SUMMARY OF A MULTI STAKEHOLDER WORKSHOP sponsored by

THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY

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ROCKVILLE, MARYLAND





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ublic opinion studies have shown that attitudes about the genetic engineering and cloning of farm animals are strongly negative—but also very vague. Many people have difficulty articulating the reasons for their concerns. Some say they object to scientists "playing God;" others "just don't like it." Sometimes it is unclear whether people are reacting to animal biotechnology specifically, or to modern methods of intensive agricultural production in general.

These kinds of responses generate a variety of reactions from those interested in animal biotechnology. Researchers and developers worry since the future market success of any products derived from cloned or genetically engineered animals will partly depend on the public's acceptance of those products. Advocates for animal welfare argue that the strong public concern about cloned and genetically engineered animals reflects specific biotechnology-related ethical concerns that should be taken into consideration by government regulators.

There are few venues through which diverse experts—let alone the general public—can learn about and discuss ethical and moral issues relating to the use of genetically engineered or cloned animals in agriculture. The U.S. laws that could be used to approve the commercialization of these animals are, by design, based on risks to health or environment identified through scientific risk assessment. For the most part, U.S. regulators are not authorized to make regulatory approvals on ethical and moral grounds if no health or safety considerations exist. (One notable exception is the Animal Welfare Act, designed to reduce the suffering of animals used in research.) And no institutionalized public forums exist through which these topics can be discussed and debated among a wide range of interested parties. To complicate matters, those of us who are not ethicists often lack even an understanding of how to talk about ethical issues; we have little knowledge of ethical frameworks or terminology and often find it difficult to articulate our deeply held values and beliefs.

In July 2004, the Pew Initiative on Food and Biotechnology held a meeting of diverse stakeholders to discuss animal biotechnology. At that meeting, participants pinpointed ethical issues as being of interest for future discussion. Following up, the Initiative sponsored a two and a half day invitational workshop in January 2005 to explore the moral and ethical aspects of genetically engineering and cloning animals.

> We sought to create a forum in which individuals from industry, academia, advocacy organizations, and government could learn how to articulate ethicsbased issues and then share their thoughts regarding the ethical and moral aspects of animal transgenesis and cloning. Our fundamental inquiry was whether or not the application of modern biotechnology to animals created novel ethical or moral issues, or whether existing moral and ethical frameworks relating to humans' use of animals could be used to address any potential concerns raised by cloned or transgenic animals

> This report summarizes the six presentations that were given at the workshop by key experts and then includes an overview of the views and ideas that that were expressed by participants in the discussions that followed. Participants did not seek consensus, so the report simply captures the issues and opinions that were raised. We hope you will find this report useful in illuminating issues relating to the ethics of genetically engineering and cloning animals.

Midral Roofennemer

Michael Rodemeyer Former Executive Director, Current Senior Consultant PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY



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INTRODUCTION 1

ANIMAL BIOTECHNOLOGY REMAINS LARGELY IN THE RESEARCH AND DEVELOPMENT STAGE IN THE U.S. AND AROUND THE WORLD. However, a number of cloned and genetically engineered (GE) animals are poised to enter the marketplace, if and when they are approved by the Food and Drug Administration (FDA). Only one GE animal has ever been commercialized in the United States. The GloFish[™], an aquarium fish genetically engineered to glow in the dark, went on the market in pet stores in January 2004 after the FDA decided the fish did not require regulatory oversight. Other GE animals are awaiting FDA approval for commercialization, including, for instance, a GE salmon with an introduced growth hormone. GE animals under development include those that would produce human or animal pharmaceuticals in their milk, are disease-resistant or have other desirable production attributes, and contain organs that could be transplanted into humans.

In some cases, genetic engineering and cloning go hand in hand, as cloning provides a means to create genetically identical copies of a GE animal. Of course, conventionally bred and wild animals can be cloned as well. Since Dolly—the first mammal to have been cloned from adult animal cells—made her debut in 1997, researchers at private companies and universities are known to have cloned mice, goats, cattle, pigs, rabbits, monkeys, cats, a horse, a mule, a banteng, a guar, and, most recently, a dog. In December 2004, the first known sale of a cloned pet (a kitten) was reported. The FDA is poised to rule in the next few months on whether or not to approve, for sale to the public, meat and dairy products from cloned animals and their progeny. If these animals and animal products are approved for human consumption, several companies are reportedly ready to sell milk, and perhaps meat, from cloned animals and their progeny—most likely cattle and swine.

The development of GE and cloned animals has not been without controversy. Animal welfare advocates have raised questions about the level of harm caused to animals in some cases. And the public remains largely uneducated and relatively cautious about the use of biotechnology in animal agriculture. According to a nationwide survey conducted in August 2003 by the Pew Initiative on Food and Biotechnology, Americans' knowledge about the use of biotechnology in agriculture remains low. Just 36% of those polled said they had heard "a great deal" or "some" about biotechnology use in food production. Also, just 24% said they had eaten GM foods, while 58% said they have not. Clearly, Americans continue not to recognize the extent to which GM foods are present in foods they eat every day. Also, Americans are far more comfortable with genetic modifications to plants than to animals. Fifty-eight percent of those polled said they oppose scientific research into the genetic engineering of animals, while 32 percent favor this type of research. In a Gallup poll conducted in May 2004, 64 percent of Americans polled said they thought it was morally wrong to clone animals.

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In order to foster discussion and learning regarding the kinds of ethical and moral concerns that make people uncomfortable with these technologies—and to explore whether these concerns are the same as those regarding conventional production agriculture or are specific to transgenesis and cloning—the Pew Initiative in January 2005 brought together approximately 40 individuals representing a wide diversity of interests in a two-and-a-half day workshop. Participants included animal biotechnology researchers from academia and industry; other representatives from the biotechnology, food, and agriculture industries; consumer and animal welfare advocates; ethicists; and federal and state agency officials. The meeting was convened and sponsored by the Pew Initiative and facilitated by mediators from RESOLVE, a nonprofit dispute resolution and public policy organization based in Washington, DC. (See Appendixes B and C for a full list of participants and staff.)

The scope of the discussions included genetically engineered and cloned animals designed for use in agricultural production. The group did not address issues specific to "laboratory animals" (i.e., mice, rats, rabbits, and primates) or invertebrates, or marker-assisted breeding. Also not discussed were the distributional impacts of animal biotechnology, such as its possible effects on small farmers or its potential to help reduce world hunger.

This report summarizes the issues that were discussed at the workshop. The first day was composed largely of presentations from six expertsone industry representative, one federal regulator, and four leading thinkers in the field of animal ethics. These talks gave participants a strong grounding both in ethical frameworks and terminology and in the ethical and moral issues associated with the human use of animals in general and animal biotechnology in particular. The six presentations are summarized in Section 2 of this report. Participants then proceeded to share their views on an array of issues relating to the ethics of genetically engineered and cloned animals, in both large group and small group settings. Section 3 includes a short summary of the issues discussed, organized into four sections: (1) the moral and ethical concerns regarding transgenesis and cloning, (2) a comparison of traditional breeding technologies to transgenesis and cloning, (3) species integrity and animal "telos," and (4) decision-making about animal welfare and ethics issues. The report ends with a brief concluding section.



SECTION 2 PRESENTATIONS

THIS SECTION INCLUDES PARAPHRASED SUMMARIES OF THE SIX PRE-SENTATIONS GIVEN ON THE FIRST DAY OF THE WORKSHOP. Dr. James Robl of Hematech, LLC, spoke first about animal biotechnology applications currently under development. Dr. Chester Gipson of the U.S. Department of Agriculture (USDA) briefed participants on federal laws relating to animal welfare. Dr. Paul Thompson of Michigan State University covered animal bioethics generally, as well as its application to biotechnology. Dr. Harold Coward of the University of Victoria gave a presentation on the views of the five major religious traditions regarding animals and animal biotechnology. Dr. Bernard Rollin of Colorado State University spoke about the emerging social ethic regarding animals and its application to animal biotechnology. And Dr. Mickey Gjerris of the Danish Centre for Bioethics and Risk Assessment talked about the views of the animal welfare community and European citizens on issues relating to animal ethics and animal biotechnology.

► JAMES ROBL, Ph.D. HEMATECH, LLC

DR. JIM ROBL is President and Chief Scientific Officer of Hematech, LLC, a technology development firm based in Sioux Falls, South Dakota. Dr. Robl briefed participants on transgenesis and cloning technologies currently being researched and developed. His comments are paraphrased below.

The challenge I was given was to talk about how cloning and transgenesis are done; their similarities to and differences from conventional breeding practices; the purposes of the technologies; and the benefits and risks to humans and animals. I will first give an overview of cloning and genetic modification technologies in general, and then talk specifically about what we are doing at Hematech.

Let's talk first about the normal reproductive process. (See figure next page.) Every animal starts out as the product of an egg and a sperm. Half of the chromosomes come from the egg, and half come from the sperm. The chromosomes from the female give rise to a female pro-nucleus, while the chromosomes from the male give rise to a male pro-nucleus. These two come together to become a fertilized egg, which then gives rise to pro-nuclear embryo. About a week after fertilization, the pro-nuclear embryo has developed into a blastocyst—a hollow ball of cells filled with fluid. A portion of the blastocyst cells, off to the side, form the fetus, while the remaining cells form the placenta. In this example, the fetus eventually becomes a calf.

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For the past 10,000 years, humans have worked to produce offspring from the animals that have the most desirable traits. This selective breeding process is the foundation of the domestication of agricultural animals. However, a cow can only have one calf per year in a normal situation, and a bull will only sire 30 to 40 calves per year in a normal situation. So, current technologies have come about because people wanted to derive more calves from particularly valuable individual animals.

Reproductive technology is not something new in agriculture. Currently, more than 80 percent of dairy cattle are artificially inseminated. Through artificial insemination, a bull can sire essentially tens of thousands of offspring instead of just tens of offspring. This technology is being widely used and has been very successful. Superovulation and embryo transfer are similar reproductive technologies that addresses the female side. This process is an attempt to create more copies of the female DNA. It is less successful than on the male side, but it still enables a female to "produce" maybe a dozen calves per year. More than 500,000 embryos are transferred each year worldwide. Finally, in vitro embryo production and transfer is the process of recovering oocytes from the cow, fertilizing them in vitro, and culturing the embryo until it can be transferred into a recipient. This is a newer technology that's being used to a lesser extent, but there are still thousands of embryos transferred each year. When I started in cloning 20 years ago, the idea was to use it to extend what we are doing with the other technologies—to propagate superior genetics to a greater extent.

So, let's talk about how cloning works. (See figure next page.) Cloning eliminates the need to have DNA from both an egg and a sperm to create an embryo. What we do is take the egg and essentially throw away the DNA, leaving an empty shell—an embryo without a nucleus. Then we take some somatic cells from an adult animal, such as skin cells, and insert those into the empty embryo. The resulting embryo then goes through the same process of developing into a blastocyst and eventually a fetus and then a cloned calf.

NORMAL REPRODUCTIVE PROCESS







DAY 40 CONCEPTUS



From one small biopsy from the back of the ear of a cow, we can produce millions of cells for such insertions. So cloning allows us to create, theoretically, an infinite number of offspring that are identical to one individual. Today, cloning is done only to a small degree in the agriculture industry. The primary interest is in developing small sets of individuals with very elite genetics.

Now let's look at how genetic engineering works. The use of skin cells allows us to do extensive genetic modifications of animals. What we do is select specific genes that code for a trait we want to see (often a very low-probability trait), and insert them into the somatic cells. Once the skin cells are genetically modified and put into an egg, the egg gives rise to a fetus. We can then also take skin cells from the fetus, and make another population of cells. Those skin cells can then be genetically modified, so that we have subsequent genetic modifications. You can go through this cycle a number of times until you finally let a fetus develop into a genetically modified calf.

