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HOME-GROWN AND CLONE-GROWN:

Why special labeling should, but most likely will not be, mandated for the meat and milk of cloned animals and their progeny.

Since advancements in science and technology have made possible the cloning of various farm animals, farmers and ranchers have begun to use this innovation to make their farming operations more profitable. These farmers view cloning as a tool for breeding more of their best meat and dairy producing livestock. However, opponents view cloning as a highly controversial procedure with many moral and ethical questions to be answered. Despite this continuing debate, the Food and Drug Administration has issued a preliminary report stating that farmers will be allowed market products from cloned animals because scientific research has not found that cloned animals pose unique health or safety threats to human consumers. Predictably, consumer groups, animal welfare advocates, religious organizations and other groups have responded to this report with demands that products from cloned animals be labeled, when marketed, in order to inform consumers as to which products are from cloned animals.

I. Introduction

Historically, farmers have attempted to improve their livestock through various breeding methods in order to make farming production more profitable.[1] The farmer's objective then is to breed animals that characteristically grow more meat or produce more milk and build herds comprised of these characteristics. This is a strategy of increasing production and thereby profits, via improved herds, which can be bred using the same effort it once took to produce less profitable herds. Treating livestock with regular

dosages of growth hormones[2] enables farmers to expend less effort, cost and time to grow their livestock to optimum bulk.[3] Farmers then slaughter their livestock younger for more profit.[4] Since farm profitability is directly connected to expending the least amount of time and cost in the production of herds with optimum characteristics; new innovations in animal reproduction will continue to allow farmers to breed increasingly profitable herds more efficiently.

In 1997, with the successful cloning of Dolly the sheep,[5] new possibilities in the partnership between farming and science were born - such as the possibility of cloning the best livestock, particularly those which are prized for their meat and milk production. With this technology, scientists have cloned some of the best livestock and dairy cows with plans of using the cloned animals for breeding stock, dairy producers and meat.[6] However, much concern has risen over the use of cloning technology in the production of food for human consumption.[7]

There is much debate over the legalities, ethics, morals, safeness and future implications of this technology. A strong influence in the direction of this debate is the recent announcement of the Food and Drug Administration (FDA) to allow milk and meat from cloned animals and their progeny to enter the American market without special tracking, labeling or regulation.[8] In consideration of the FDA's announcement, opponents of cloned foods have focused on the possible solution of mandated labeling for food from cloned animals.[9] However, as illustrated by case law and failed legislation concerning genetically modified (GM) foods, special labeling for cloned foods is not likely to be mandated. This leaves opponents of cloned animal products with the remedy of using their consumer power to influence the market and thereby encourage companies

to voluntarily label their products as "cloned-free" or otherwise.

The science of animal cloning.

The idea of cloning an animal to create a new, almost identical animal is intriguing. However, some argue that the reality of cloning is far removed from reports and pictures of cloning success stories.[10] Part of the opposition to cloning stems from the high rate of failed attempts and the low rate of the production of viable, cloned animals. Dolly the sheep was the first mammal to be cloned from adult DNA. She was born after 276 failed attempts.[11] The high amount of failed attempts per successful clone has not significantly decreased since 1997.[12] These figures highlight the fact that advancements in cloning technology and methods are necessary before scientists can truly consider the cloning process "successful."

The process of "somatic cell nuclear transfer" (SCNT), is the highly inefficient method by which scientists cloned Dolly and now, livestock for human consumption.[13] Data suggests that over ninety-five percent of cloning attempts result in miscarriage or offspring that cannot survive infancy.[14] Livestock clones, which do survive gestation, are often born with abnormally large placentae and/or large bodies; this is known as "Large Offspring Syndrome" (LOS).[15] Furthermore, cloned animals tend to suffer from an abnormally weak immune system which invariably results in infections, tumor growth and other health problems.[16] About one third of cloned calves die in infancy. Many more clones appear healthy in infancy but die of unknown causes or develop health problems in adulthood.[17]

The SCNT process of reproductive cloning is attempted by taking genetic material out of the nucleus of the cell of the adult animal which is being cloned; and

putting that genetic material into the nucleus of an ovum cell which has had its nucleus and genetic material removed. The ovum cell is then stimulated, through electric shock or chemical reaction, in order to cause mitosis[18]. Cell division, by mitosis, then creates an embryo which is then implanted into the uterus of a surrogate host where the embryo will most likely terminate, but might develop until birth. It is important to note that SCNT only clones nuclear (chromosomal) DNA and not the mitochondrial DNA of the donor of the adult cell. The clone will inherit the mitochondrial DNA of the donor of the ovum cell.[19] Therefore, when SCNT is used, the resulting clone will not be a true clone. Instead, the clone's cells will have the nuclear DNA of one animal's cell, but the mitochondrial DNA of another animal's ovum cell. In contrast, a true clone would have the same nuclear and mitochondrial DNA as its original.

Cloning presents potential profitability to farmers, but dilemmas for others. The undesirable effects, moral concerns and ethical difficulties of cloning have prompted those who oppose animal cloning to lobby lawmakers to enact legislation that would compel farmers to label animal products from cloned animals.

II. The Dilemmas and Benefits of Cloning

The farmers and scientists who plan to market products from cloned animals seem convinced of the ability of cloned animal products to rival current products from conventionally bred animals both in quality and in economic efficiency. Even the FDA has agreed that products from cloned animals are essentially the same as the animal products currently marketed.[20] Opponents of cloned animal products have remained skeptical of these claims. Opponents base their arguments on moral, ethical, religious

and economic concerns. These concerns result from the consumer's inability to distinguish between foods which they find offensive and foods which are benign to their sensibilities. The inability to distinguish between offensive and inoffensive foods can be remedied simply by mandated labeling. Opponents argue that labeling foods from cloned animals should be mandated and at the very least voluntary labeling should be allowed.

A. Government involvement in the debate surrounding animal cloning for food.

The United States government has yet to oppose the allowance of cloned animals in the human food supply, and most likely will not oppose cloned foods in the future. However, the governments of many other countries, supported by animal welfare advocates, religious organizations and various consumer groups have yet to accept the prospect of cloned animals entering the market because idea of consuming cloned animals is unethical if not immoral to many of these groups. To many more people, the thought of consuming cloned animals is simply too abnormal to be appetizing.

