safe. In late October 2003, FDA released a draft assessment of the safety of food from clones or their progeny and found that there did not appear to be a food safety risk. The agency did issue a cautionary statement, however, by

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[63] Jaenisch, *supra* note 34.
[64] Wilmut, supra note 35.
[65] Jose B. Cibelli et al., *The Health Profile of Cloned Animals*, 20 NATURE BIOTECHNOLOGY, 13-14 (Jan. 2002) [hereinafter "Health of Cloned Animals"].
[66] Audrey Cooper, *Cloned Cows Die in California*, ASSOCIATED PRESS, Apr. 3, 2001, *available at* http://www.jhu.edu/~newslett/04-5-01/Science/6.html.
[67] John Travis, *Dolly was Lucky*, Science News Online, (Oct. 20, 2001), *at* http://www.sciencenews.org/20011020/bob15.asp.
[68] Simon Collins, *Cloned Animals Dying at AgResearch*, NEW ZEALAND HERALD, Nov. 14, 2002, *available at* http://www.nzherald.co.nz/category/story.cfm?c_id=82&objectid=3004259.
[69] Health of Cloned Animals, *supra* note 65.

stating that "[a]dditional data on the health status of progeny, and composition of milk and meat from clones and their progeny would serve to further increase the confidence in these conclusions."[70] Before allowing cloned animals on the market, FDA needs to review long term studies. The draft assessment is not scientifically persuasive because the agency relied on a single study of milk from cloned animals and no data at all on cloned meat.[71]

In 2002, the National Academy of Sciences also noted the paucity of data on the safety of food from cloned animals, stating that "[t]here are to date no published comparative analytical data assessing the composition of meat and milk products of somatic cell clones, their offspring, and conventionally bred individuals."[72] FDA must recognize that any conclusion about the safety of food products from cloned animals is premature, since there are virtually no data to support any such conclusion.

Moreover, it is important that FDA conduct a thorough review of the science showing that cloning inherently produces unstable animals, and thoroughly address any potential food safety issues from such instabilities.[73] This information shows that even cloned animals that appear healthy may suddenly become sick or have concealed illnesses that could affect food safety. For instance, the National Academy of Sciences' report, *Animal Biotechnology: Science Based Concerns*, stated the following:

> A number of datasets suggest that the health and wellbeing of neonatal and young somatic cell clones often are impaired relative to those of normal individuals. Direct effects of any abnormalities in patterns of gene expression on food safety are unknown. However, because stress from these developmental problems might result in shedding of pathogens in fecal material, resulting in a higher load of undesirable microbes on the carcass, the food safety of products, especially such as veal, from young somatic cell cloned animals might indirectly present a food safety concern.[74]

The head of one cloning company said that the data his company has collected on surviving cloned cows "suggested to the vets that some of them should be dead."[75] Dolly's creator, Ian Wilmut, warned that even small imbalances in a clone's hormone, protein, or fat levels could compromise the safety of its milk or meat, stating "[i]f companies start marketing this food and there are problems it will bring the whole

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[70] Animal Cloning Risk Assessment, *supra* note 28, at 11.
[71] *Id.*
[72] NAS 2002 study, *supra* note 26.
[73] *See generally, e.g.,* Merritt McKinney, *Flawed Genetic 'Marking' Seen in Cloned Animals*, REUTERS HEALTH, May 29, 2001; Yong-Kook Kang et al., *Aberrant Methylation of Donor Genome in Cloned Bovine Embryos*, 28 NATURE GENETICS 173 (2001), *available at* http://www.nature.com/ng/journal/v28/n2/full/ng0601_173.html; Rick Weiss, *Clone Study Casts Doubt on Stem Cells*, WASH. POST, July 6, 2001, at A-1.
[74] NAS 2002 study *supra* note 26, at 64-5.
[75] *Duplicate Dinner*, NEW SCIENTIST, May 19, 2001.

technology into disrepute."[76] Wilmut also pointed out that most studies of cloned livestock are of relatively young animals, while studies in mice have shown health problems at proportionally later ages.[77]

Due to the lack of long term food safety data, and the FDA's admission that these studies need to be done, it would be irresponsible and would put the safety of consumers at risk if the agency announced that cloned meat and milk can be sold to the public. Instead, FDA should find that animal cloning is not generally recognized as safe due to the food safety concerns.