I want to give you two examples of how transgenic applications are being used in agriculture. First, researchers have inserted extra copies of beta or kappa casein into dairy cattle to increase milk protein. Second, they have inserted an insulin-like growth hormone gene into swine to reduce fat and increase feed efficiency.

Essentially no attempts have been made thus far to commercialize transgenic animals for food production (except for one effort in Australia to commercialize a swine line with a growth hormone gene). The agricultural transgenics industry is made up of only a handful of people. Most of them are doing academic research, not commercial research. I'm not aware of anyone who is moving toward putting a transgenic animal into commercial agricultural food production. I'd love to do that myself. I think there are great things that could be done. But the fact is that most people have decided to wait and monitor public opinion before they invest the millions of dollars required to put a transgenicanimal-derived agriculture product on the market.

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> James Robl Hematech

CLONING PROCESS



Polyclonal antibodies...can be used to treat infections (e.g., staph, which is notorious for being resistant to antibiotics), cancer, organ transplant rejection, autoimmune disease, antitoxins, and biodefense. The only source of polyclonal antibodies at present is people who volunteer to donate plasma. So, humans are currently the production system. But the human production system has many limitations. So, we at Hematech would like to make a cow that could be used as a human polyclonal antibody production system.

James Robl Hematech Another application of cloning and genetic modification is the production of human therapeutic proteins in the milk of transgenic animals. This application involves the use of the mammary gland of transgenic sheep, goats, and cows as a protein production machine. The drugs that can be created include human antithrombin III (ATryn), monoclonal antibodies, alpha lactalbumin, serum albumin, lactoferrin, and bile salt-stimulated lipase. This process could be a less expensive method of production, but it also might be a better method of production. Only a few companies are focused on creating products in the mammary glands of transgenic animals. The industry has had its ups and downs, and I would characterize it as not terribly robust. One company that is close to commercial production is GTC Biotherapeutics. Their ATryn protein is under government review in Europe. The fact is, biotech companies have up to a dozen ways to produce proteins. Animal production systems are most valuable only when the proteins can't be produced in any other way. As a result, this will probably never be a huge industry, in my view.

We at Hematech are focused on products that cannot be produced in any other fashion. In particular, we are working on the production of human polyclonal antibodies in bovine blood. (There are other well-established production systems for producing human monoclonal antibodies.) Let me explain what polcy-clonal antibodies are. You may notice that when your blood clots, you get the red clot and a yellow-ish liquid. That liquid is the plasma or serum. Circulating throughout the serum part of your blood are millions of kinds of antibodies. These antibodies are Y-shaped molecules that have essentially two "hands" that can "grab onto" a bacteria or virus. They are part of the body's own defense mechanisms, which keep us from getting infections. "Polyclonal" refers to "vast kinds." If you want antibodies that will attack anything—that will code to any problem—then you need polyclonal antibodies.

Polyclonal antibodies have a number of potential applications. They can be used to treat infections (e.g., staph, which is notorious for being resistant to antibiotics), cancer, organ transplant rejection, autoimmune disease, antitoxins, and biodefense. The only source of polyclonal antibodies at present is people who volunteer to donate plasma. So, humans are currently the production system. But the human production system has many limitations. For example, you can't "hyperimmunize" people before they give plasma.

So, we at Hematech would like to make a cow that could be used as a human polyclonal antibody production system. This slide (see next page) gives an overview of what we are doing. First we genetically modify cells. Then we clone them to make embryos, and ultimately cows. We then formulate vaccines and immunize the cows with them. Then we collect the plasma from the cows, and the plasma goes through a purification process to produce a bulk product. This product is put into bottles, shipped off, and used to treat patients. Throughout this process, we have very stringent documentation and quality control.

Let's talk more about the two steps we use to make the cow that will serve as the polyclonal antibody production system. First, we have to introduce the human antibody genes. Two genes are needed—a heavy chain and a light chain. These are very long DNA sequences (10 million base pairs). A microchromosome vector is required to do this. Second, we also have to inactivate the cow's own antibody genes. There are multiple genes that need to be inactivated, and to inactivate them requires gene targeting.

So far we have developed many calves that carry the human microchromosome. We have also cloned calves that have both copies of one gene knocked out by gene targeting.

Next I'll describe our animal production system. Our animal facility is registered with the USDA to do research. We have an Institutional Animal Care and Use Committee (IACUC) that oversees the research. We do rigorous evaluations of all of our animal experiments. Our facility is accredited by the American Association for the Accreditation of Laboratory Animal Care, so we take our animal concerns very seriously, including issues of animal welfare. We have an elaborate animal production system that is designed such that the resulting human therapeutic will be safe for humans, and the animals' needs are met.

I'll now show you some pictures of our facility (not included in this report). The first is a photo of recipient cows that we use for embryo transfer. About 30 days before they are due to deliver, we move them to a special facility. There, the calves are recovered by Cesarean section. We have a staff of veterinarians available at all times. The calves are then moved to an indoor small-calf facility, in individual pens, for the first week after birth. This is a very clean, very sterile environment. If there are any health issues, they can be treated at this time. The calves are then moved into individual calf huts. Calf huts are an established system-used commonly in the dairy industry-that works very well to keep calves healthy. The huts are in a barn-like building with open sides. So the calves get fresh air but are separated physically from each other, so we don't have disease transmission. It's a dry, clean environment. After weaning, the calves are moved to another facility that contains pens where they are kept with their brothers and sisters for the first time. Once they are a little older they are moved to a different type of facility with larger pens. Eventually they go into the plasma production facility.

CLONE EMBRYO

< CELLS

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HEMATECH'S HUMAN POLYCLONAL ANTIBODY PRODUCTION SYSTEM

PURIFY PRODUCT

BULK API

MONITOR RESPONSE TO IMMUNIZATION

IMMUNIZE COW >>

FORMULATE

VACCINE

PRODUCT

COLLECT BULK

MAINTAIN COW

QUALITY CONTROL OŨALITY ASSURANĆE/ DOCUMENTATION

The plasma is collected from the cows via plasmapheresis. The process is exactly the same as is used with humans, with the same machine. We brought in experts to help us set up the plasmapheresis system. We also did an intensive study to look at the impacts on the animals of plasmapheresis frequency and volume. We looked at long list of end points, including the health of the animal, stress on the animal, and so forth. We found that the animals adapt to this very quickly. They get to a point where they walk in and stand calmly while the plasma is being collected. Also, remember that we are seeking to produce antibodies from these animals. Antibody production is probably as good an endpoint as you can get for looking at health and stress levels. If a cow is stressed, it is not going to produce perfect antibodies. We did a study comparing the immunization response in our clones to that of a control group, and they came out almost identical to each other.

Overall, then, the potential benefits of the genetic modification of animals are as follows. The benefits for the target animals include improved health and welfare through transgenic modification and through a better understanding of animal physiology, genetics, and management. There also could be a reduction in the number of animals needed for meat and milk production. The benefits for humans include novel or lower-cost treatments for disease, improved understanding of disease, and more nutritious or lower-cost meat and milk.

Let's also look at the potential risks. The risks for the target animal include negative outcomes affecting the health and welfare of the animal. Under current federal guidelines, however, animal welfare issues are monitored and addressed appropriately to minimize suffering. There also could be negative consequences from random gene insertions. The random insertions could cause harmful gene mutations which must be tested in homozygous animals. The risk also exists of narrowing the genetic diversity contained within a breed. The risks for humans, I think, if current regulatory guidelines are followed, are not significant. The therapeutics produced in animals must be as safe and effective as those produced through any other system.

I'll end by showing you photos of our first set of cloned calves (not included in this report), which were born in January 1998. They are still around and are nice healthy animals. Here also is a group of transchromosomic Jersey bulls. There are about ten of them in total. And this last photo is of a chimeric steer, which was derived from a mix of cells from two different embryos.



A SHORT QUESTION AND ANSWER PERIOD FOLLOWED

Dr. Robl's presentation. To start, one participant asked if the cows' immune response is affected when the genes that code for making antibodies are knocked out. She also wanted to know whether the inserted human antibodies function effectively for the cow. Dr. Robl answered that a cow's immune response is affected when the cow's own antibody genes are knocked out and not replaced with human genes. To deal with that, the researchers can either replace the bovine antibody cells via transfusion or treat the cow with antibody therapeutics. In response to the second question, Dr. Robl said he does not yet know how well the human antibodies will work for the cows, but human and bovine antibodies are very similar, so he believes the difference will not be significant.

Another participant observed that some people and organizations would question whether the sterile conditions of Hematech's indoor small-calf facility, as well as the practice of using C-sections to deliver cloned calves, were humane.

Next, a participant asked whether Dr. Robl felt that Hematech's practices with regard to IACUCs and animal welfare were typical of other companies in the industry. Dr. Robl said he knows the other companies in the industry quite well, since it is a relatively small group, and he is comfortable saying that they all meet the same requirements and standards as Hematech.

Another person asked Dr. Robl to talk about the role of the IACUC. Dr. Robl deferred the question to Jerry Pommer, a workshop participant from Hematech who chairs their IACUC. Pommer said that Hematech's IACUC has six members who review each research project. They review the care of the animals, the veterinary care to be provided, and any procedures that are to be done. C-sections are the only invasive process Hematech uses, he said, and they do use pain medications. He also noted that the USDA can inspect the facility at any time.

Finally, a participant asked if Hematech had an organized process for "finding out what it is you don't know you don't know,"(i.e., predicting unintended consequences). Dr. Robl said he thinks they can anticipate any risks that may arise, particularly through the IACUC. They look at whether something will cause pain and suffering, for example, and they have a veterinary staff that is responsible for monitoring the animals and making decisions. If they find that an animal is experiencing undue stress or suffering, Dr. Robl said, it is the veterinarians who make the decision to euthanize or not. Company management does not override those kinds of decisions. Dr. Robl also said that, in the field of cloning in general, substantial effort is being made to identify and characterize problems that might arise. Hematech's focus, he said, is on trying to reduce negative outcomes, and they would like to have all healthy calves, all born naturally. In the last several months, he added, they have spent about 20 percent of their time evaluating management systems to look at how they can produce live, healthy calves and maintain them in the early critical period. It is also an economic issue for them, he said. They need to have healthy animals, so they spend a lot of money to determine how to do that.

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> CHESTER GIPSON, DVM U.S. DEPARTMENT OF AGRICULTURE'S ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Dr. Chester Gipson is Deputy Administrator of Animal Care at the Animal and Plant Health Inspection Service (APHIS) of the USDA. Dr. Gipson presented on animal welfare and biotechnology. His remarks are paraphrased below.

Today I'm going to talk about what animal welfare is, who is responsible for it, why it is important, and the challenges facing agriculture. Any evaluation of animal welfare in the U.S. must consider the Animal Welfare Act (AWA), the Horse Protection Act, the Humane Slaughter Act, and the Animal Health Protection Act (AHPA).

The present-day Animal Welfare Act came about after a Dalmatian named "Pepper" was stolen by a dog dealer in 1965 and was later found being used in research. Life and Sports Illustrated carried the story, which led to a public outcry and ultimately to the passage of the Laboratory Animal Welfare Act (LAWA) in 1966. The LAWA provided for the humane care and treatment of certain animals in regulated activities. The USDA's APHIS was charged with enforcing the law. In 1989, APHIS's Animal Care Unit was created solely for this purpose.

In the original LAWA, the definition of "animal" included dogs, cats, nonhuman primates, guinea pigs, hamsters, and rabbits. The law authorized the Secretary of Agriculture to regulate the transport, sale, and handling of these animals, pre-research or "for other purposes." It also allowed for the licensing of dog and cat dealers.

The law was modified in 1970 to ensure the humane treatment of animals for research or exhibition by regulating their transport, sale, housing, care, handling, and treatment in commerce, exhibition, and all stages of experimentation. "Animal" in this amendment was defined as all warm-blooded vertebrates as determined by the Secretary, excluding horses not used in research and farm animals used as food or fiber or used for improving animal nutrition, breeding, management, production efficiency, and the quality of food and fiber.