In the FDA's recently published Draft Risk Assessment of cloned food for human consumption, released December 28, 2006, the FDA denied any potential health or safety risks associated with cloned food.[21] The FDA also gave the public ninety days to respond to the Draft Risk Assessment before issuance of a formal statement of policy, which is expected to allow the sale of cloned animal products for human consumption without special labeling.[22] The governments of other nations await this formal statement and are expected to thereafter issue their own policy statements and laws regarding animal cloning for human consumption.[23] The FDA's Risk Assessment states that with the exception of meat and milk from cloned sheep[24]; the same from adult cloned bovine[25],

adult cloned swine[26], and adult cloned goats[27] were safe for human consumption as compared to conventionally bred and raised comparators. Additionally, the products of the progeny of cloned farm animals pose no risk for food consumption as compared to conventionally bred and raised animals.[28] The FDA's determination that the food from cloned animals is safe has heated the debate as to whether cloned foods should be allowed.

B. Farmers have embraced cloning technology.

That the FDA has tentatively approved cloned foods is a victory for farmers who have already used cloning to bolster their herds and have sold clones as breeding stock to other farmers. Farmers and ranchers argue that by cloning their best breeding stock they can create herds reflecting characteristics preferred by the breeders of clones. These traits include, but are not limited to, high milk production, lean meat, fast rate of growth.[29]

Instead of selling the semen from a highly prized bull for in-vitro fertilization, farmers and ranchers will presumably be able to clone the prized bull and have almost an exact copy of the original animal to sell to other farmers and ranchers. Using a clone as breeding stock will presumably produce livestock more closely resembling the cloned prizewinning bull than the method of breeding which produces, through in-vitro fertilization, the offspring of the prizewinning animal.[30] Essentially, cloning eliminates much of the unpredictability apparent in conventional breeding methods.[31] This is to say that any farmer who so desires, can have a copy of an original prize winning bull with which to sire their herd. This cloned bull would be used instead of semen from the original bull to inseminate multiple cows in hopes of any resulting offspring having the

desired characteristics of the original bull so that offspring can be used to sire a herd.

Presumably, having a herd made up of the offspring of a cloned prize winning bull will result in more of the best meat.[32] Furthermore, more of the best meat in the market will result in lower cost of meat due to the economic principles of supply and demand.[33] This same principle would doubtless be applied to the cloning of dairy herds. Clone farming is optimistically predicted have a trickle down effect so that the poorest people in the world will be able to afford better meat and milk.[34] However, this logic is flawed because, just as the people of the poorest nations rejected GM foods which were said to come from plants which were modified to yield higher amounts of more nutritious and longer lasting produce, cloned foods are expected to be rejected by many of the world's poorest people due to religious and ethical concerns.[35]

C. Animal welfare advocates oppose cloning for moral and ethical reasons.

Despite the benefits that farmers and ranchers see in cloning, the public of the United States and countries around the world are concerned about the implications and hazards of cloning. Animal welfare advocates are concerned with the harmful effects that cloning has on the clones, their surrogate mothers, and the herds and flocks they may help produce. Animal welfare advocates are concerned that the process of cloning is flawed as evidenced by its low success rates. They argue that the science of cloning needs further research and more effective procedures must be developed before cloning becomes part of an industry that is already submerged in animal welfare controversy.

The chances that a cloning attempt will even produce an embryo are very slim, that the embryo will result in a live birth are even more slim. The probability that a live birth will not result in the sudden death of the animal, or a sickly animal are even less

likely. The low success rate is due to the fact that cloning using the SCNT process damages cells.[36] Damage to the cells may take place during the process of gene imprinting, which is disrupted during cloning.[37] Imprinting is the natural process by which the genes in the gamete cells from one parent switch on and the genes from the other parent switch off so that the offspring will have a physical trait. This is to say that in SCNT, when the adult cell from which an animal is cloned is going through the process of cloning; the genes making the adult cell perform its function, for example, as a skin cell, must be switched off and the genes which will make the adult cell perform as an embryonic cell will then be turned on.[38] This process may result in some genes being switched on when they should be switched off and vice versa.[39] Presently scientists cannot control genetic imprinting because it is not fully understood and this causes such a low success rate of cloning.[40]

Animal welfare advocates are even more troubled by the implications of cloned animals which are born sickly and kept alive just long enough to be slaughtered.[41] Once born, clones tend to have a much higher rate of sickness and deformity.[42] There have been large quantities of failed attempts resulting in many miscarried, sick and deformed animals.[43] Thus, if an animal is doing poorly and the farmer knows it will not survive to adulthood, he can order the animal slaughtered so long as it can stand.[44] However, if the cloned offspring lives but is sickly, it will be given antibiotics which will not be recorded and when the animal is eventually slaughtered, its meat is more likely to pass antibiotic resistant food born illnesses on to those who consume its meat or milk.[45] Additionally, if the cloned animal does survive, the milk or meat it produces may present health risks to consumers.[46] This is because hormone imbalances resulting from the cloning process,

which are undetectable, can compromise the composition of the animal product.[47] Therefore, the consumption of cloned animal products is potentially harmful.

Another problem that animal welfare advocates have with cloned animals is that the birth defects common to clones adversely affect the health of their surrogate host. When pregnant with the embryo of a clone, the surrogate host tends to produce a larger volume of amniotic fluid and larger placentae than when impregnated with a conventional embryo.[48] Therefore, it is more difficult for a surrogate mother to give birth naturally and without severe complications.[49] Some of these birthing complications result in death to the surrogate and possibly the offspring.[50] In a minority of cases, these problems do not arise, however these occurrences cannot be predicted due to the lack of scientific information and knowledge of cloning procedures.[51] Furthermore, animal welfare advocates argue that after generations of cloning, a herd of cloned animals and their progeny will be less adapted to their environment than the bacteria and viruses that make them sick.[52] The herd will therefore be less resistant to disease and overall less healthy and less fit for human consumption than now.

D. Religious groups oppose animal cloning.

Many religious groups have perceived advances in animal cloning as immoral and controversial. Some fear that advances in animal cloning will be used in stem cell research, fetal farming and human cloning. Still others believe that their 'God' has given humans the duty not to misuse animals, and feel that cloning does just that. Others believe that diversity is part of divine design and cloning results in lack of diversity in animal populations. These religious ideas have turned many followers against cloning

altogether.