(3) Animal Cloning Is Not Generally Recognized as Effective.

In addition to not being generally recognized as safe for animals and consumers, animal cloning is not generally recognized among the scientific community as being effective. Because animal cloning has extremely high failure rates, it should be regulated as a "new animal drug."

The rate of live animal births resulting from the implantation of cloned animal embryos into surrogate females is very low. For example, Ian Wilmut and his team of scientists implanted 277 cloned sheep embryos in surrogate ewes, from which only thirteen pregnancies resulted and Dolly was the only successful birth.[78] Even after several years of additional research and the development of new methods for extracting and transferring genetic material, well over 99% of all cloning attempts still fail.[79] Even when nuclear transfers produce embryos that are successfully implanted in surrogates, only 3% to 5% of these pregnancies produce offspring that live to adulthood.[80]

In another case, researchers at Texas A&M University set out to compare the development rates of cloned cattle derived from somatic and fetal cells. Only 17% of 322 adult somatic cell nuclear transfers and 12% of 332 fetal cell nuclear transfers developed into embryos.[81] Of these, 26 adult-cell-derived embryos and 32 fetal-cell-derived embryos were successfully implanted in surrogate mothers. After 40 days of pregnancy, six of the adult-cell-derived fetuses and three of the fetal-cell-derived fetuses survived. After 290 days of pregnancy, the experiment's only viable calf was born—a clone derived from an adult somatic cell. The project's 654 total nuclear cell transfers and 58 pregnancies had resulted in only one viable offspring.[82] But even this meager success rate was tainted. "The cloned calf produced in this experiment possessed significant metabolic and cardiopulmonary abnormalities similar to those observed in previous

[76] *Id.*
[77] James Meek, *Tears of a Clone*, THE GUARDIAN (London), Apr. 29, 2002.
[78] Sharon Begley et al., *Little Lamb, Who Made Thee?*, NEWSWEEK, Mar. 10, 1997, at 52.
[79] 2001 NAS, *supra* note 32.
[80] Weiss, *supra* note 33.
[81] Jonathan R. Hill et al., *Development Rates of Male Bovine Nuclear Transfer Embryos Derived From Adult and Fetal Cells*, 62 BIOLOGY REPROD., 1135 (2000) [hereinafter "Development rates"].
[82] Two embryos were surgically removed for study after 40 days of pregnancy and thus it is impossible to know for sure whether these would have survived to viability.

studies," the researchers reported. In addition, the calf was born with diabetes mellitus and was found to be susceptible to severe immune-system deficiencies.[83] These high failure rates show that animal cloning is not safe or efficacious. One scientist explained, "[i]f a drug for headaches worked only 2 percent of the time, the FDA wouldn't approve it. [But] that's where we're at [with cloning]."[84] Due to the high failure rates of cloning, FDA should find that somatic cell nuclear transfer in animals is not exempt from being a "new animal drug."

C. Somatic Cell Nuclear Transfer in Animals Is a New Animal Drug Because It Has Not Been Used to a Material Extent or for A Material Time.

SCNT should also be regulated as a "new animal drug" because it has not been used to a material extent or for a material time. Animal cloning squarely meets the second prong of the "new animal drug" definition because it is a novel and highly experimental technology.

The first animal clone from an adult cell, Dolly the sheep, was produced in 1996. The head of this scientific team, Ian Wilmut, warned in 2001 that commercial production of meat and dairy products from cloned animals should not be allowed until large-scale controlled trials have been conducted. It has not even been ten years since the first cloned animal was produced using somatic cell nuclear transfer and scientific evidence from large scale cloning trials has not been produced. Companies that are developing cloned meat and milk products have only been producing these animals for a few years. In order to argue that animal cloning has been used for a material extent and time, there needs to be evidence that cloned animals and cloned animal products, such as milk and meat have either been used for decades or significant long term studies have been done. Neither evidence of long term use, nor any long term studies exist for cloned animals products.