The AWA was amended again in 1976. This amendment refined the regulations on transport and commerce and required that covered animals have a health certification prior to transport and commerce. The amendment also included details on licensing methods, payments, and penalties. It described how regulated institutions are to be licensed, and what the penalties would be if they are not licensed. It also outlawed the interstate or foreign transport of animals for fighting ventures.



In 1985, the AWA was further amended by the 1985 Farm Bill. These provisions sought to: minimize the pain and distress suffered by animals, further define humane care; direct the Secretary of Agriculture to consider alternatives to any procedures likely to cause pain or distress; require the establishment of Institutional Care and Use Committees (IACUCs) at research institutions; form an information service at the National Agriculture Library (the Animal Welfare Information Center); and establish penalties for the release of trade secrets.

The AWA was also amended by the 1990 Farm Bill through the Pet Theft Act, which focused mostly on stolen dogs. It included a mandatory holding period for dogs and cats acquired by an exhibitor or dealer. Another provision required a certification for random source dogs and cats, to ensure that they did not come from a questionable source.

The AWA was amended by the Farm Bill again in 2002. The definition of "animal" was refined to exclude birds, rats, and mice "bred for use in research." Since under our regulations we already cover rats and mice not bred for use in research, this means we will add pet bird breeders, dealers, exhibitors, and transporters to our enforcement. We are currently in the process of writing proposed rules for birds.

It should be noted that the definition of animals covered by the AWA still excludes horses not used in research and other farm animals (including livestock and poultry) intended for use as food or fiber or for use in improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. (See box below for a complete listing of the animals currently covered under the AWA.)

So, with the various amendments since 1966, the AWA today ensures (or in the case of birds, will ensure) adequate veterinary care, proper housing, safe transportation, shelter from the elements, adequate feeding and watering, humane handling practices, qualified personnel at regulated facilities, proper sanitation, and recordkeeping for all warm-blooded vertebrates. The minimum standards of the AWA are listed in the Animal Care regulations and standards (9 CFR Parts 1, 2, 3, and 4), as well as in specified interpretive rules. The law is enforced through owners' compliance, unannounced inspections, investigations, and penalties. The unannounced inspections are the strength of our program. All of Animal Care's regulations, standards, and policies can be found at www.aphis.usda.gov/ ac/publications.html. The box below outlines who is affected and not affected by the AWA today.

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ANIMALS CURRENTLY COVERED BY THE ANIMAL WELFARE ACT REGULATIONS

Any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as but not limited to livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

It seems that the recent animal welfare issues brought forth by animal welfare/ rights organizations are more about the intense agricultural production systems we use in the U.S. than about the AWA. This is a heated topic at present. Animal welfare in general is very much on the public's mind. I get more than 100 emails a day regarding the care of animals.

Another law worth mentioning is the Horse Protection Act. That came about because of the Tennessee Walking Horse industry, which used the practice of "soring" to train horses. This law deals with cruel and unusual treatment practices toward horses, and specifically is designed to eliminate soring, a practice that causes pain, irritation, or inflammation to the lower limbs or feet of a horse for the sole purpose of achieving an accentuated gait (e.g., the walking horse gait). Unfortunately soring still goes on today to some extent. Since there are people who strongly oppose the Horse Protection Act and believe that soring is an acceptable means of training, we often request the help of U.S. marshals in ensuring the protection of Animal Care inspectors.

The Humane Slaughter Act is also relevant here. The USDA's Food Safety and Inspection Service is responsible for its enforcement. It basically covers "hoof stock" (that is, cattle, swine, and lamb, but not poultry). The law is enforced at slaughter establishments. Animal Care has no jurisdiction in the slaughter of animals.

The Animal Health Protection Act (AHPA) is not a welfare act, but it does include a "28-hour law," which requires that transporters of animals in commerce stop and give those animals rest and water at least once every 28 hours. The AHPA affects importation; exportation; interstate movement; the detection, control, and eradication of diseases and pests; the seizure, quarantine, and disposal of diseased animals; and so forth. Its focus is to contain diseases like BSE and the Asian bird flu. The AHPA provides us with the legal authority we need to develop cooperative agreements to carry out our charge.

The appropriation and transfer of funds allowed under the AHPA make it one of the few ways to obtain millions of dollars in contingency funds to deal with disease eradication. Therefore, the law is used quite a bit. About five years ago, for example, we declared an emergency for a disease called pseudo-rabies. Funds from the AHPA were used to eradicate that disease.

THE AWA TODAY AFFECTS:

Dealers, breeders, exhibitors, and transporters of rats, mice, and birds, and animals in biomedical research and teaching

THE AWA DOES NOT AFFECT:

The retail pet trade, primary and secondary schools, field trials, coursing events, dog and cat shows, farm animals in production agriculture and agricultural exhibits, rodeos, horse or dog racing, or livestock shows

Finally, it's important to note that, in addition to the federal animal welfare laws, most states have animal cruelty laws that deal with animal welfare issues.

The challenges faced by Animal Care include the public's and regulated industry's acceptance and understanding of the science of animal welfare. Public education is an issue. The USDA is active in many areas that the public is not aware of or, in some cases, does not understand. Many decisions by lawmakers are made based on misunderstandings. The public and state legislators, in my experience, do not understand production agriculture or how food gets to the marketplace.

There is sometimes a real lack of understanding and communication. For example, at one time we had a problem with salmonella and other diseases affecting chickens in a certain U.S. state. We were talking to people about removing the dead chickens using a front-loading machine called a Bobcat. The legislators of that state wanted to know why we were putting bobcats (as in the feline type) in with the chickens. Also, in Texas there are lots of "cattle guards"—grates in the road to keep cattle from crossing. Someone mentioned the 12,000 cattle guards in Texas. This resulted in APHIS being told to decrease its budget by firing the 12,000 cattle guards. Our legislators need to better understand production agriculture!

It's great for me to be here to discuss this with you. I like to see people be a part of something rather than a victim of it. You may not be able to dictate what happens, but you can certainly positively influence what happens. We have a lot of work to do. The production agriculture agenda is moving. If you want to get on our mailing list, please let me know.

In response to questions following his presentation, Dr. Gipson elaborated on what types of animals are and are not covered under the AWA. He explained that research on farm animals that are genetically engineered to produce more meat or to grow faster are not covered under the law, because those uses are excluded in the definition of "animal." He also noted that cloned cats would be covered by the law in the same manner as non-cloned cats. Dr. Gipson also noted that transgenic livestock used in biomedical research (e.g., those being created to produce human vaccines in their milk) are covered by the AWA, but some confusion remains about whether the law will cover those animals once the commercialization of the products begins.

One meeting participant noted that certain regulations of the USDA's Agricultural Research Service and the National Institutes of Health do cover rats, mice, and farm animals used in research at universities. So, the welfare of those animals is considered to some extent, even though they are not covered by the AWA.

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The real issues that keep coming up regarding animal rights seem to have more to do with the intense agricultural production systems we use in the U.S. than with the AWA. That's what people are really concerned about.

> Chester Gipson, USDA APHIS



► PAUL THOMPSON, Ph.D. DEPARTMENT OF PHILOSOPHY, MICHIGAN STATE UNIVERSITY

Dr. Paul Thompson is Professor of Agricultural, Food, and Community Ethics in the Department of Philosophy at Michigan State University. His talk covered "Animal Bioethics 101." His paraphrased comments are as follows.

Well, I've been charged with covering a couple semesters of ethics courses in 50 minutes or less!

So, I'm going to boil it down and give you a general survey of what people have thought about how to think and talk about ethics. I'm first going to cover basic concepts in ethics, then some schools of ethics. Because I have been asked to describe how philosophers approach the issues, I won't shy away from some arcane terminology and theoretical traditions. Then I'll move to animal ethics and animal ethics in biotechnology.

The little stick figure drawing in this slide represents someone who is trying to decide what he should do. (See figure below.) He could represent a group or an individual or society as a whole. But there are constraints on the decision maker. We don't ever make decisions without some constraints. Technology is a fairly large set of constraints. Some things are not technically feasible, so we don't consider them. Also, we have a set of law and policy constraints. Some options we don't consider because they are illegal or they violate personal or organizational policies or rules. A third set of constraints are those of customs and norms, which are not as explicit as policies or rules. Customs and norms are often very effective in shaping our decisions, though we may not even be aware of them. For example, suppose you go to Taco Bell for lunch. Do you barge up to the counter and bang on it and demand immediate service? No, you get in line and wait your turn. You know that you are supposed to queue up for service. There are no laws to specify that we must do that, but if you don't think it's a pretty robust customary norm, just try to violate it. So, our decisions are framed by these three kinds of constraints.



When we finally decide to do something (engage in conduct) like order food or undertake experiments, that conduct has consequences. The consequences I have in mind are those that affect health, wealth, and well being. The consequences make you or others feel good or bad, or make you or others better or worse off in terms of health or money. This is a very simple model of human decisions, but it is capable of generating a lot of ethical complexity and richness.

So, what I want to do now is add some ethics to this model. In the consequences category, we can talk about those consequences as either beneficial or harmful. We can see impacts on health, for example, as benefits or harms. Now we're starting to talk ethically. We're making value judgments here; for instance, perhaps we decide that being dead is a bad thing. There is a tendency among scientists to think that notions such as "life" or "health" are not valueladen, but as soon as we start thinking about death as an outcome that is in some way adverse, we are starting to talk ethics.

Similarly we can talk about at least two of the sets of constraints—law and policy and customs and norms—in fairly explicitly ethical terms. If we think that we have a right to be served next when we get to the front of the line, and if we think the counterperson has a duty to serve us, then we are talking about those constraints in ethical terms. Generally speaking, this language of rights and duties is ethically charged. We can also talk about the conduct itself as having an ethical component. We think of some actions as being virtuous or good and others as being vices or bad. So, we have three sets of concepts there.

So, how do philosophers generate systematic approaches in ethics? How do you decide what the right action is? For the last 250 years, there's been a lot of energy expended by philosophers regarding this problem. The strategy they've taken mirrors that of scientists; they've sought to simplify and focus on the smallest elements possible. This strategy is known as Reductionism. There are several types of Reductionism.

The first I'll mention is Utilitarianism. Utilitarians tend to focus on benefits and harms, and say that what matters is the impacts of an action on health and well being. Utilitarians tend to talk about rights and duties, and about what's virtuous regarding the way certain conduct creates certain consequences. You can get into a lot of detail regarding how the costs and benefits should be weighed, of course.

Another school of Reductionist thought is Deontology, which says that what really matters are the characteristics of the person, their ability to act freely, and their ability to be guided by their own sense of what's right. The autonomy of the human being is ethically basic to Deontologists. So, goodness or badness is measured only in terms of how it affects autonomy and freedom.

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► Paul Thompson, Michigan State University 16

Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals

What if you use biotech to make an animal that lacks all ability to feel pain and has no aspects of subjectivity? What if you create a kind of "loaf" animal—a blob that produces meat and eggs? This is a dream come true, right? You have no animal welfare or animal rights problems! Yet this causes the most queasiness and anxiety to members of the public.

Paul Thompson, Michigan State University

There is another approach to thinking about rights and duties known as Contractualism. It suggests that we have these implicit social agreements that are ethically important. For example, we generally sort of agree that the person at the front of the line deserves to be served next. This school is mostly focused on what our rights and duties ought to be. Contractualists may emphasize that there are certain rational interests we engage in, and say that we need to look carefully at our rational interests to determine what our rights and duties ought to be.

Finally we have the category of Virtue Ethics. Virtue Ethics suggests that the idea of what a good person is reflects a fairly complex set of relationships between the person who's acting and others in the community. People are bound up in networks of family, neighbors, society, and so forth, and they have different responsibilities to each of these groups. These are fairly complex relationships and there are different ideas for how to act virtuously in each of these sets of relationships. So in Virtue Ethics, you have a model of what a virtuous person is. The question becomes, what would (name your favorite virtuous person) do?