There are five components to the religious objection to animal cloning.[53] Those components are that: it is unnatural; cloning creates a lack of diversity in the animal's genome; it is theologically unacceptable; cloning creates animal welfare problems; and, cloning is a use of animals that was unintended by God.[54]

The argument concerning unnaturalness is arguably weak. There are few people, even from religious organizations, who do not take advantage of unnaturally manufactured commodities and who have not taken advantage of "unnatural" medical procedures to save a life, make a life or elevate the quality of life for both humans and animals. However, the unnaturalness argument is closely associated with the argument that a lack of diversity is opposed to divine design.[55] The association between these arguments is that; animals are programmed by nature, or divine design, to reproduce in a manner that ensures the diversity of the gene pool of each species. To disrupt this fundamental design of nature can create instability in the process of natural selection from generation to generation.[56] This, over time, can result in significant genomic flaws and even extinction of a cloned species that is unable to adapt to an ever-changing environment.[57] Therefore the progeny of such animals would suffer from a lack of diversity so genetic flaws and weaknesses wont be bred out and weaknesses could be compounded by an ever changing and diversifying, evolving and adapting environment.[58] Moreover, the characteristic strengths for which a line of animals is cloned may become weaknesses if the animals are not allowed to reproduce in order to compete in their changing environment.[59]

The third argument, that cloning is theologically unacceptable follows that

theology provides that a creator has set up reproduction as a means to create a world full of diversity and originality, creating clones upon clones would disrupt this divinely made plan for reproductive diversification.[60] This goes directly against God's command to creatures on earth to "be fruitful and multiply."[61] This means that cloning would be theologically impermissible for any result.[62]

The next contention is that cloning is unethical because large numbers of failed pregnancies, premature deaths, birth defects, problem pregnancies and health issues raise significant animal welfare concerns.[63] Religious leaders and animal welfare advocates agree that before animal cloning should be allowed on an industrial scale, it would be necessary to find solutions and cures to these maladies before they are produced on a wide scale.[64] Furthermore, animal cloning may open the door to more animal testing in science when this has been a highly controversial use of animals already. [65] The world's largest religions believe that humans are charged with the duty by God to care for and respect animals as God's first creations and as weaker, dumber species at human's control and disposal. [66] This is especially a prevailing concern where scientists and farmers have been known to violate the bounds of ethical and moral behavior in their treatment of animals. [67] The Church of Scotland suggests that "producing animals for manufacture" (to be slaughtered on a schedule made to accommodate the factory production of meat) takes a step too far in the direction of making animals commodities, instead of a respected creature of God.[68]

Because cloning has produced these religious issues, some religious groups have lobbied and filed law suits to force the FDA to allow or mandate labeling to inform consumers, in order for them to follow their religious practices.[69] This has not yet met

success.

E. Concerns of the general public.

Food suppliers and producers are concerned that when meat and milk from cloned animals is allowed into the market, international consumers will stop buying American products.[70] This scenario first occurred as a reaction to the FDA's refusal to mandate labeling of dairy products that came from cows that were given the synthetic growth hormone, rbGH.[71] Dairy producers suffered losses in sales locally and internationally.[72] Ben and Jerry's ice cream responded by labeling their products as rbGH-free.[73] There is evidence that people in the United Kingdom, Australia, New Zealand, Japan and elsewhere, will not want to buy American foods which may contain products of cloned animals.[74] These fears of consumers would be eradicated by FDA mandated labeling of meat and milk from cloned animals.[75]

People feel they have a right to know what they are buying and putting into their bodies.[76] Some argue that because the prospect of eating products from cloned animals is controversial, producers and farmers should be required to track and label potentially offensive products.[77] In response to that argument, the FDA has stated in its Risk Analysis that, scientifically, there is no difference in composition or health risk to the consumer between cloned animals and conventionally bred animals. Therefore, there is no "science-based reason to apply additional safeguards"[78] because the health risks and concerns which exist in clones, also exist in conventionally reproduced animals, though to a lesser degree. [79] Although health risks have been assessed by the FDA, there is scientific evidence that cloned animals have a higher risk of immune deficiencies than conventionally reproduced animals.[80] Therefore, slaughterhouses will be slaughtering

more animals infected with food borne illnesses and in effect, there will be a higher percentage of contaminated meats in the market.[81] Moreover, since clones have a higher incident rate of illness and debilitation and deformity, there will be a larger number of these malformed and sick animals in the food supply. In markets which have recently struggled with mad cow disease, this is a real fear.[82]

People are concerned that the lack of long-term studies on the effects of eating products from cloned animals will later result in findings that the meat and dairy products from cloned animals is in fact unsafe. People are afraid that in the same way pharmaceutical products are approved by the FDA and later found to be unsafe, cloned food will eventually found unsafe or unhealthy.[83]

While many people are concerned about the health risk to humans, much of the problem with allowing unlabelled cloned food in the market has to do with what the media is calling the "yuck factor."[84] Therefore, many consumer health concerns are only a vehicle to get politicians and legislators to enjoin farmers and ranchers from allowing meat and milk into the food supply.[85] Currently, the FDA has asked farmers to keep cloned meat and milk out of the food supply - voluntarily.[86] However, farmers say that cloned animals and their progeny have no doubt been slaughtered and sold as food despite the FDA's requests to keep such animals off the market.[87]

Health concerns also center on the possibility that animals could be cloned which have been genetically modified to contain pharmaceuticals in their milk etc.[88] People are afraid that GM animals will be cloned, the products from which must have special testing and labeling before it is sold.[89] The gist of these concerns is that animals with pharmaceutical qualities could be cloned and sold for human consumption as a clone

rather than a GM product, thereby bypassing government restrictions on GM foods.[90] The FDA states that this is simply not going to happen.[91] Cloned animals are not considered by the FDA to be GM because their genes are not altered in the SCNT process, and merely a "twin" is born.[92] However, as previously stated, a case can be made that an animal which is cloned through the SCNT process is, in fact, GM; since its cell composition is modified to contain nuclear DNA from one animal and mitochondrial DNA from another. If cloned animals were found to be GM they would have to undergo more stringent testing to ensure that they were safe for human consumption.[93] However, the FDA has not categorized cloned animals as GM.

The FDA has not found any safety concerns with the sale of meat and milk from currently clone-able animals or their progeny, with the exception of meat and milk from cloned sheep.[94] Therefore, these health concerns will likely be dismissed because the FDA bases its opinions on scientific evidence rather than public concern for morals or ethics and there has been no scientific evidence of risks to humans from consuming products from cloned animals.[95]

F. Economic concerns of cloning without labeling.

Cloned food products will effect the international market and therefore, presents economic risks to American exporters.[96] European, Australian, Japanese, and New Zealand markets are expected to refuse American cloned produce just as they refused American GM foods.[97] Foreign milk and meat producers which can verify that their herds are clone-free, plan to dominate the milk and meat market where unlabeled American products are predicted to falter.[98]

Foreign consumer groups are alarmed by cloned food because surrogate hosts of clone embryos are given high doses of hormones in order for the cloned embryo to implant and grow, and once the cloned animal is successfully birthed, it may well suffer from a severely weakened immune system.[99] Sickened animals will then be given hormones, steroids and antibiotics thereby allowing pharmaceuticals into the food supply.[100] To these consumer groups, products from animals treated with synthetic hormones and antibiotics are undesirable and perhaps detestable. Furthermore, the U.S. Academy of Sciences has issued a warning that slaughtered clones may increase the amount of food borne bacteria in the supply.[101] Foreign importers and governments are quick to prohibit the importation of products which may bring an increase of food born illnesses into the food supply unchecked.[102] European consumers are weary of the FDA's findings that cloned animals are safe.[103] This is especially true in light of the fact that the American Center for Food Safety in Washington has received testimony from farmers stating that their reports to the FDA, which state that their cloned animals were having health problems not found in conventionally bred animals, have been ignored.[104]