The Supreme Court explained that "the Act is designed so that drugs on the market . . . will have mustered the requisite scientifically reliable evidence of effectiveness long before they are in a position to drop out of active regulation by ceasing to be a 'new drug.' "[85] Before animal cloning drops out of active regulation by ceasing to be a new animal drug, there needs to be long term consistent scientific data showing that animal cloning is safe and effective. Given the small amount of animal cloning data available, FDA should find that somatic cell nuclear transfer in animals meets the second part of the "new animal drug" definition and therefore, should be regulated by FDA.

D. Finding that Animal Cloning is a New Animal Drug Is Consistent with FDA's Regulatory Approach to Human Cloning and Transgenic Animals.

[83] Development Rates, *supra* note 81, at 1138.
[84] Sharon Cohen, *supra* note 10.
[85] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 631 (1973) (explaining that "a drug can be generally recognized' by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon 'substantial evidence") (internal quotation marks omitted).

Finding that animal cloning is within the definition of drug is consistent with FDA's inclusion of human cloning and transgenic animals under the FFDCA's drug provisions. With human cloning, FDA explained to Congress that human cloning is subject to FDA's jurisdiction under the FFDCA's drug provisions.[86] FDA has jurisdiction over human cloning because cloning is "not sexual reproduction, since genetic material is derived from only one, not two, individuals. There is no sperm involved."[87] FDA issued a "Dear Colleague" letter announcing that no human cloning research could proceed until an investigational new drug application was in effect.[88]

In addition to regulating human cloning under the drug provisions, FDA also regulates transgenic animals under the new animal drug regulations. FDA explains that "[a]bsent a new, special law for regulating transgenic animals, the Federal government is directed to apply the existing laws. The animal drug provisions of the Federal Food, Drug, and Cosmetic Act best fit transgenic animals that have agronomic traits now being investigated and developed."[89] Transgenic salmon for instance are currently being reviewed by FDA under the new animal drug regulations. By regulating animal cloning under the new animal drug provisions, FDA will be acting consistently with its prior exercise of jurisdiction over human cloning and transgenic salmon.

E. The Health and Human Services Department Must Establish an Advisory Committee to Consider the Ethical Issues Related to SCNT.

A majority of Americans feel that the ethical issues implicated in animal cloning merit attention; thus the undersigned request the creation of a committee to address these ethical issues. A 2006 survey revealed that 63% of Americans believed that the federal government, the FDA in particular, should factor in ethical considerations when making decisions on animal cloning. Section 222, 42 U.S.C. 217a, of the Public Health Service Act, provides the United States Health and Human Services Department ("HHS"), the parent department of the FDA, authority to constitute advisory committees at the discretion of its secretary. CFS petitions the Secretary of HHS to invoke this authority to establish an advisory committee to address the broad societal issues related to animal cloning, as HHS has done in the context of human genetic technologies.[90]

An advisory committee on animal cloning must address public concerns including the animal welfare and religious concerns discussed below. The public discourse on animal

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[86] Zoon testimony, *supra* note 38. (explaining that the "use of cloning technology to clone a human being would be subject to both the biologics provisions of the Public Health Service (PHS) Act and the drug and device provisions of the Federal Food, Drug, and Cosmetic Act).

[87] *Id.*

[88] *Id.*

[89] John Matheson, *Will Transgenic Fish Be The First Ag-Biotech Food-Producing Animals?,* 14 FDA VETERINARIAN NEWSL., May/June 1999 *available at* http://www.fda.gov/cvm/may99.html.