So, these are the three or four broad Reductionist traditions in philosophy. All of them have a model for how one should reach an ethical decision.

One of the problems with so many models is that you have a question about which model is right. Philosophers who actually work with people who have to make decisions (i.e., non-philosophers) often prefer the idea of Pluralism, which is to say that all of these traditions contribute to moral understanding, and it's a mistake to separate them. They say that we have to include all of these types of moral discourse.

So, let's compare Reductionists and Pluralists for a moment. Reductionists say that right action is a function of specified values and decision rules (always respect people's freedom, for example). Reductionists also say that the task of a philosopher is thus to give a complete specification as to what an ethical action is. This approach is monological and theory driven. It's a way of reasoning out a problem by oneself—one person can sit in a room alone and use one of these approaches and come to a decision.

Pluralism says that right action is a function of agreement, overlap, or consensus among multiple competing perspectives. So, you have a clear sense of what to do only when competing perspectives agree. The task for a philosopher, under this approach, is not to make a decision but to maintain openness to all the different possibilities and to avoid foreclosure. Pluralism is dialogical and process driven. You have to have different voices, with different ethical systems, engaging in dialogue to reach a decision. It demands a concrete social process to build agreement. No one can do this sitting alone in their office.

For Reductionists, the key problem is specifying and defending a theory that successfully renders all ethical situations according to a common set of terms and conditions. The stumbling block is that certain ethical intuitions (i.e., strongly felt or held beliefs) just don't fit. Every theory has some of these stumbling blocks. For Pluralists, the key problem is characterizing the conditions for fair deliberation, consensus, and agreement, and then trying to effect such conditions under real-world constraints. It's very difficult to do. And the stumbling block is that it doesn't give you an answer. It can be very dissatisfying. Also, the quality of decision-making will depend on who you have in the room. If you have people in the room who think, for example, that only Greeks or men "count" morally, then you are going to get a particular kind of answer out of them.

So, that's a broad-brush introduction to ethics. Let's move on to animalsrelated issues.

Animal issues have been important in philosophy since the ancient Greeks. In fact, philosophers have been responsible, in part, for increased concern about how animals are treated and considered.

The Utilitarian view naturally focuses on consequences with regard to health and welfare. A Utilitarian philosopher might ask: How does a given action impact well being, disease, and discomfort? And why draw the line at impacts that only affect human beings? They believe it's arbitrary to do that. It's like drawing the line at Greeks or men. So, Utilitarians say we shouldn't be arbitrary, we should think about the impacts on animals of our decisions and actions. This has resulted in a philosophical animal welfare view. The argument is that animals experience some of the same kinds of impacts on health and well being as humans, so it's logically inconsistent to ignore these impacts. This is the pattern of argument that Peter Singer put forth in the book Animal Liberation, which was the bestselling book written by a philosopher in the 20th century.

The philosophical animal rights view is a bit different. The focus is: Are there reasons for thinking that animals have rights? Is there something inherent about animals that makes us think we should act toward them the same way we act toward other humans? One way to get at this is through a version of Deontology. A Deontologist would say that animals have some sort of subjective life. Each animal has its own "self," its own personality. There's a temperament there, and a memory. Animals have something about them (a psyche, perhaps?) that is the carrier of their subjective life, and we have a duty to respect that about them. In this vein, some philosophers have argued it is always wrong to treat a being as if it were just a means to our own ends. This is the view of Tom Regan, author of The Case for Animal Rights. This is the philosopher's view that generates the most radical transformation in our views. It leads to the idea that we should never eat an animal, for example ("moral vegetarianism").

Another version of the philosophical animal rights view is the Pluralistic social contract. The argument here is that we implicitly agree on a moral condition expressed in terms of rights. Society has come to expect that we owe duties of decent care and treatment to animals. Bernard Rollin has espoused this view most clearly, with regard to animal "telos." It's about our sense of what our duties are. He will explain this later in his talk, I presume.

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Getting now to the specific issue of animal biotechnology, let's talk about the "blind hen problem." This is a case that was discussed in the literature by Peter Sandøe. He talks about a group of congenitally blind hens, which could have been bred into a strain. Danish researchers found that, in modern poultry production, these blind hens were far less stressed. When hens can't see, they exhibit much higher levels of well-being in confined environments. I'm guessing these hens aren't too productive, though I don't know. But this looks like a good way to solve this animal welfare problem, right? Just use blind hens. They will be much better off. But when this example is discussed in public, people start throwing tomatoes! Let me be clear that I'm not advocating this strategy. It's just an example to get us talking. It's an example of what you could do with biotechnology. What if you use biotech to make an animal that lacks all ability to feel pain and has no aspects of subjectivity? What if you create a kind of "loaf" animal—a blob that produces meat and eggs. This is a dream come true, right? You have no animal welfare or animal rights problems! Yet this causes the most queasiness and anxiety to members of the public.

So, there is a philosophical problem here because from the Utilitarian view or rights view it seems like no one should disagree with creating a "loaf" that produces meat. Even the most radical animal ethics views don't logically lead to the conclusion that there's anything wrong with taking animal biotechnology as far as it possibly can to change, for example, animals' ability to feel pain or to have a subjective life. Yet it is clearly the case that most people have strong intuitions that something is wrong with that.

How do we deal with that? Well, one alternative is to say that animals should be "natural." But philosophers don't like this. Whenever people have wanted to do something wrong, they've said it was "natural." The oppression of women, bans on interracial marriage, and the like have in the past all been argued to be "natural."

Maybe the most promising alternative is to say that taking a purely instrumental view of life or living things (including not just whole organisms but general life processes), is really contrary to our view of what the virtuous person would do. Virtuous people have some sense of awe about the process of life. This moves you into the tradition of Virtue Ethics. But this view has consequences too, because it suggests that there may be problems with less extreme types of animal biotechnology. It certainly demands that people doing biotech at least have to prove to us that they are virtuous people. We need to know that they are not treating animals in a purely instrumental way, and that they are thinking about whether they are going too far, and so forth. This is an extraordinary demand to make on people, really, because in the U.S. we typically don't require people to act virtuously.

So, I think this is where we stand philosophically. I don't think we have very good explanations for what troubles people about biotech. As you look at the different philosophical models, you do get some explanations of why we shouldn't transform animals in ways that negatively impact animal health or welfare (e.g., creating an animal that will live its life in pain). But you get no good explanation of what addresses the leading qualm about the direction animal biotechnology might go if it reaches its logical conclusion.

IN THE QUESTION AND ANSWER SESSION THAT FOLLOWED:

Dr. Thompson's presentation, one workshop participant pointed out that people have bred dogs for centuries in ways that are detrimental to the dogs' well-being (e.g., English bulldogs, which have breathing problems). Dr. Thompson agreed, and said he did not have a good explanation for some of the deep inconsistencies that we as a society have. He suggested that the "nonsentient loaf animal" might be more acceptable to people if it were not genetically engineered "down" from a sentient animal, but created by working "up" from a "bag of cells." If scientists started with cell culture and ended up with meat and eggs, maybe it would not bother people, he said. There is not much difference from a biological standpoint, but taking away capacities from an animal seems wrong, while adding properties to cells in a Petri dish does not seem quite as wrong.

Another workshop participant asked what kind of dialogue process society should use to address the ethical questions regarding animal biotechnology. Dr. Thompson noted that, in Europe, some efforts have been made to introduce dialogues (on these topics) that are public but not legally binding. These processes have not caught on in the U.S. The closest we have, he said, are the Presidential Bioethics Commission and the IACUCs at universities and companies.

Finally, one participant pointed out a difference in the way people use language in discussing these issues. He noted that Dr. Robl talked about "benefits and risks," while Dr. Thompson's discussion of Utilitarianism used the terms "benefits and harms." "Benefits" and "harms" sound definite, the participant said, while "risks" sounds indefinite. The participant added that he thinks biotechnology promises only potential benefits, while posing real harms to animals.

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Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals

Genetic modifications to animals might be seen as acceptable [to Hindus] if there are clear benefits for humans that could not be achieved in any other way. Also, the genetic modification would have to make the animals no less happy nor less able to progress "up the ladder" to rebirth as a human.

Harold Coward,University of Victoria



► HAROLD COWARD, Ph.D. CENTRE FOR STUDIES IN RELIGION AND SOCIETY, UNIVERSITY OF VICTORIA

Dr. Harold Coward is Professor of History and Founding Director of the Centre for Studies in Religion and Society at the University of Victoria in Victoria, British Columbia. He spoke about the moral and ethical approaches to the use of animals in Hinduism, Buddhism, Judaism, Islam, and Christianity. His remarks are paraphrased below.

Well, I have the problem of covering thousands of years of religious tradition in 45 minutes. Religions focus mostly on duties and virtues approaches, and they set up models. They emphasize freedom and responsibilities. Like ethicists, religious scholars have pluralism too. We try to make policies by taking into account the views of all the major religious traditions. This is done via dialogue and focus groups. Regarding biotechnology, we have ethics theologians from different traditions who look at its use with regard to animals and foods. Today I'm going to talk about Hinduism and Buddhism first, then the European traditions of Judaism, Islam, and Christianity.

HINDUISM: Animals, for Hindus, are human souls in different bodily form. Eating an animal is thus quasi-cannibalism. Humans are reincarnated, and they may have been animals in past lives and they may be reborn as animals in future lives. Animals have no free choice, but humans do. Animals have to "burn off" bad karma; then they can be reborn as humans. Hindus follow ahimsa, or the doctrine of not harming any living creature—animal or human. For them, the divine exists equally in all beings. As a result, millions of Hindus eat no fish, no meat, and no eggs. But many others do eat chicken and fish but not red meat. They would probably still refuse to kill animals, but they would eat those killed by others. Some Hindu philosophers reject all research on laboratory animals, while others allow some. If the benefits to humans outweigh the pain the animals experience, and if there's no other way to get the benefits, then research on animals may be seen as acceptable.

Hindus haven't said much about cloned or transgenic animals. Genetic modifications to animals might be seen as acceptable if there are clear benefits for humans that could not be achieved in any other way. Also, the genetic modification would have to make the animals no less happy nor less able to progress "up the ladder" to rebirth as a human. That said, one orthodox Hindu colleague of mine told me that the genetic modification of animals presumes a right of humans over other life forms, which is seen as wrong. He also asked what the human motives were for doing this, and said human greed seems paramount. Hindus think life is about the reasonable control of wants and greed.

To sum up, then, Hindus see animals as beings like humans. There is a strong vegetarian practice. Some Hindu scholars agree with these points but still would allow for genetic modification under certain conditions. We are awaiting good scholarly studies by Hindu ethicists on the topic.

BUDDHISM: Like Hindus, Buddhists stress nonviolence to all beings. This requires that one not harm any sentient being. As a general rule, Buddhists cannot hurt or kill any human or animal, nor eat meat. But they can go to war or kill in self defense, and some do eat meat. Tibetan Buddhists do eat meat because they can't grow crops at the altitudes at which they live. But they only kill as many cattle as are really needed. There is no hunting for sport. Buddhists also allow for the possibility of eating meat that wasn't slaughtered specifically for oneself. But devout Buddhists are supposed to live on fruits, vegetables, and grains. Eating meat is seen as a kind of cannibalism.

Regarding animal biotechnology, the primary concern seems to be human motivation. A Buddhist colleague of mine questioned the motivations for the use of GM animals for food or other purposes. He said it's a problem of commodifying life for food. He worries about the profit motivations of capitalist societies. This suggests a new approach to assessing biotechnology. Buddhists say that actions based on bad intentions result in bad consequences, while actions based on good intentions result in good consequences. This is different than saying cloning or genetic modification is bad in and of itself. If our eagerness to do genetic modification is motivated by generosity, for example, then it will bring about good results. A Buddhist rule of thumb is to ask: Is our motive due to greed or ill will? Can we be clear on why we are doing it? Can we be clear how it will reduce the suffering of animals? The acceptable motivation is that it will reduce the suffering of humans and other species. Another Buddhist scholar I spoke with, however, condemned any instrumental use of animals for any reason. He said that animals can't be treated as objects without regard for their own wishes and aspirations. He said cloned or GM animals raise questions about humans' ability to alter life.