Before European importers can import and sale cloned American meat and milk, the European Union must approve of the entrance of cloned animals in the European Food supply.[105] Then each European nation must approve the entrance of cloned animals into its food supply.[106] EU officials have drafted preliminary regulations, in light of the FDA's Draft Risk Assessment, stating that food from cloned animals is considered "novel" and must pass safety tests before marketing. The regulations, however, do not address whether milk and meat from the progeny of cloned animals should be considered "novel" or not.[107] European food safety administrators have been known to follow the

FDA's suit once a new product is deemed marketable.[108] European administrators are expected to publish their decisions regarding the sale of cloned foods in EU markets, but are waiting for the FDA to publish a more definitive opinion on the safety and marketability of food from cloned animals and their progeny.[109]

American producers can ensure their domination in the international meat and milk markets if they label offending food to calm consumer discomfort. In the event that American meat and milk producers do not resolve the labeling issue with respect to cloned foods, other markets specifically that of New Zealand, will have a foothold in the clone-free and GM-free markets.[110] These producers have already vowed to remain clone free and to track their animals "from field to fork" as is the practice already.[111] Because cloning meat is ethically controversial and creates concerns for some cultures, foreign milk and meat producers, who label and track their products and can guarantee that such products are clone-free, may begin to dominate some international markets where American products once dominated.

It is, therefore, upon their concerns for animal welfare, religious practice, economic viability and public discomfort that, those who oppose cloned food, build their case for labeling. The scientists and farmers who wish to mass-produce cloned animals for human consumption have been preliminarily backed by the policies of the FDA. Those policies dictate whether or not labeling of cloned food is a possibility. Although the crux of this debate is over whether labeling should be mandatory, voluntary labeling is an alternative. Labeling would serve the interests of farmers and scientists by still allowing cloned foods to be produced; but also, the interests of consumers would be served by allowing the public to practice their freedom to choose whether to purchase

products, which may potentially offend some.

II. Federal Regulation of Cloned Foods

In the controversy surrounding cloned foods, opponents of foods from cloned animals have lobbied legislators to halt cloned foods from being marketed; to have cloned foods labeled; and, to have cloned foods undergo further pre/post-market health and safety testing. Lobbying the legislature has been unsuccessful thus far. There has been no litigation to date; however, the FDA has yet to issue a formal statement allowing cloned animal products to enter the market without more extensive testing or labeling. Currently, only administrative law concerning the sale of foods and labeling govern cloned foods. More specifically, the FDA and USDA are the administrative agencies which maintain authority over the production and sale of foods. It is through these agencies that cloned foods will most likely be allowed in the market without any additional restrictions.

The Office of Science and Technology Policy (OSTP) bestow the authority of the FDA and USDA to regulate cloned foods.[112] In 1986, this executive agency set forth the Coordinated Framework for Regulation of Biotechnology outlining the "regulatory structure" by which administrative agencies now regulate cloned animal products.[113] After issuing the Coordinated Framework, the OSTP issued a policy statement which defined the scope, direction and duties within the regulatory structure.[114] This policy essentially formulated a method by which the agencies regulating cloned foods would take a science-based approach to making decisions regarding the safety and regulation of foods.[115] In the case of cloned foods, the regulating agencies are the FDA and the USDA. Under the Coordinated Framework, when making decisions regarding the safety

and regulation of foods, the FDA and the USDA use "peer-reviewed scientific literature, the National Academy of Sciences and other scientific entities, public meetings, meetings of scientists addressing specific issues and products, and other forms of scientific advisory panels."[116] Therefore, while these two administrative agencies regulate cloned animal products under different authority and under their separately enacted regulations, they must make decisions regarding the regulation of foods using science rather than public sentiment as persuasive authority. This is not to say that the industries subject to regulation have no influence on the regulating administrative agency either through peer reviews or lobbying groups or otherwise.

In the 1980's federal legislation was passed concerning the inconsistent and false labeling, claims, and advertising of foods. This occurred through the Nutrition Labeling and Education Act (NLEA) of 1990, which took effect in 1994.[117] Under this Act, the USDA, through its Food Safety and Inspection Service (FSIS), and the FDA regulate food labeling while the Federal Trade Commission (FTC) regulates advertising.[118] The FSIS regulates the labeling of meat and poultry, while the FDA regulates all other food product labeling.[119]

A. The FDA.

The FDA has the authority to mandate labeling for cloned foods. This authority is mandated in the Food, Drug and Cosmetic Act (FDCA). Specifically, two sections of the FDCA mandate provisions for food labeling that can be applied to cloned foods. Those provisions are: Sec. 403(a), which mandates foods to be properly labeled such that customers will be informed of the food's material facts; and Sec. 403(q)(2)(A), which states that a label must list additional nutrients if such a mandate would "assist consumers

to maintain healthy dietary practices."[120] Whether food is from cloned animals or not is considered by many to be a "material fact"; especially in light of the moral and ethical concerns of consumers and the possibility of increased incidents of food born illness from cloned foods.[121] Additionally, higher incidents of food born illnesses, and animal birth defects, and sicknesses illustrate the need for labeling which would help consumers distinguish between products from cloned animals in order to maintain healthy dietary practices.[122]

The FDA has stated that their decision to allow cloned foods, unlabeled, into the food supply was based on scientific data showing no risk to consumers.[123] Furthermore, the FDA assures consumers that food safety regulations already in place are sufficient to protect consumer health and restricts diet-disease claims to those claims that are "substantially supported by scientific agreement."[124] In deciding whether to allow a food to be marketed, the Food and Drug Administration Modernization Act of 1997 allows the FDA to consider health claims based on statements made by U.S. Government scientific bodies which are responsible for public health, such as the National Academy of Science or its subdivisions.[125] Therefore, if a government body does not make a statement contrary to the claim that cloned foods are safe, then the FDA will dismiss all health claims. This alone should incite consumer fear. However, if food is not considered adulterated, nor an additive, the FDA requires only notification as opposed to approval, before the food is distributed commercially.[126] A food is considered adulterated under the FDCA when it "bears or contains any poisonous or deleterious substance which may render it injurious to health."[127] This is to say that, the FDA can only be compelled to consider consumer health concerns brought by the public when such health claims are

based on statements made by Government scientific bodies, when the food is adulterated or when the food is an additive. The FDA has not found that any of these three conditions apply to cloned animal products.[128]

The FDA regulates several components of food labeling through the FDCA. First, the FDCA does not allow manufacturers and producers of food products to mislabel their products by putting false or misleading labels on food products then allow them into interstate commerce.[129] Second, the FDA may only require manufacturers to describe their product using its common name.[130] Last, the FDA requires labeling when a food "differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted."[131] In the case of cloned food, the FDA may require manufacturers of cloned animal food products to label those products as "cloned" if the FDA finds that cloned animal products are materially different from their conventional counterpart such that the lack of labeling would fail to provide all "material information." Moreover, the FDA may mandate specific labeling if it determines that certain information is so necessary that its omission would make the label misleading.[132] Many opponents of cloned food argue that it would be misleading not to disclose whether food is made from cloned animals or not.