[90] For example, consider the Department of Human and Health Services' Secretary's Advisory Committee on Genetics, Health and Society (SACGHS), established pursuant to 42 U.S.C. § 217a to serve as a public forum for deliberations on societal issues raised by the development and use of genetic technologies.

cloning is constructed and informed by an array of ethical systems. This petition has discussed the base concerns related to the marketing of the products of SCNT animals or their progeny, particularly consumer health and general animal welfare. These anxieties explain some of the public's strong aversion to the widespread use of this reproductive technology.[91]

A recent survey tells, however, that 63% of consumers would refuse to buy food from cloned animals even if the federal government labeled these products "safe."[92] This apprehension is inspired by sources ranging from the consideration of the basic interests of animals to religious tenet.[93] Approval or even non-regulation of cloned animals for market will invariably result in an increased employment of live SCNT methods in opposition to these beliefs and public concern. HHS has the authority to, and should, acknowledge these ethical concerns in its decision-making process.

A number of animal welfare organizations oppose the use of animal cloning.[94] In a society increasingly cognizant of the ethical implications of the mass production, maintenance and slaughter of animals for human consumption,[95] the usage of SCNT technology to produce factory-farm animals is a marked step backward. Even a system of ethics that grants only minimal consideration to the fundamental interests of animals, such as the avoidance of unnecessary pain, would regard these procedures as unjustifiable. As described previously, the high mortality rate and suffering of surrogates and clones raises animal welfare concerns. Furthermore, the proliferation of SCNT reproductive technologies can only further "objectify" or "commodify" animals, treating these living beings as mere test models and products for manufacture. Approval or non-regulation of cloned animals will bring the agriculture industry one step closer to realizing its self-fulfilling view that factory-farm animals are nothing more than 'machines' for use by humans to convert simple resources, such as grain, to more complex resources, such as milk, eggs, and meat.[96] This result makes animal cloning ethically offensive to a wide range of animal welfare advocates.

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[91] *See Pew Initiative Poll, supra* note 11 (reporting that 66% of American consumers are uncomfortable with animal cloning).

[92] *See Dairy Industry Support Continued FDA Ban on Selling Cloned-Cow Milk*, WASHINGTON TIMES, July 12, 2005 (citing poll by International Food Information Council), *available at* http://www.organicconsumers.org/Toxic/clone.cfm.

[93] *See FDA to Consider Morals, Ethics in Animal Cloning*, FDA WEEK, (Sept. 23, 2005).

[94] *See, e.g.*, Press Release, Humane Society of the United States, HSUS Asks the FDA to Ban Sales of Product from Cloned Farm Animals (Oct. 9, 2002), *available at* http://www.hsus.org/press_and_publications/press_releases/hsus_asks_the_fda_to_ban_sales_of_products_from_cloned_farm_animals.html.

[95] *See, e.g.*, Downed Animal Protection Act, H.R. 3931 & S. 1779, 109th Cong. (2005) (proposing the "Downed Animal Protection Act" in part to prevent "unnecessary suffering"); H.R. Con. Res 175 & S. Con. Res. 45, 107th Cong. (2001) (calling for the full enforcement of the Humane Methods of Slaughter Act).

[96] *See, e.g.*, F. Proudfoot, H. Hulan, & D. Ramey, *The Effect of Four Stocking Densities on Broiler Caracas Grade, the Incidence of Breast Blisters, and Other Performance Traits*, 58 POULTRY JOURNAL 791 (1979) (reporting results of an experiment seeking to determine the economically optimal space requirements for chickens raised for meat).

Religious groups have also rejected animal cloning on ethical grounds. In 1995, more than 200 U.S. religious leaders, including those from the Protestant, Catholic, Jewish, Muslim, Hindu and Buddhist faiths, announced a joint opposition to the patenting of animal genes, tissue, organs, and organisms, citing the belief that genetic manipulation and subsequent claims to exclusivity over the final product shifted "authorship" of life from 'God' to scientists and transnational companies.[97] In fact, religious groups who renounce SCNT in animals view cloning in general as tantamount to 'playing God.'[98]