So, with regard to the use of animals in science, Buddhists say you must consider three factors: the intentions of the act, the means used, and its consequences. With animal biotechnology, if the intentions are good and the consequences are needed and beneficial (in terms of human lives saved, etc.), then maybe it's justifiable. However, there are clearly differences among Buddhist thinkers on this subject.

JUDAISM: Judaism has moral and legal rules regarding animals. Jews see animals as a part of God's creation for which we have responsibility, therefore cruelty to animals is not allowed. Blood sports and hunting are forbidden. Kosher slaughter rituals are designed to minimize suffering. Animals must be vegetarian in order to be eaten. And the Talmud says that animals should be fed before humans, not restrained unnaturally, and not worked on the Sabbath. (Due to the latter requirements, it's questionable whether factory-farmed animals can ever be deemed kosher.)

Animal biotechnology is now a hot topic among Jewish thinkers. The overriding principle from Genesis 1:28 (regarding man's dominion over animals) is that God has made humans collaborators with Him in fashioning the processes of creation to reach its destined end and to spare humans travail. But there is tension between the role of humans in completing the process of creation and biblical prohibitions against certain forms of interference in the natural order (e.g., the mixing of species).

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The conclusions of Jewish Law scholars so far regarding genetic modification are as follows. Genetic modification does not constitute a violation of the prohibition against crossbreeding. This is in part because the process does not involve sexual acts across species. Also, the physical appearance of the resulting animal is of key importance. Because the tomato with the fish gene looks like a tomato, it is acceptable. And a cow with pig genes is still a cow since its general appearance is not changed. GM chickens are kosher so long as they look like ordinary chickens, even if they have genes from a nonkosher donor. If an animal is fed forbidden foods, it's still OK since the food is completely destroyed in the digestion process. The overall thinking, then, is that anything that benefits people is encouraged, as long as there are no associated dangers and it doesn't cause suffering to the animal.

ISLAM: Islam is similar to Judaism and Christianity in terms of its views of animals. In general, these Western religions give privilege to humans, while Hinduism and Buddhism do not. Like the Torah, the Qur'an forbids cruelty to animals, but it also goes further to suggest that animals possess some rationality and that all species are "communities" like human communities. Mohammed urged his followers to show compassion to animals and treat all animals gently, because they are part of God's family. In the afterlife, he said, one receives rewards in relation to how we treat animals in this life. Islam also teaches that animals possess a psyche; they have a lower-level consciousness than humans, but it's higher than just instinct. And they communicate with God. Humans, they say, have spiritual volition and greater freedom of action. We are God's vice-regents on earth. As such, we have stewardship responsibilities. Islam condemns blood sports and the use of animals in cosmetics research or the killing of animals for floor coverings. Animals can be killed only when needed for food, and then only in a ritual way (Halal) that minimizes suffering.

In current guides for Muslim shoppers, GMOs are not mentioned, and no problems with factory farming are raised. The rules in the guides mostly center on avoiding products that may contain alcohol or pork. Three academies of Islamic Law (that met in Morocco, Saudi Arabia, and India) have held discussions on genetic modification. The key question for them is, Have humans taken on the power of creation through genetic modification? Because that belongs to Allah alone. The thought is thus that science shouldn't create things, but it should make understandable the facts of Allah's creation. These scholars thus see cloning as a miracle made possible by Allah, and genetic modification as knowledge made possible by Allah. If successful, it must have the consent of Allah. None of the elements in cloning are human made; all were made by Allah. So there is no change in the birth of the creation. The only difference is in how fertilization takes place. Thus it is then still an act of Allah. So, cloning is not creation nor a partnership in creation, since Allah is the creator of all things. At this point, Islamic scholars accept cloning for animals, but not for humans. They say that research in the field of cloning should be restricted so that it becomes a means of betterment for the world, not a cause of chaos and disturbance, and it should not result in suffering for animals.

CHRISTIANITY: The mainstream attitude in Christianity until recently was that animals are here for our use. They have no immortal soul and no intrinsic worth. As stated in Genesis, man has dominion over animals. Humans can thus exploit animals to our own advantage however we see fit. Christians' views on these matters were influenced by the Greeks. In particular, Aristotle exerted major influence over Augustine and Aquinas. Aristotle argued that nature made animals and plants for the sake of humans. Augustine followed suit, saying that animals and animal suffering are here for the physical and spiritual benefit of humans.

This view is now being questioned, however, as a misreading of the Bible. Many Christians now view animals and humans together as parts of God's creation all of which God blesses as good and inherently valuable. There is an all-inclusive view of God as good in the first chapter of Genesis, where it appears that humans and all animals were vegetarian. In the "original sin" story, we bring the animals down with us and we all become meat eaters. So, in Christian environmental ethics in the last 50 years, humans have come to be seen more as a part of the natural world. Albert Schweitzer, for example, said we must be at least ecologically respectful and just in killing animals. The "dominion" role of humans, it is now thought, is to work with God as "stewards" of nature, including animals, with compassion for animals and their pain. Many theologians now offer an ecosystem concept in which humans and animals are an interdependent part of nature—a nature created by God. The idea is that animals are suffused with God's Spirit.

I should note that many of my comments regarding Christianity and genetic engineering that follow here are drawn from the Engineering Genesis book, written by a group in the UK that was affiliated with the Church of Scotland. That book looked at three case studies: one involving animals as producers of medically useful proteins; the second involving animals as sources of "sparepart" organs; and the third involving the use of animals engineered to exhibit human disease as scientific models for research on potential therapies. In the first two cases, little animal suffering would appear to be involved. In the third, there is likely considerable suffering, which must be justified by the human good that is achieved. Thus the use of GM techniques to produce a protein in milk is considered ethically acceptable. But the use of GM animals as donors of organs for human use is seen as a radical extension of our God-given relationship with animals, and changes the way we look at them. The thought is that we must not view animals as merely spare-parts factories. To take a heart from an animal is a major step and should be done only in case of human need and after all other methods (e.g., the prevention of heart problems through diet) are tried. The mouse genetically engineered to develop cancer is even more of a problem; it is seen as ethically unacceptable no matter how compelling the reasons for doing it. Instead, we should search out alternative methods of research.

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Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals

The use of GM animals as donors of organs for human use is seen as a radical extension of our [Christian] God-given relationship with animals, and changes the way we look at them. The thought is that we must not view animals as merely spareparts factories. To take a heart from an animal is a major step and should be done only in case of human need and after all other methods (e.g., the prevention of heart problems through diet) are tried.

Harold Coward,
 University of Victoria

Cloning raises questions and big problems for Christian theologians. It could be argued that creating animals on demand goes against God's plan for biodiversity as set forth in the Bible. It's an act of hubris and irresponsibility, and hubris is the greatest sin. So the cloning of animals is seen to be the greatest wrong. But some small-scale cloning work has been approved by the Church of Scotland (i.e., the use of cloning to produce a few founders of GM cattle lines for small-scale medical applications). If the reason for cloning is rooted in economics, convenience, or the demands of human preference, then it is clearly unacceptable. From a Christian viewpoint, humans must show respect for their fellow creatures.

So, that's a brief summary of the five major religious traditions' views of animals and animal biotechnology. In preparing this talk, I did try to map out areas of agreement among all the traditions, but I failed! There are no obvious agreements, and a lot more work is required. But, as in ethics, we have religious pluralism. A lot of models are being brought together and discussed together.

IN THE QUESTION AND ANSWER SESSION THAT FOLLOWED:

Dr. Coward's presentation, Michael Appleby, a workshop participant who co-authored the Engineering Genesis book, clarified that the book was not intended as an exposition of the Christian perspective regarding animal biotechnology. The book was organized by Donald Bruce, an employee of the Church of Scotland, but it was co-authored by a group of people that included at least three non-Christians.

Another workshop participant, directing a question toward Dr. Appleby, asked how eating pigs could be considered respectful but using pigs to develop organs to save human lives could be seen as not respectful. Dr. Appleby said that when a new activity is begun that has not been undertaken before, it is important to ask if that new activity is justified. One of the powerful arguments about xenotransplantation, he said, is that it is necessary because there is a shortage of organs for human use. But, is xenotransplantation the best way to respond to that perceived need? Or are there other ways that would be better? Dr. Appleby said the answer is not unequivocal. Dr. Coward added that some Christian theologians do advocate vegetarianism, on the basis that Genesis 1 suggests that we all once were vegetarians. But that is not a mainstream thought. Another participant then noted that doctors have been using pig heart valves in medicine for about 40 years. How does that compare, he asked, to the use of GE pigs for whole heart xenotransplantation? Dr. Appleby first pointed out that there was not consensus among the Engineering Genesis authors on all issues. Regarding pig heart valves, he said the thought was that heart valves are not living when they are put into humans, and the rest of the pig is used for food. Xenotransplantation, by contrast, involves the modification of a pig for a new, solely human purpose. It opens the possibility that the pig is purely a means to our own ends.

The "cancer mouse" was also discussed. Dr. Coward said that what seems to be unacceptable in that case is that the animal is modified to be certain it gets a disease. The traditional breeding of an animal species that may develop a disease is not seen as quite as objectionable. Another participant pointed out that we may be making "sins of omission" if we choose not to breed the predisposition to disease out of animals, because we could do that using traditional breeding technologies.

One participant then asked whether, under Hindu or Buddhist traditions, animals' souls can reach the next level more quickly if they perform a good deed or serve a purpose, like a seeing-eye dog or a GE cow that produces human drugs in its milk. Dr. Coward said theologians still need to wrestle with that question, though he thinks the answer could be yes. The emphasis, he said, would be on the changes in the karma of the animal and of the humans manipulating the DNA of the animals. The humans are the ones with free choice, he explained. Animals have no choice. That's why and how they build up good karma—by putting up with having no choice. Also, Hindus believe that what we do affects not only our karma individually, but our family and society and the universe.

One participant asked whether, under the different religious traditions, it is acceptable to alter a cow so that it will produce more milk, given that there is already an abundance of milk on the market. If the modification is not meeting a real human need, Dr. Coward said, and reflects primarily corporate greed, then it is probably not considered acceptable by any religion.

Dr. Coward closed by saying that, in all of the religious traditions, the ethical positions are not cast in stone. They constantly evolve as new problems are presented and times change. What religious leaders do is compare activities against what the great thinkers and leaders over the centuries have said. This process is underway, he said, and we can expect clearer answers in a few years' time.

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BERNARD ROLLIN, Ph.D. DEPARTMENT OF PHILOSOPHY, COLORADO STATE UNIVERSITY

Dr. Bernard Rollin is University Distinguished Professor in the Department of Philosophy at Colorado State University. He briefed the group on ethical and moral issues relating to modern agricultural practices and animal biotechnology. His paraphrased comments are as follows.

The issue of animal treatment has become a major social and cultural issue internationally over the past 20–30 years. A Gallup poll done two years ago found that 75 percent of the U.S. public wants proper care of farm animals leg-islated or guaranteed by legislation. I'm going to explain the emerging social ethic regarding animals, and then tie it to biotechnology. A number of animal scientists have done surveys regarding what I call the new social ethic and found that it has been confirmed.

Whether or not religion plays a significant role in one's life, the Bible serves as a template for the concepts that undergird our thinking. In the Noah story, one finds metaphorically articulated the notion that animals rest in human hands. There is a human obligation to care for animals. God preserves humans, and in turn humans preserve animals. This is very different from the view of Christianity described earlier in this meeting. Elsewhere in the Bible, farm animals are singled out. The Bible articulates a concept of "animal husbandry." ("Husband" is thought to be derived from "hus/bond"-one who is bonded to the household.) Under the ethic of husbandry, we are to avoid deliberate cruelty, or depriving animals of sustenance, care, and protection. We also must put them in optimal environments. In turn, they provide us with toil, products, and ultimately their lives. But while they live, they live well. The Bible says that the Lord is our shepherd. We as humans want no more from God than the shepherd provides to his sheep. Our power over animals creates a strong moral bond that would appear unbreakable except to sadists and psychopaths. Anti-cruelty laws were intended for those people.