Under the FDCA, Congress specifically limited the type of information that the FDA could compel food companies to place on their labels.[133] That information is limited to ingredients, net weight of the contents of a package, name and address of the manufacturer or the party responsible for marketing the food, and a precise statement identifying the food.[134] After the NLEA of 1990 was passed, Congress amended the

FDCA "complete nutrition labeling."[135] Now, the NLEA requires manufacturers to only disclose that information which is necessary to allow consumers to make prudent choices concerning food.[136] The FDA may decide to exclude from a label any information not necessary to this end.[137] The FDA has not formally stated their intention to mandate the labeling of cloned animal products. This is unlikely in light of the FDA's preliminary determination that meat and milk from cloned animals is presumed GRAS, and is considered essentially the same as meat and milk from their conventionally bred counterparts.[138]

The FDA's preliminary determination that cloned foods are safe will not quiet consumer demands for voluntary labeling of cloned food products. However, the FDA also regulates voluntary labels. Voluntary labels are not permitted to imply that a food, which contains cloned food, is better than foods that do not contain products from cloned animals.[139] The FDA, under the FDCA, would consider such a label to be misleading.[140] In 2001, the FDA adopted voluntary labeling guidelines in response to consumer demand that GM products be labeled. The FDA issued this statement about those guidelines:

> "We are still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed . . . . We are, therefore, reaffirming our decision to not require special labeling of all bioengineered foods. We are providing guidance to assist manufacturers who wish to label their foods voluntarily as being made with or without the use of bioengineered ingredients. While the use of bioengineering is not a material fact, many consumers are interested in the information, and some manufacturers may want to respond to this

consumer desire."[141]

These guidelines, however, may be applied to cloned food since cloning is considered genetic engineering if not genetic modification. Therefore, even if the FDA does not mandate labeling because the process by which food is cloned is not considered a "material fact," manufacturers may voluntarily label their food products to assist their consumers.

Consistent with the Coordinated Framework's science-based risk assessment, the FDA has established its standpoint that cloned food is not substantially or materially different from the food produced from conventionally reproduced animals and further, cloned foods do not present health risks different from the health risks associated with conventionally bred animal products.[142] As far as labeling cloned food, special labeling will only be mandated by the FDA if the cloned food "differs from its traditional counterpart so that its common or usual name no longer applies or if there exists a safety or usage issue to which consumers must be alerted."[143] The FDA has not published findings that there is any substantial difference between cloned and conventional animals or the meat or their milk products thereof.[144] The FDA thereby has concluded that no reason exists which would scientifically support a mandate of labeling of cloned foods. Therefore, it is most likely that labeling for cloned foods will not be mandated by the FDA.

B. Cloned food regulation under the USDA.

If the FDA is unwilling or unable to provide a solution to those desiring cloned food to be labeled, it may be possible to find a solution under the USDA. Under the

USDA, one possible solution to the labeling dispute concerning cloned foods is to redefine the term "organic foods" to include those products from animals reproduced conventionally.[145] Of course, such animals would also have to be raised in a manner that is already prescribed for those animals whose products will bear the "organic" label. This solution would ensure that clone-free foods would be labeled. This would also ensure that clone-free foods would be certified and regulated by the Government via the USDA. However, if clone-free foods were labeled voluntarily, this label would encounter the same difficulties that the early organic label faced, the difficulty of regulating and ensuring that the foods were in fact clone-free, and therefore certifiably organic.

The OFPA is the directive under which the USDA regulates organic crops and livestock and the foods derived from them.[146] In 2004, the USDA defined the scope and enforcement of the production of organic foods in the Organic Foods Production Act (OFPA).[147] The OFPA does not govern foods that are not regulated by the USDA.[148] Under the OFPA "livestock" is defined as "any cattle, sheep, goats, swine, poultry, equine animals, used for food or in the production of food."[149] This does not distinguish between livestock reproduced through conventional means and livestock reproduced through cloning. This term would have to be redefined should lawmakers decide to label, as organic, only those products from animals that have not been cloned. Furthermore, such a definition should address whether products from the conventionally reproduced progeny of cloned animals should be labeled as organic.

The USDA also derives its authority over cloned animals through the Meat Inspection Act.[150] Under this Act, meat from cloned cattle may only be marketed if it

conforms to the USDA's requirement[151] that downed cattle not be slaughtered for human consumption. Then cloned meat must pass the USDA's pre and post slaughter inspection to ensure that such meat conforms to the FDA's provisions that no adulterated food shall be sold for human consumption.[152] The Meat Inspection Act helps ensure that most animal products are safe for human consumption. However, consumers are well aware that unsafe meats do find their way into the market despite inspections and regulations.[153] Furthermore, this Act does nothing to dispel consumer discomfort with the novelty of cloned animals being sold as food.[154]

It would be virtually impossible for the USDA to enforce a regulation which requires producers to label meat that is cloned. Because the animals have not been genetically modified with proteins or chemicals foreign to their species, a DNA test of an animal could not conclude whether the animal was in fact a clone or the offspring of clone.[155] Furthermore, once a cloned animal reproduces offspring through conventional means, and that offspring is then allowed to reproduce conventionally, it is not known when the animal should no longer not be labeled as 'cloned' for purposes of marketing its milk or meat.[156] It is evident then, that if the USDA should regulate cloned animal products, it must define the term "cloned animal" and must determine a method of deciphering between animals cloned and not cloned, a potentially impossible task.[157]

The unwillingness of the FDA to mandate food labeling, and the USDA's potential, substantial difficulty in regulating clone-free foods as organic presents a major problem for opponents of cloned food. The failure of these administrative agencies to provide the necessary legislation to serve the needs of consumers demonstrates the lack of control the public has over knowing what foods it consumes.