Some Christian groups reason that animal cloning is contrary to God's mandate as expressed in the Book of Genesis. For example, R. Albert Mohler, Jr., president of the Southern Baptist Theological Seminary, explains that the "rulership" or "dominion" over animals delegated by God to human-kind in Genesis was indeed "limited."[99] He continues to assert that human-kind has no theological license to manipulate 'mechanistically' God's creation and threaten Earth's divinely balanced biodiversity.[100] Mohler concludes this discussion by calling the "genetic revolution" the "greatest ethical challenge of the new millennium." [101]

Finally, many fear that animal cloning is merely a stepping stone in the path to human cloning and eugenics. Leading scientists acknowledge that SCNT procedures developed on mammalian animals would remain essentially the same if utilized to produce human clones.[102] Many citizens feel that the continued cloning of animals represents a scientific "transgression"[103] and is a dangerous precedent which will be cited widely by proponents of SCNT as they push for permission to apply these technologies to human beings.

The diverse ethical concerns discussed herein must be addressed in detail before animal products produced via SCNT are marketed for human consumption. The strong public opposition to this technology illustrates that an ethical consciousness directs the public debate on animal cloning in America. Hence, CFS requests that HHS establish an advisory committee, mirroring the Secretary's Advisory Committee on Genetic, Health

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[97] *See* PAUL FLAMAN, GENETIC ENGINEERING: CHRISTIAN VALUES AND CATHOLIC TEACHING 31 (Paulist Press 2002), *quoting* JEREMY RIFKIN, THE BIOTECH CENTURY 65-6 (Tarcher 1998).
[98] *See, e.g.*, *FDA to Consider Morals, Ethics in Animal Cloning*, *supra* note 93.
[99] *See* R. Albert Mohler, Jr., President, Southern Baptist Theological Seminary, *The Brave New World of Cloning: A Christian Worldview Perspective*, THE HENRY INSTITUTE ARTICLE COMPILATION, http://www.henryinstitute.org/article_read.php?cid=7.
[100] *Id.*
[101] *Id.* While a survey of religious perspectives will reveal that not all religious teachers agree wholeheartedly with Mohler's theological conclusions, such an inquiry will affirm that the religious community in the United States is conflicted on the issue of SCNT in animals. *See generally* ISSUES FOR THE MILLENNIUM: CLONING AND GENETIC TECHNOLOGIES, Bioethics conference on cloning at Boston University adapted to video, *available at* http://www.meta-library.net/iftm/index-body.html.
[102] *See, e.g.*, The President's Council on Bioethics, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), *available at* http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf. However, this committee did not address animal cloning.
[103] *See FDA to Consider Morals, Ethics in Animal Cloning*, *supra* note 93.

and Society, to deliberate both publicly and officially the ethical challenges presented by animal cloning.[104]

Specifically, CFS petitions HHS, under authority from 42 U.S.C. 217a, section 222 of the Public Health Service, to create an advisory committee to: (1) provided a forum for experts to discuss, deliberate, and formulate advice and recommendations on the range of sensitive human safety, ethical, legal and other social issues raised by the development and proliferation of SCNT technologies in animals; (2) assist HHS and other federal agencies in exploring issues raised by the development and application of these genetic technologies; (3) make recommendations to the Secretary of HHS concerning how to address these issues. Thus, this committee must consist of authorities knowledgeable in religion, ethics, and animal welfare, as well as molecular biology, genetics, public health, health care, social sciences, consumer advocacy and law.

F. Before Acting on each NADA for SCNT in Animals, FDA Must Prepare an Environmental Impact Statement.

When applying the New Animal Drug provision to SCNT in animals, FDA must, pursuant to NEPA, 42 U.S.C. §§ 4321-4347, and the Code of Federal Regulations, 21 C.F.R. §§ 25.15, 511.1(b)(10), 514.1(b)(14), consider environment factors in its decision making process. Due to the uncertainty surrounding the long-term environmental impact of the introduction of cloned animals into the food-supply, CFS petitions FDA to prepare a full "environmental impact statement" for each new animal drug application (NADA) based on SCNT.[105]