Despite this concept of husbandry, we have seen the relentless march of commercialism. After World War II, we saw farmland loss, population growth, and fear of an inadequate food supply. Industrial approaches to agriculture were created to assure enough food production. The traditional concept of husbandry involves putting square pegs in square holes (i.e., growing animals in ways that meet their needs and suit their natures). Now, technological "sanders" allow us to put square pegs in round holes (i.e., produce animals under conditions that are suboptimal for the animal). Productivity has been severed from husbandry. Note also that in 1900, half the U.S. population lived on small farms. One hundred years later, fewer than 2 percent live on such farms. Small farmers are a thing of the past. The Biblical message seems irrelevant. New production systems have created suffering for animals. Animals cannot, in confinement, express their true biological and psychological natures. New diseases, called "production diseases," which were either nonexistent or unimportant before, have proliferated. These include liver abscesses, environmental mastitis, and shipping fever, among others. These all have catapulted into prominence. A lot of people in veterinary medicine see these "production diseases" as bad, because they show that the systems are essentially pathogenic. Also, attention to individual animals has vanished in economies of scale. Workers who understand and care about the animals and who are "animal smart" have been replaced by minimum wage laborers who are not knowledgeable about animals. Whatever intelligence exists resides in the system, not in the humans. Humananimal interactions are a major factor in animal welfare, disease resistance, and so forth. Our long-standing bond with these agricultural animals has been severely tested and even severed.

My thesis is that western ranchers are the last big group of people who still have husbandry as a set of values. I was having dinner with ranchers not long ago. I asked them how many had spent more on an animal than the animal was economically worth. All of them said they had. Agricultural economists would tell you that's wrong, I said, "one does not spend \$20 to produce something that sells for \$10!" The ranchers responded that "this is not a widget we are talking about; it's a living thing with whom we have a relationship." I've talked to 20,000 of these people and I have a good sense of those values.

I'll contrast that with a story I heard from an animal scientist at Colorado State University. His son-in-law is a cattleman who grew up raising pigs on the side. He got a job at one point as manager of a feeder pig barn. He detected a disease, and found out he could fix it cost-effectively. The boss said, no, we don't try to cure these problems; we just kill the animals and start again. So this kid bought his own medicine and came in on Sunday and medicated the animals, and they got better. The boss's response? He fired him. But the kid said, you can't fire me, I did it on my own time with my own money. So he stayed at that point, but he ended up quitting 6 months later. He said to his father-in-law, I know you wanted me to work in agriculture, and so I'm sorry I quit, but this ain't agriculture.

Industrialized agriculture has led to other problems, such as environmental problems and the loss of rural communities. I've heard the estimate that with the confinement of pigs as the method of choice, we've lost 80 percent of small swine producers. Lots of those former swine-farming communities are now essentially ghost towns. And now manure disposal is a huge issue. I visited a large swine operation in Utah; the guard proudly told me they produce as much excrement as the city of Los Angeles. That's sobering.

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When husbandry reigned, society needed only a minimalistic social ethic regarding animal treatment—namely the ethic to prohibit deliberate cruelty. Why? Because there was a measure of self-interest in husbandry-based agriculture. If you didn't treat the animals well, they didn't produce, and you were out of business. That's not necessarily true under industrial agriculture. If you can appeal to people's self-interest, you just need an ethic forbidding outright neglect by sadists and psychopaths. A lot of animal activists use the word "cruelty" to refer to anything that causes suffering. But historically, cruelty means deviant, willful, purposeful infliction of pain and suffering. Psychopaths and teenage boys are most likely to do this. In the Middle Ages, St. Thomas Aquinas said that animals had no souls or moral status, but that we should worry about animal abuse if for no other reason than that people who abuse animals often grow up to be psychopaths. Our last 15 serial killers had early histories of animal abuse, as do 80 percent of violent offenders at Leavenworth prison.

Until about three decades ago, "anti-cruelty" was the socially articulated ethic for animal treatment, with the exception of a few voices after Darwin published, who said that if we are continuous with animals we should extend ethics to them. But many others drowned them out, with the argument that Darwin said humans are at the top of the heap.

If you look at some of the changes in the social use of animals in the mid 20th century, it was a whole new ballgame. We saw the growth of confinement agriculture and the advent of large amounts of research and testing on animals. If we made a pie chart of all the suffering that animals experience at human hands, we'd see that deliberate cruelty is only a small part of animal suffering. We now inflict lots of pain and suffering on animals for nonsadistic reasons, in agriculture and research and toxicological testing.

Thirty years ago, in the late 1960s, society began to worry about this other 99 percent of the suffering going on that was not the result of cruelty. We became more morally sensitive. The media discovered that "animals sell papers." So, we needed a new ethic for treating animals. People tried to prosecute fur trappers, researchers, the veal industry, and so forth, for animal cruelty and consistently the judges threw out these cases because they said the behavior isn't deviant, it's serving human need. In the 1890s, a judge threw out a cruelty charge on a tame pigeon shoot that was organized to raise money for charity. The thought was that these are good people raising money for a good purpose.

So, we need a new ethic. Where does that new ethic come from? Paul Thompson in his excellent talk earlier pointed out that Peter Singer wrote a book that was his own new ethic. But it didn't attract a lot of ranchers. In order to establish a new ethic, you can't teach, you can only remind. To establish a new ethic, I have to show you that you already believe what I want you to believe. It's the judo vs. sumo notion. In sumo you take two big guys and they try to knock each other out. In judo one person uses another person's force against them.

I'll mention two examples from U.S. history in the 20th century—a sumo example and a judo example. A sumo attempt to change social ethics was Prohibition. It didn't work! People actually drank more. There was a certain amount of thrill in breaking the law. It made bootleggers out of honest people, and it gave gangsters a foothold in legitimate business, which we never got rid of. An example of a judo attempt was the civil rights movement. The civil rights movement involved people pointing out to other people that their behavior disagreed with what they already believe as Americans, namely that all people should be treated equally and that black people are people! If Johnson or King had been wrong—if their statements did not match what people already knew to be true deep down—then the civil rights movement wouldn't have worked, and would have been as irrelevant as Prohibition.

So, 25 years ago, I decided that society would apply human ethical concepts, appropriately modified, to cover animals. It dawned on me that every society faces the problem of two goods: the good of the group and the good of the individual. Totalitarian societies favor the former. Anarchism favors the latter. Our society has made the best historical compromise between the two. We promote the general welfare, while protecting individual rights. This compromise is based on beliefs about human nature—for example, that people don't want to be tortured, want to hold on to their wealth, want the freedom to worship as they please, and so forth. If society would begin to worry about animal treatment, it would select certain fundamental aspects of the animal's nature and legally guarantee that those were rights the animal would enjoy. For example, when we wrote the lab animal laws back in the 1970s, a USDA official said we had assured that animals have the right not to suffer pain when it could be alleviated.

By the way, this is the sense in which I give a lecture regarding "animal rights as a mainstream phenomenon." You really shouldn't use the term "animal rights" in talking about people who are abolitionists or animal liberationists. Peter Singer doesn't believe anything has rights, for example, but he certainly believes in animal liberation. "Rights" just means guaranteed protections for the entity in question. I think that's very important. It's not just a legal trick, because our social ethic is encoded in our legal/moral system. If you want to look at agriculture, this is what's been going on in Europe. Sweden in 1988 essentially abolished confinement agriculture. More recently, the EU made a decree that gives swine producers 10 years to get rid of sow stalls.

By the way, as further evidence of what I'm saying to you: About 2,500 state laws were floated last year pertaining to the protection of animal welfare. Go back 20 years, you might find two per year. If proper animal treatment doesn't happen naturally, people want it to happen through the legal system. Now notice this is not an ethic of abolition of animal use. It is, in my view, an intent to restore the ancient contract, to use animals fairly.

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Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals

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Bernard Rollin, Colorado State University

I appropriated a concept from Aristotle. If human rights protect human nature, animal rights should protect animal nature. I adopted Aristotle's notion of "telos," which means the "nature" of an animal. Telos is the pig-ness of a pig, the dog-ness of a dog. It seems pretty much a matter of common sense, therefore, that laws that protect animals should protect the fundamental aspects of their nature. That's in the Swedish law, for example, where cows are granted the right to graze.

With this ethic in mind, I do not see genetic engineering, cloning, or biotechnology as intrinsically wrong or always causing problems. I think the biotech revolution will make the computer revolution look like the hula hoop. Whether or not it's good or bad simply depends on the mindset with which it is deployed. If it's deployed with an industrial mindset, you can make animals suffer greatly. This happened, for example, with the Beltsville pigs, who were engineered with the human growth hormone gene. They did grow leaner and faster, but they had lots of problems, including lethargy, lameness, uncoordinated gait, bulging eyes, thickened skin, gastric ulcers, degenerative joint disease, heart disease, various kinds of pneumonia, and anomalous sexual behavior. But, could you do something less than that, that would increase productivity but harm animals less? That's what we need to be alert to.

So, I have enunciated a principle of "conservation of welfare." In producing transgenic animals, the GM animals should be no worse off afterwards than their parents were. I asked genetic engineers if they would buy this principle, and they did. Biomedical researchers wouldn't buy it, however. The animal models for human disease they aspire to engineer genetically are the most vexing problem in this regard. Some of the diseases they create in animals are of incredible horror and cause the animals much suffering.

So, what about transgenesis and environmental despoliation? It depends on the mindset of those who deploy it. I'm very proud of those who have written scientific papers that have argued for excessive caution in releasing transgenic organisms in an ecosystem. I think there are good grounds for that. Since we don't know what the implications of releasing things are, that seems intelligent. (If there were a flag for the human race, it should have "oops" on it!) I think that's pretty well operative now. We had a project at CSU that put a gene for rubber into a sunflower plant, and we put incredible restrictions on the growing of it, since sunflowers are a weed in Colorado.

Assuming cloning is perfected and causes no harm to animals, I don't see any problems with it. There are risks regarding creating a monoculture of animals. But I think these risks are minimal since there will always be people who don't want the same thing as everyone else. I think a bigger issue is being wrong about what we need to proliferate. As an example, the dairy bull who was the major sire for the American herd was later found to have a blood disease, which created a lot of hassle later on. So, how do we know we are cloning the right animal?

With the advent of genetic engineering, the concept of animal telos has been again cast into prominence. We can certainly change an animal's telos through genetic engineering. One argument that has been made is, given that the emerging social ethic is that we should respect an animals' telos, it follows that we should not alter an animal's telos. This underlies a major concern about genetic engineering. But it rests on a logical error. If an animal has a set of needs and interests, then we are obliged to not violate those interests and to attempt to accommodate them, because that matters to the animal. It does not mean that we cannot change the telos. We must respect it, but we can change it. If we alter the telos in a way that different things matter to the animal, or in a way that doesn't matter to the animal, we aren't violating the animal's telos. Consider domestic animals: One can argue that humans have changed or genetically engineered animals from the parent stock. Dogs are the classic example. Not many look or act much like their wolf ancestors. I doubt that anyone would argue that it would be better to have left the telos alone and not bred those animals if we keep them in human households. So, suppose we make animals better able to resist diseases? That changes the telos, but it makes it better.