III. Constitutional problems with labeling cloned foods.

Some consumers believe that the U.S. Constitution guarantees them the right to know what they are purchasing.[158] However, this claimed "right-to-know"[159] is unconfirmed by black letter law. The fact that there is a debate over whether consumers have a "right to know," implies that even if such a right exists, it is extremely limited.[160] Consumers believe that they have a right to know whether they are purchasing or consuming a product by which they are offended[161]; that they have a right to make informed consumer decisions[162]; and that the right to Freedom of Religion guarantees the right of consumers to know what they consume.[163] However, if such freedoms exist, they must be balanced against the merchant's right to freedom of commercial speech and free interstate trade.[164]

A. Judicial interpretation of regulatory law.

There exists no case law suggesting the right of consumers to be informed when they purchase and/or consume cloned animal products. Nor is there case law discussing whether producers have a right not to disclose that they are selling cloned animal products after the FDA has deemed such products marketable. The lack of case law on the issue of farm animal cloning for human consumption is because this issue is very new to the law. The only legal precedents on these issues are preliminary statements have been published by the FDA concerning whether the products from such animals should be allowed in the food supply.[165] Therefore, we must look to litigation on similar subjects to get an idea of how courts may rule in the issue of animal cloning for food. Litigation concerning GM foods provides ample incite into how consumer issues will be decided in future cloned animal litigation. Concerning the labeling of GM foods, courts

have generally decided in favor of the FDA, that labeling should not be mandated. The same can therefore be expected in cases involving cloned food labeling.[166]

Outlined in Alliance for Bio-Integrity v. Shalala is an explanation of why courts have sided with the FDA on whether consumer's have a right to know whether food they buy and consume is GM or natural. This case was brought in 1998 by consumer groups, religious leaders and scientists, all challenging the FDA's 1992 policy statement that GM food was not materially different from non-GM food.[167] Summary Judgment was granted in 2000 in favor of the FDA.[168]

The Plaintiffs made several arguments challenging the policy statement. The Plaintiff's first argument was that the FDA's policy statement was a substantive rule and did not comply with the requirement of the Administrative Procedure's Act (APA) that substantive rules are to be enforced after a formal notice and comment process.[169] The Court rejected this argument stating that a substantive rule has the "force and effect of law."[170] Moreover, when an agency issues a policy statement, such a statement is to "advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power."[171] The Court therefore found that there was no APA violation and that the plain language of the statement rendered the 1992 policy statement an interpretive, not a substantive, rule.[172]

As in Shalala, a court is likely to determine that when the FDA issues their policy statement (that cloned foods, like GM foods, do not present a health risk) without formal notice and a comment process, this will, most likely, not violate the APA. Therefore, the FDA will probably be allowed to continue to presume that cloned animal products are GRAS and allow producers to market these products in compliance with food regulation

statutes.

Another of the Plaintiff's arguments was that the FDA's presumption that GM foods were generally regarded as safe (GRAS) was incorrect.[173] Therefore, the GRAS presumption violated section 409 of FDCA and was therefore "arbitrary and capricious."[174] The Plaintiffs based this argument on statements that were made by members of the FDA to the effect that GM foods were not GRAS. The court rejected this argument stating that the FDA's interpretation of the FDCA was valid and controlling.[175] The court further stated the FDA's decision to presume the GRAS status of GM foods is therefore not arbitrary and capricious.[176]

Likewise, if the FDA presumes cloned food to be GRAS under the FDCA, then cloned food will be considered GRAS. This is because the court in Shalala has held that the FDA's interpretation of the definition of GRAS foods in the FDCA is determinative.[177]

The Plaintiffs next argued that the FDA's failure to require special labeling for GM foods was in violation of Section 321(n) because the consumer's interest and the interest of religious groups should have been considered "material" under the statute.[178] The court found the statute unclear and deferred to the agency's interpretation that consumer interests, aside from health interests, were not "material" and therefore the statute did not mandate the labeling of GM foods.[179]

Much in the same way that the court held that the FDA's interpretation of section 321(n) to be controlling, a court will most likely hold that consumer and religious interests should not be considered "material" to a decision made by the FDA not to mandate labeling in the case of cloned foods. As stated above, absent scientific evidence

to the contrary, the FDA, under the Coordinated Framework, will not consider any but scientific evidence concerning the safety of food.

The Plaintiffs next argued that GM foods should be labeled because the process by which foods had been genetically modified was considered "material" under section 321(n) of the FDCA.[180] Deferring once more to the FDA's decision that the process of genetic modification was not "arbitrary and capricious," the court overruled this argument of the Plaintiffs.[181]

Even though there are multiple methods by which scientists genetically modify plants and animals for food; information stating which method was used in genetic modification is not considered "material" so as to require labeling. Therefore, it is unlikely that the one process by which animals are cloned would be "material" to require the FDA to mandate labeling of cloned foods.

The Plaintiff's final argument was that the lack of labeling violated their Constitutional right to freedom of religion under the First Amendment and violated the Religious Freedom Restoration Act (RFRA) of 1993.[182] The court held that the FDA's decision not to mandate labeling did not violate their freedom to exercise religion because it was "neutrally and generally applied." Furthermore, their RFRA claim was not upheld since the FDA's decision "does not place 'substantial pressure' on any of the Plaintiffs, nor does it force them to abandon their religious beliefs or practices."[183]

Like the court in Shalala, a court is likely to defer to the FDA's determination that labeling for cloned foods should not be mandatory, even where this presents an inconvenience for those who are religiously restricted from eating cloned foods, and even though labeling is the only way to inform consumers as to whether food is cloned or not.

Like the court held in Shalala, not labeling cloned foods does not force anyone not to practice their chosen religion. Furthermore, those who wish to be sure that they do not eat cloned products can always raise their own uncloned livestock.

Shalala illustrates that the courts will likely give deference to the FDA. Furthermore, the consumer's "right to know" is easily diffused in light of the agency's authority not to mandate labeling. This leaves little basis on which consumers can argue that the FDA should be forced to mandate labeling for cloned animal products.

B. Legislative failure.

There have been both state and federal legislative attempts to protect the consumer's right to know what is in their food. To date all such attempts have failed on the state and federal levels. Unsuccessful federal legislation includes the Genetically Engineered Food Safety Act (GEFSA) and the Genetically Engineered Food Right to Know Act (GEFRKA).[184]

GEFSA would have amended the FDCA to include GM products in its definition of "food additive." This would have forced the FDA to give a pre-market review of all GM products and removed the GRAS presumption.[185] Because most GM foods and all cloned foods do not have components which are different from those in conventional foods; the FDA has determined that such foods are presumed GRAS and therefore are not required to undergo a pre-market review.[186] However, some foods and drugs that have been presumed GRAS in the past have later been found to be unsafe. The GEFSA would have destroyed the GRAS presumption for GM and possibly cloned foods.[187]

GEFRKA attempted to resolve the labeling dispute which first rose in the GM foods debate and has been revived in the cloned foods debate. This Act would have

amended the FDCA to require genetically engineered foods to be labeled as to that fact.[188] However, as the court illustrated in Shalala, the FDCA already contains a provision defining what is material to the decision of what is to be labeled and the FDA's interpretation of that provision is judicially acceptable. Therefore, under the current FDCA, the FDA has full discretion as to what should be labeled and statutes like GEFRKA are unnecessary.