The lack of rigorous scientific research on the lasting environmental effects of the widespread commercialization of cloned animals prevents the issuance of a "finding of no significant impact" by FDA.[106] Although FDA claims a strong belief in their conclusions about food safety, FDA has admitted to the paucity of valid scientific research attesting to the exact genetic composition of the products of cloned animals or their progeny.[107] Not surprisingly, numerous questions remain regarding the effect that the proliferation of SCNT animal cloning will have on animal disease rates given the concomitant reduction in biodiversity.[108] Other environmental concerns abound with the

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[104] It is worth noting that the same ethical concerns arise in the context of transgenic animals. Before FDA permits transgenic animals to be introduced into the American food supply, this advisory panel should address these concerns as well.

[105] *See* 42 U.S.C. § 4332, 21 C.F.R. § 25.21, and 40 C.F.R. § 1508.27.

[106] *See, e.g.*, *Found. on Econ. Trends v. Heckler.* 756 F. 2d 143, 152-55 (D.C. Cir. 1985) (discussing considerable environmental considerations required under NEPA with respect to the introduction of new biotechnology).

[107] Animal Cloning: A Risk Assessment, supra note 28.

[108] *See, e.g.*, Carol A. Morgan, *Veterinarians in the Cloning Lab: Obligation or Odious?*, 9 SOC'Y FOR VETERINARY MED. ETHICS NEWSL. 10 (May 2003) (discussion possibility of monoculture resulting from cloning and subsequent increased likelihood of epidemic), *available at* http://www.vetmed.wsu.edu/org_SVME/images/vol9-2.pdf; *see also* Christopher Mario, *A Spark of Science, a Storm of Controversy*, U.S. 1 NEWSPAPER, March 5, 1997 (noting positions against animal cloning), *available at* http://www.princetoninfo.com/clone.html.

extensive application of SCNT technologies in American food production. Comprehensive studies must be conducted to identify and examine the range of these environmental effects. Moreover, the degree to which the environmental impact of SCNT in animals is "uncertain" or "unknown" compels review under § 25.21 and 40 C.F.R. §§ 1508.27(b)(5) and 1508.27(b)(4).

Additionally, FDA may not invoke the categorical exclusions included in the Code of Federal Regulations, 21 C.F.R. §§ 25.30, 25.33, to avoid environmental considerations in its decision-making process. The public has a right to know that health and environmental effects of animal cloning have been analyzed and considered. Action on the NADA for SCNT in animals will also increase the use of such technology, precluding exclusion under §25.33(a). Finally, some in the dairy industry have stated that they will utilize this technology, in part, to create dairy cows;[109] FDA routinely classifies such animals as 'food animals,' precluding exclusion under § 25.33(d)(1). FDA must take into account the environmental impact of action on the NADA for SCNT in animals, because the statutory exclusions do not apply.

V. Environmental Impact

The specific actions requested by petitioners are categorically excluded under 21 C.F.R. § 25.30(h) and therefore do not require the preparation of an environmental assessment.

VI. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition

VII. Conclusion

For the reasons contained herein, petitioner respectfully requests that FDA initiate the following actions:

1. Issuance of an interpretive rule requiring all producers of animal clones to comply with the Federal Food and Drug Cosmetic Act's new animal drug requirements and FDA's implementing regulations before permitting the sale of any cloned animals or cloned food products, including reviewing the health risks from consuming milk or meat products from the offspring of cloned animals.

2. Conversion of its voluntary moratorium on food or feed from cloned animals into a mandatory moratorium until each product of cloning completes the new animal drug process.

[109] Gillis, *supra* note 16.

3. Preparation of an Environmental Impact Statement ("EIS") evaluating the environmental and health effects of each new animal drug petition.

4. Creation of an Advisory Committee to address the ethical issues of animal cloning by HHS.

As established in 21 C.F.R. § 10.30(e)(2), petitioner request that the agency provide an answer to this citizen petition within 180 days. In the absence of an affirmative response, petitioner will be compelled to consider litigation in order to achieve the agency action requested.

Respectfully submitted,

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Joseph Mendelson III
Legal Director

October 12, 2006