Here's where the controversy is: We currently keep animals under conditions that patently violate their natures. Pigs under natural conditions will traverse up to a mile a day in foraging. Chickens do not naturally want to live in battery cages. It is now recognized that confinement production systems frustrate numerous aspects of chicken behavior and pig behavior and result in a mode of suffering for the animal. Not pain always, but fear, frustration, and social isolation. So, suppose we identify the genes that code for the drive to nest in chickens. Say we could create a chicken that wants to nest in a cage. We've changed the nature of the animal so that it is better suited to the conditions under which we keep it. Is that morally wrong? I would say not. It's preventing animal suffering and producing happiness. Can we determine if an animal is happy? I'd argue that it's easier to detect animal happiness than it is human happiness. Look at dogs and horses, for example—they make it obvious. With people, you never know. Suffering can be occasioned in many ways, from pain to not satisfying basic drives. If we can eliminate the nesting urge, then there's less suffering.

Why does it appear to some people that it is morally problematic to mess with an animal's telos to alleviate suffering? Most people don't even realize how animals are kept now, so they don't know how bad it is. They aren't using the right measures.

So, the maxim to respect telos does not mean we can't change telos. We must respect conservation of welfare. There are many positive ways we could change an animal's telos. If we want to do this. Maybe we would be wise to develop animals that are "decerebrate," i.e. "brainless" and incapable of suffering.

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With this ethic [telos] in mind, I do not see genetic engineering, cloning, or biotechnology as intrinsically wrong or always causing problems. I think the biotech revolution will make the computer revolution look like the hula hoop. Whether or not it's good or bad simply depends on the mindset with which it is deployed. If it's deployed with an industrial mindset, you can make animals suffer greatly.

► Bernard Rollin, Colorado State University

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One more point: Telos for me is not a hard and fast metaphysical category, because species change on a regular basis. It just gives us an idea of how to change individual sorts of animals. If it's a rabbit, it's going to want this and that. It's not in itself a fixed entity, as in the Bible or for Aristotle. If we insert a gene into a dog that gives it a great difficulty in breathing, as with the English Bulldog, we haven't hurt the dog-ness, we've hurt the individual. So, there is no such thing as "species integrity." Species are snapshots of a dynamic biological process. You can't argue species integrity without a strong theological base.

A QUESTION AND ANSWER PERIOD FOLLOWED DR. ROLLIN'S TALK

The first questioner pointed out that a lot of people are not satisfied with their lives or their jobs. If we could find a gene that changed the telos of these people so they would be happy with a job cleaning toilets, would that be acceptable? Dr. Rollin said no, it would not be. We have a nonnegotiable set of beliefs about what a human being is, he said. A human is rational and free. Our notion about what constitutes a cow is much more plastic.

Another participant said he was not convinced by Dr. Rollin's answer. The general public's view of a cow is not very plastic, he said. That's why the public balks at things like the blind hen. Dr. Rollin disagreed. He said a recent exposé about problems stemming from dog breeding did not result in any kind of public outcry. The participant said he thinks dogs are a special case. He said perhaps there are two different responses. One is to include a concept of animal nature into concepts of animal welfare. The other is to say that, in addition to animal welfare, we should consider dignity. Dr. Rollin said he thinks dignity is an ill-defined concept.

Another participant said he was interested in benchmarks of definitions for words like "distress," so we can use them as comparators. Dr. Rollin said the Animal Welfare Act requires the USDA to define distress, which they are now working to do. After the USDA defined "pain," he said, a vast literature on the subject was developed; he said the same thing is likely to happen once they define "distress."



Another participant talked about how philosophers dislike the concept of "naturalness." Look at what we've done to domestic animals, he said. In the show ring, we have fat little Herefords. By old standards, they would be grotesque. We have done a lot with conventional breeding, he said, with cattle, sheep, dogs, and so forth.

One participant then asked what the rule of thumb should be for deciding whether to change an animal's telos or simply to change the method of production so that we don't need to change the animal's telos. Dr. Rollin referred to the maxim, "Don't lower the river, raise the bridge." He suggested that it might be easier and wiser to simply go back to systems that are not so harsh rather than trying to adapt animals to fit the industrialized systems.

She then asked a second question: If you have a decerebrated chicken, is it OK to breed one that is just one big breast? If it does not matter to the animal, Dr. Rollin said, then yes. It is not really a chicken anyway. In fact, he said, why not just clone sides of beef, or make meat protein in fermentation vats?

Another participant asked Dr. Rollin if he could convince a rancher that it is OK to change a steer's telos as long as its interests were met. Dr. Rollin said he would need to argue that there was no other method for ensuring that the animal does not suffer. The participant said the rancher would respond that there is another method—just let them graze. Exactly, said Dr. Rollin. That's going to be a social decision, he said. Do people want cheaper meat at the expense of animal welfare? (He added that raising sows in group pens rather than individual stalls decreases the capitalization of the building by half. So, ensuring animal welfare may not be prohibitively expensive.) I don't know what the U.S. public would do, Dr. Rollin concluded, adding that nobody has asked the public, and they are too uninformed on these issues to even know they need to take a position.

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Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals

MICKEY GJERRIS, Ph.D. DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT, ROYAL VETERINARY AND AGRICULTURAL UNIVERSITY

Dr. Mickey Gjerris is Assistant Professor at the Danish Centre for Bioethics and Risk Assessment, which is part of the Danish Research Institute on Food Economics at the Royal Veterinary and Agricultural University in Denmark. Dr. Gjerris gave a presentation titled "Staying Good while Playing God," on European attitudes, concerns, and propsed policies regarding farm animal welfare and ethical issues. His paraphrased comments are as follows.

I want to note first that much of what I'm going to talk about is work that has been done in cooperation with Dr. Peter Sandøe, my colleague at the Danish Centre for Bioethics and Risk Assessment.

I'm going to talk today about public perceptions of biotechnology. Some of these views are not my views; they are the public's views. The question is, How do we stay good while "playing God?" Biotechnology raises serious concerns in the public eye.

I want to talk first about the role of ethics in the biotechnology debate. There are five aspects to it. First, ethics help to analyze and systematize the content of the ethical concerns raised in connection with biotechnology. If we can make a pig without a brain, some people will argue that we shouldn't play God. Then other people will argue that that's not a rational argument. Ethics tries to put words to these concerns, so we can have rational conversations rather than just yelling at each other. Second, ethics can help people discuss the relationship between ethical concerns and the wider societal and philosophical context that shapes them. You won't get far if you don't talk about where the various views come from. There's a serious lack of data in the ethical debate today. It's a political debate rather than a discussion. To have a dialogue, you have to know your opponent and how he or she was shaped. Third, ethics can evaluate the different aspects of biotechnology and their impact on society. The unforeseeable side effects of all technologies are usually the most important. When people invented the car, they quickly realized you could kill people by hitting them. But they didn't realize right away that burning fossil fuel killed people too. Ethics is a way to try to evaluate what will happen. Fourth, ethics reminds us that it (ethics) is something we all do-we shouldn't leave it to "professionals." And fifth, we have to be reminded that ethics is a lantern or a torch, not a hammer. It's a way of looking at life. It's not like plumbing. You don't just call an ethicist if you have a problem with your ethics. All ethicists have been asked to solve problems, but they can't really do that. Ethics is a way of highlighting a problem and a way of becoming aware of new problems.

Now let's look at European attitudes toward animal biotechnology. Since 1991, the Eurobarometer survey has examined the attitudes of the European public, including attitudes regarding biotechnology. The Eurobarometer is a survey of 1,000 people in each country. It shows in general that the European public makes balanced judgments on the use of biotechnology on animals. It shows that the public can and does differentiate between medical and agricultural applications of biotechnology. Also, it reveals that people do not become more positive toward biotechnology the more they know about it. That's contrary to common belief. But there is no empirical evidence that educating people about biotech will increase their acceptance of it. Education may help people make up their minds, but not necessarily in favor of it. The Eurobarometer also showed that the public has become slightly more positive toward biotech in the period between 1991 and 2002. Finally, the survey revealed that people are most skeptical about biotechnology as applied to animals and/or food production. They just don't like it.

Surveys have also asked respondents about which applications of biotechnology should be encouraged. This slide outlines the results of a 1998 survey. (See figure below.) In this poll, people seemed to favor most the application of genetic testing to detect inheritable diseases, and the introduction of human genes into bacteria to produce medicines or vaccines. Applications of biotechnology to food and animals did not fare as well in public opinion. Xenotransplantation was found to be the least-appealing option.

This next slide shows similar results from the Eurobarometer survey in 1999. (See figure next page.) The use of genetic engineering on crops and food, and the cloning of animals, all came out at the low end of public acceptance.

The most recent Eurobarometer survey showed the results by European country. These data reveal that public understanding does not equal public acceptance. In Southern Europe, for example, it's been shown that people don't know a lot about biotech. Nonetheless, the people in this region are more likely to support the use of biotechnology than those in the northern countries. It's like they are saying, "We don't know what it is, but let's have it!" So, there's no simple equation that says knowledge equals acceptance.

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SHOULD BIOTECHNOLOGY BE ENCOURAGED?

APPLICATION		<pre>"SHOULD BE ENCOURAGED" EU mean score (-2=low; +2=high)</pre>	
Using genetic testing to detect diseases we might inherit from our parents such as cystic fibrosis/muscoviscidosis/thalassaemia			
Introducing human genes into bacteria to produce medicines or vaccines, for example to produce insulin for diabetes			
Taking genes from plant species and transferring them into crop plants, to make them more resistant to insect pests –		Mean scores in the	
Developing genetically modified animals for laboratory research studies, such as a mouse that has genes which cause it to develop cancer	->> -0.07	judgement of to what extent different applications of aene	
Use modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change the taste Introducing human genes into animals to produce organs for human transplants, such as pigs for human heart transplants		technology should be encouraged in EU in 1996, Based on	
		Durant, J. et al (eds), 1998, p.234, 260	

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Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals

In the debate about the genetic engineering and cloning of animals in Europe, the focus quickly shifts to the consequences that could occur if and when the technology is used on humans. It's the slippery slope concern.

Mickey Gjerris, Royal Veterinary and Agricultural University

ATTITUDES TO 7 APPLICATIONS OF BIOTECHNOLOGY IN EU

(EUROBAROMETER, EB 52.1, 1999)

So, what are the ethical concerns about biotechnology? Drawing from the Eurobarometer survey and a qualitative interview study done in Denmark in 2000, as well as our own experience from years of working on these matters at the Danish Centre for Bioethics and Risk Assessment, I think the ethical concerns can be placed in four categories: Dangers to human health and environment; animal welfare; "other moral concerns;" and usefulness. The "other moral concerns" category includes everything besides health, environmental, and animal welfare issues, and is usually not regarded as scientific or even rational. It's the stuff you can't do empirical studies on—you can't measure or quantify it. It's interesting, too, that usefulness is a concern. People want to know why we are doing this and what the motivations are behind it.

In the debate about the genetic engineering and cloning of animals in Europe, the focus quickly shifts to the consequences that could occur if and when the technology is used on humans. It's the slippery slope concern. Also, the European public doesn't seem to consider genetic engineering or cloning of animals as special or different; rather, they lump these issues in general discussions about ethical limits to the human use of animals, and the relationship of humans and animals. Overall, the debate is growing, as the list of possible applications grows and thereby the need for guidelines and regulations increases. And now we are treating animals as "bioreactors," so it is becoming more obvious to people that we need to discuss these applications. Finally, the debate is characterized by a growing political understanding of the need for socially robust solutions, in light of the case of GM crops.

The EC has put out a draft project plan for looking at issues relating to farm animal cloning and public perceptions. It's being coordinated by my organization, the Danish Centre for Bioethics and Risk Assessment. What we are supposed to do is to stimulate informed public debate across Europe on farm animal cloning and ensure public participation in the forming of policies and regulation on a European level. We also are charged with making recommendations on European



regulation and on guidelines covering research on farm animal cloning and its subsequent applications. Deliverables from the project include a report on the state of the art and objectives of farm animal cloning science; reports on the legal and ethical aspects of farm animal cloning; a series of articles for leading newspapers and magazines to stimulate public debate; and a participatory conference and two workshops on different aspects of farm animal cloning, with high public involvement; and a set of recommendations on future guidelines and regulation. This work will be published on the internet as it is finished (www. bioethics.kvl.dk/cloninginpublic). Part of the idea is to make the public interact with scientists, to try to get away from the expert/public differentiation. Scientists are human too! And it's helpful if you can make them talk about their fears, desires, and so forth.