These proposed amendments were unsuccessful because they attempted to amend the FDCA, which is considered satisfactory and already sets procedures for labeling and reviewing unsafe products. Enacting another statute to these effects would be redundant.

C. Constitutional hurdles.

The rights of food producers; particularly, the First Amendment Right to Commercial Free Speech, free interstate trade provided by the Commerce Clause, and Federal Preemption; provide additional hurdles for those hoping to enact state or federal legislation requiring the labeling of cloned food.

As determined in Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n , the First Amendment Right to Free Speech encompasses the right to speak or not to speak at one's free will.[189] This applies to both individuals and to commercial entities.[190] The commercial entities may be compelled to speak or not only when the commercial speech does not have to do with illegal activity and is not misleading.[191] Commercial speech may be regulated if (1) there is an identifiable, substantial government interest in compelling the speech; (2) the government interest would be "directly advanced" through the regulated speech; and (3) the regulation places no more a burden on the corporation than is necessary to accomplish the task.[192] In the context of labeling food, corporate

food producers may be required to label certain facts about cloned food if these three factors are met; even absent a mandate to do so by the FDA.

Using this test, the U.S. Court of Appeals for the 2d Circuit overruled a Vermont statute requiring dairy manufacturers to label dairy products which had come from cows that had been given rbST - a synthetic growth hormone used to stimulate milk production.[193] In International Dairy Foods Association (IDFA) v. Amestoy the IDFA argued that the Vermont statute was unconstitutional because the government interest in mandating labeling was insubstantial.[194] The court agreed with the IDFA and held that the government interest was insubstantial because it was based on consumer interest and the public's "right to know" and not scientific evidence of harm to consumers of rbST.[195] Because rbST had not been shown to effect public health, consumer interest and the public's right to know was not enough to compel commercial speech of a factual and accurate statement.[196] The purpose of this decision is to prevent consumer interest from controlling mandated information on labels.[197] Too much information is thought to result in information overload and be unhelpful to consumers.[198]

Because the food from cloned animals is presumed GRAS, and therefore presumed to possess no health risks different from the health risks associated with other animal products, the holding in Amestoy would apply to a State law compelling commercial speech to disclose to the public which foods contain cloned animal products. Consumer interest in knowing whether foods contain cloned animal products would therefore not be the substantial interest necessary to compel commercial speech. If there is no scientific evidence of a risk to human health from cloned foods, then a "right to know" is likely not the substantial interest necessary to compel labeling of cloned

products.[199] Therefore, producers of cloned food will most likely not be required to label cloned animal products unless and until it is found that: (1) there is a substantial and identifiable government interest in forcing producers to label food as from cloned animals; (2) that government interest would be advanced through cloned food being labeled as such; and (3) the regulation forcing the labeling of cloned food would place no more of a burden on the producer than necessary to serve the government interest.

Under the Commerce Clause of the Federal Constitution, free trade among the states shall not be interrupted by discriminating against or isolating a state.[200] If one state should adopt legislation requiring food from cloned animals to be labeled, a burden would be placed on the out of state producers to comply with the legislation or otherwise be forced not to sell their products in that state. Therefore, out of state producers could only sell their products to merchants outside of the legislating state. This would isolate the legislating state because the legislation would have forced that State out of interstate trade, which is a violation of the Commerce Clause.[201] Absent a valid health concern, this legislation would violate the rights of the suppliers of other States to free interstate trade.[202] The Commerce Clause would most likely work to invalidate legislation that requires labeling since consumer interest and consumer right to know are insufficient bases for such legislation.[203]

The Supremacy Clause in the Constitution prohibits States from enacting laws preempted by Federal law. Any Federal laws concerning food labeling which have preemptive power may preempt State laws enacted to compel suppliers to label foods from cloned animals. Therefore, the FDCA's nutrition labeling requirements, amended by NLEA of 1990, may preempt future clone labeling state laws.[204] The NLEA's

amendment expressly prohibits the States from enacting food labeling regulations concerning a food product's established identity; sale under a common name; imitation foods; misleading containers; package forms; representations of definition, quality, and dietary use; artificial flavoring; nutritional information; and nutrition levels and health-related claims.[205] Furthermore, the FDCA prohibits states from enacting legislation which would permit food suppliers to label their food products differently than that which is compelled by the FDA through the FDCA.[206] Since the FDCA already regulates food labeling and because the FDA and USDA have been established by Congress to preside over food safety and public health concerns derived from commercial products; Administrative law from the FDA and USDA may preempt any attempt by state legislatures to regulate the same.[207] Therefore, any state mandated labeling of cloned animal products, different from the FDA's labeling requirements regulating the same, would be preempted.[208]

Because of the lack of scientifically proven harm to the public from foods containing cloned animal products, the courts, Congress, and the FDA, through the Constitution, have not found sufficient reason to compel mandatory labeling of cloned products. In balancing the consumer's interests and their "right to know" and the supplier's interest in free speech and free trade, the courts have generally favored suppliers in lawsuits concerning food-labeling mandates.

IV. Conclusion

The FDA has allowed food suppliers to voluntarily label their food so long as the label is consistent with FDA guidelines in that they are not false or misleading.[209] This is the easiest solution to quieting consumer fears. It achieves what consumers want, the

choice. Voluntary labeling would give consumers the power to choose whether to buy or not to buy, product containing cloned food. Another solution is that the organic food label may designate products that are not produced through cloning. However, until a method of labeling cloned food is established, consumers will not have the option to act under their own initiative to buy clone-free foods. This fact strengthens the consumer's contention, that, unlabeled cloned foods do not give the consumer the choice not to spend money on a product that the consumer finds offensive.

Under guidelines for voluntary labeling, labels stating that a food is not from cloned animals will be under the same scrutiny as foods labeled as being from cloned animals.[210] This however will result in debates and regulations concerning what information should be allowed, and what information is too much in attempts to preclude labels which are considered false or misleading.[211] Therefore, so long as it serves a substantial state interest and does not interfere with interstate trade or conflicts with federal regulations, states may enact legislation which requires more extensive testing or review before a food is sold.[212]

Furthermore, if foods are to be labeled as "clone-free" there must be a method in place to track and certify clone-free livestock.[213] The FDA has suggested certification programs to ensure that labeled rbST products were labeled accurately.[214] If applied to cloned animal products, this would be a way for state legislatures to ensure proper tracking of cloned animal products.

Farmers have used and plan to continue to use cloning to increase their profits. Farmers have spent incredible amounts of money to clone their best meat producing livestock and prize winning dairy producers. Because clones are expensive, farmers claim

that their cloned livestock would be used as breeding stock until the end of their lives, and then would be slaughtered for meat. Furthermore, cloned dairy cows would be cloned and bred for their ability to produce uncommonly large amounts of milk.[215] Because the FDA based its opinions, statements and policy on scientific findings, in publishing its Draft Risk Assessment on cloned food, the FDA has effectively eliminated the possibility of mandating labeling for such food. Unless cloned animal products are proven, scientifically, to be unsafe for human consumption, it is likely that cloned foods will be allowed to be sold without labeling.

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[132] See 21 U.S.C. §343(a); see also Degnan, 2000, at 302- 04; See Frederick H. Degnan, The Food Label and the Right-to-Know, 52 Food & Drug L.J. 49, 53 (1997).
[133] 21 U.S.C. 403
[134] Degnan, 2000, at 302 (citing 21 U.S.C. §343(e), (g), (i).
[135] Degnan, supra note 134, at 302.
[136] Degnan, supra note 134 at 303.

[137] Food Labeling: Health Claims; Dietary Guidance, 68 Fed. Reg. 227,66040, 227,66046 (Nov. 25, 2003) (to be codified at 21 C.F.R. pt 101).
[138] Animal Cloning: Proposed Risk Management Plan for Clones and Their Progeny, 72 Fed. Reg. 136 (Jan. 3, 2007).
[139] See Degnan, 2000, at 308-09.
[140] See Degnan, 2000, at 308-09.
[141] Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).
[142] Animal Cloning: A Draft Risk Assessment, Food and Drug Admin., supra note 8, at 308.
[143] Statement of Policy, 57 Fed. Reg. 22,991, supra note 114. The FDA used this example to explain the policy: "[I]f a tomato has had a peanut protein introduced into it and there is insufficient information to demonstrate that the introduced protein could not cause an allergic reaction in a susceptible population, a label declaration would be required to alert consumers who are allergic to peanuts so they could avoid that tomato, even if its basic taste and texture remained unchanged. Such information would be a material fact whose omission may make the label of the tomato misleading under section 403(a)..." Id.
144 Animal Cloning: A Draft Risk Assessment, Food and Drug Admin., supra note 8, at 308.
145 Associated Press, 2007, supra note 73.
146 Policy Development Committee for consideration by the National Organic Standards Board, National Organic Program Scope, at 1 (Sept. 28, 2004), *available at* http://www.ams.usda.gov/nosb/meetingbooks/Oct2004/NOPScope9_04.pdf.
[147] National Organic Program Scope, supra note 146.
[148] National Organic Program Scope, supra note 146.
149 National Organic Program Scope, supra note 146, at 2.
[150] Meat Inspection Act. 21 U.S.C. §§601 et seq (2004).
151 Farm Sanctuary, Downed Animal…, (2005), http://www.nodowners.org/index.htm.
[152] 21 U.S.C. §342; 9 C.F.R. §301.2(y); 21 U.S.C. §331.
[153] See Center for Disease Control, Yellow Book: Health Information for International Travel, Center for Disease Control, 2005-2006, at ch 4.
[154] See Kelly A. Leggio, Comment, Limitations on the Consumer's Right to Know: Settling the Debate over Labeling of Genetically Modified Foods in the United States, 38 San Diego L. Rev. 893, 917-18 (2001).
[155] Karen Kaplan & Jia-Rui Chong, supra note 9.
[156] Associated Press, 2007, supra note 73.
[157] Associated Press, 2007, supra note 73.
[158] See Cynthia D. Fisher, Comment, The Genie Is out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods, 4 J. Legal Advoc. & Prac. 88, 117-18 (2002).
[159] See Fisher, supra note 158, at 117.
[160] See Leggio, supra note 154, at 917-18.
[161] See Leggio, supra note 154.
[162] See Galant, supra note 113, at 140-47.
[163] U.S. Const. amend. I. See Leggio, supra note 154, at 923-24.
[164] Galant, supra note 113, at 144.
[165] Animal Cloning: Proposed Risk Management Plan for Clones and Their Progeny, 72 Fed. Reg. 136 (Jan. 3, 2007).
[166] Galant, supra note 113, at 149.
[167] Shalala, 116 F. Supp. 2d at 170.
[168] Id. at 181.
[169] Id. at 172 (citing 5 U.S.C. §553 (1994)).
[170] Id.
[171] Id. (quoting Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979)).
[172] Id. at 173.
[173] Id. at 175.
[174] Id. at 175.
[175] Galant, supra note 113, at 151.
[176] Shalala, 116 F. Supp. 2d at 177-78.
[177] Id.

[178] Id. at 178.
[179] Id. at 178-79.
[180] Id. at 179.
[181] Id.
[182] Id. at 179-80.
[183] Id. at 180-81.
[184] Galant, supra note 113, at 153.
[185] Genetically Engineered Food Safety Act, H.R. 3883, 106th Cong. (2000); S. 2315, 106th Cong. (2000).
[186] Shalala, 116 F. Supp. 2d. at 178.
[187] Galant, supra note 113, at 153.
[188] Genetically Engineered Food Right to Know Act, H.R. 2916, 108th Cong. (2003).
[189] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 562-63 (1980).
[190] See Amestoy, 92 F.3d 67 at 71 (1996) (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 562-63 (1980)).
[191] Cent. Hudson Gas, 447 U.S. at 563, 566.
[192] Id. at 566.
[193] Amestoy, 92 F.3d at 69.
[194] Id. at 69-70.
[195] Id. at 73.
[196] Id. at 74.
[197] See Galant, supra note 113.
[198] See Galant, supra note 113.
[199] See Galant, supra note 113, at 157.
[200] See U.S. Const. art. I, §8, cl. 3 (reserving this power to the U.S. Congress); see also Dean Milk Co. v. City of Madison, 340 U.S. 349 (1951).
[201] Dean Milk Co., 340 U.S. at 356.
[202] Id.
[203] See Galant, supra note 113, at 157.
[204] See 21 U.S.C. §343-1(a).
[205] Id.
[206] Id.
[207] Emily Robertson, Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act, 9 B.U. J. Sci. & Tech. L. 156, 166 (2003).
[208] Statement of Policy, 57 Fed. Reg. 22,991, supra note 114.
[209] See Draft Guidance for Industry, supra note 141, at 4840.
[210] Draft Guidance for Industry, supra note 141, at 4840.
[211] Leggio, supra note 154, at 945.
[212] See Id.
[213] See Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatrotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).
[214] Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatrotropin, supra note 213, at 6280.