A side note: When I was a kid I was very fond of Elvis Presley. I had a poster of him that said, "500,000 people can't be wrong." Well, I suppose 6 billion flies can't be wrong either, right? Given what flies eat, I think we've got to be careful not to go along with the majority, just because it is the majority. Even though it is basic in every democratic society to regulate according to what society wants, we sometimes make decisions on behalf of people too. They may disagree and vote differently the next time, but dialogue is not about doing what the majority wants, but about arguing one's viewpoints in a civilized and respectful manner. Otherwise we will end up in a society dominated by the lowest common denominator instead of ideals. And who would want that?

So, I want to go back and get into more detail about two of the categories of ethical concerns that I mentioned earlier: "Other moral concerns" and "usefulness."

What are "other moral concerns"? These are complex questions about social justice, democracy, globalization, and law. It's about the "integrity" of the animals, and whether what we are doing is fair to the Third World. People want to know if it will increase the divide between peoples, or bring us together. It's about how to regulate this in a pluralistic society. How can you force people to live by an ethical standard that they don't share? Is there some sort of basic agreement in a society about what the rights and the wrongs are? In my country, we are 5.5 million people, and we have only about 100,000 immigrants. We are a very homogeneous society. Clearly, we have an easier time finding agreement among us than you do here in the U.S.

"Animal integrity" can be seen as a notion that tries to capture the general feeling of uneasiness that will not go away, even when a technology has been proven to be without risks and without welfare problems. Integrity may not really mean anything in itself, but it stands for something to the people who raise the issue. It means something to them. People get annoyed when they are told it doesn't mean anything. Now we have researchers creating a mouse with a human ear growing out of its back. [The ear was constructed by engrafting a scaffold structure onto the animal that was infiltrated by human skin tissue.] We are trying to make a substitute for humans. When you show people this, you get the "yuck" factor. It makes people sick. People feel that it's wrong. So they say we need to preserve the integrity of the mouse. I think it's based on our everyday common sense.

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"Animal integrity" can be seen as a notion that tries to capture the general feeling of uneasiness that will not go away, even when a technology has been proven to be without risks and without welfare problems. Integrity may not really mean anything in itself, but it stands for something to the people who raise the issue. It means something to them. People get annoyed when they are told it doesn't mean anything.

> Mickey Gjerris, Royal Veterinary and Agricultural University

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Une thing we should learn is that to introduce biotechnology on a large scale, socially robust limits must be placed on the use of the technology. We must ensure that public concerns are being heard. The principle of proportionality will perhaps not give scientists the freedom they want, but it will ensure that applications of animal biotechnology that stand up to public scrutiny are not discarded alongside with the unacceptable ones. That's what happened with GM crops

Mickey Gjerris,
 Royal Veterinary and
 Agricultural University

Take the example of the blind hens. These were not a result of genetic modification. They were from a strain that was bred normally. In Europe, it's hard to sell eggs from hens in battery cages to some segments of the population. They want "free-range" eggs. But chickens grown in free-range situations will peck at each other, and even cannibalize each other. So you have a lot of welfare problems with the production of free-range eggs. But if the chickens are blind, it works much better. They don't peck at each other. So, you can save animals' lives. A perfect solution, right? But these blind hens were never developed into a production strain because people were very uncomfortable with it.

I define "integrity" in terms of "familiarity" and "estrangement." I am familiar with this bottle of water. [Dr. Gjerris holds up a bottle of water.] There is nothing strange about it. It is known in its totality to me. By that I mean that I know what it is for and how it fits into a human context. By describing its usefulness to me, I have given a thorough description of it. There is nothing mysterious or unknown about it. There is no additional meaning to it than the meaning that humans have put into it. Ponder then another example: At weddings in my country, the groom has to stand up and talk about why he loves his wife. But of course that's impossible to do. You can't explain why you love someone. You can't put that into words very well, though you can say a lot of nice things about them. It's the same thing with animals. We can say that a cow produces milk or is used for meat or produces a nice leather hide. But there is more to a cow than that. Those sheep they are using in research in Scotland (for pharmaceutical protein production)-they are calling them "bioreactors." It's not a sheep anymore, it's a bioreactor! We know animals, but parts of them are also strangers to us. The more we disregard the things that aren't there for our sake, the more familiar they become to us and the more they lose their integrity. If you forget the alien part of them, and think we can know them totally, we give wrong descriptions of them and also even lose interest in them. We are familiar with animals, but they are also strange to us because there is more to them than we can know about them.

In Denmark we had a committee looking into how to regulate the cloning and genetic modification of animals. This committee made recommendations to the Danish parliament. The committee said, first, that the government should have specific legislation governing the cloning and genetic modification of animals. They also recommended that animal biotechnology only be allowed when it serves a substantial goal. Those goals include basic research, applied research for the improvement of health and the environment, the production and breeding of animals that produce compounds of substantial benefit to health or the environment, or for teaching at universities and the training of personnel. The committee also recommended that the "principle of proportionality" be employed. So, as a ground rule, it's wrong to do animal biotechnology. But if there's some substantial reason for you to do it and you can prove it to us, then you may be granted the ability to do it. So, these recommendations would create some very strong legislation. The concept behind it is different than allowing anything except what's specifically prohibited. It's a shift in the burden of proof. This could seem rather harsh. The question is how the term "substantial goal" will be interpreted. I'd say there's a 95 percent probability that this will be enacted into law. We are in the middle of an election, so it's not entirely clear. But it is very likely to be accepted.

So, how should we proceed? I'm not an extremist. I think there is value to biotechnology. I think part of my role as a human is to promote what I believe is right. So here's my idea. One thing we should learn is that to introduce biotechnology on a large scale, socially robust limits must be placed on the use of the technology. We must ensure that public concerns are being heard. The principle of proportionality will perhaps not give scientists the freedom they want, but it will ensure that applications of animal biotechnology that stand up to public scrutiny are not discarded alongside with the unacceptable ones. That's what happened with GM crops. You have to make people feel that you take them seriously, in order for them to take you seriously. GM crops were rejected in Europe partly because the ethical concerns of the general public were deemed irrelevant or less important. Maybe those who disagree with each other will never reach agreement, but it is helpful if the general public can feel they are being listened to.

IN THE QUESTION AND ANSWER PERIOD THAT FOLLOWED DR. GJERRIS'S TALK:

One participant asked if we have to take the public seriously when 75 percent of them say that the cloned sheep Dolly "violates God's will." Dr. Gjerris said yes, we do need to take them seriously, and, more important, we need to find out what they mean by that. Are they saying there ought to be limits on what humans should do? If they are fundamentalist Christians, Dr. Gjerris said, you cannot force them not to be fundamentalists. We can say that, unless you have a 51 percent majority, you cannot control policy. But perhaps we should regulate these animals in such a way that those people will not have to live in discord with their beliefs. We could label cloned meat, for example.

Another participant asked about the methodology that was used in the Danish qualitative study of public opinion. Dr. Gjerris said they used seven focus groups with 35 people in total, each in different locations and including a real diversity of people. The point of the study was not to make a large survey, he said, but to gather information that could be used to evaluate already-existing large surveys, such as the Eurobarometer. The most stunning thing about it, he added, was that nobody said they didn't like gene technology. They said they could see some uses for it. Dr. Gjerris noted that a similar but larger study was conducted in Britain. In the project now being done in the EU, they are holding workshops and small consensus conferences. They invite experts and ordinary people and make them discuss the problems and solutions and try to help them reach agreement.

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Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals One participant pointed out that polls in the U.S. have come up with similar data to those in the European studies. In a Gallup poll, she said, 64 percent of Americans said they thought it was wrong to clone animals. That percentage was higher than those who thought abortion was wrong. In a different study, 62 percent of respondents said they would be unlikely to buy food from cloned animals. In a Pew Initiative on Food and Biotechnology survey, she also noted, 6 out of 10 were comfortable eating food from GE plants, while only about 4 out of 10 were comfortable eating food from GE animals. So, she said, there is substantial discomfort in this country as well.

One workshop participant then asked Dr. Gjerris to elaborate on the point he closed with. We could come up with a lot of examples of ambiguity in moral and legal principles, the participant said. How far do you have to go to pin down definitions of terms? Is it okay to start with paradigm cases? Dr. Gjerris responded that ethics is not about rules. Its point is to make people take responsibility for what they do. The problem arises, he explained, when we move from the individual level to the society level. You open up a possibility for misuse if you have the people who make the legislation and then the people who interpret it do so in totally different ways. So, you have to be somewhat specific, but you have to have room for change in the future. In the proposed Danish regulation, Dr. Gjerris said, you could have said that applications that affect economic progress are good, because money and human health go hand in hand. So, he said, you have to go down one level in the definitions, but you probably cannot go too far. You have to find some middle ground.

Finally, one participant pointed out that cloning has been around for a long time. Two scientists, in fact, started cloning frogs in the 1940s. Dolly received attention simply because she was cloned from an adult animal cell. Dr. Gjerris agreed, but added that if you've been doing something wrong for a long time, that does not make it right. He said that Europeans are now looking at conventional farming and conventional breeding. The issues relating to cloning and biotechnology, he said, are opening their eyes about how we relate to nature, and part of the concern is not that we will change nature, but that we will be changed by changing it.



SECTION 3 DISCUSSIONS

THIS SECTION CONTAINS AN OVERVIEW OF THE IDEAS AND VIEWPOINTS DISCUSSED AMONG WORKSHOP PARTICIPANTS IN THE DAY AND A HALF THAT REMAINED AFTER THE PRESENTATIONS. These discussions took place in both full group and small work group settings.

In the first full-group discussion, numerous participants simply remarked about how interesting and eye-opening the presentations and initial discussions were, and how infrequently they had the opportunity to talk about these issues among a broad cross-section of experts. "As scientists," one person said, "it's important for us to hear about the religious and ethical issues. We aren't used to hearing those." A participant from a university added, "It's been very interesting for me-someone in academia-to hear more from the biotech companies. It's good for us to learn about this." "The opportunity to do the background reading and hear the speakers," a consumer group representative said, "was just terrific." Several people said the presentations made them realize that people with different backgrounds and expertise sometimes use terminology differently and often hold differing underlying assumptions and values, and that participants should be alert to this in the discussions that were to follow. One agency official noted that it was difficult to see how government could convene dialogues like this, so she hoped that organizations like the Pew Initiative would continue to be willing to sponsor them.

The substantive ideas that were raised in the ensuing workshop discussions are summarized below according to topic area. The four general categories of topics discussed were: specific moral and ethical concerns relating to transgenesis and cloning; a comparison of traditional breeding technologies to transgenesis and cloning; the concepts of species integrity and animal telos; and venues for making decisions regarding animal welfare and ethics.

MORAL AND ETHICAL CONCERNS REGARDING TRANSGENESIS AND CLONING

Early on, participants summed up what they saw to be the specific ethical and moral concerns regarding transgenesis and cloning. Some of the views expressed were held by participants themselves; others were views participants had heard in the presentations, in public opinion polls, or otherwise secondhand.

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"As scientists," one person said, "it's important for us to hear about the religious and ethical issues. We aren't used to hearing those."



For example, participants said some people clearly just feel there is something intrinsically immoral about the processes of transgenesis and cloning. They "just don't like it." They feel it is akin to "playing God." They may also feel that animal biotechnology negatively alters our view of our relationship to animals and to the natural world more broadly.

Regarding transgenesis specifically, some people believe we should not be altering animal biology in such a specific way. They raise the concern that manipulating DNA has the potential to violate an animal's fundamental nature. "An animal is a being or has a being," one person said, "and that animal's nature should be taken into account as we decide what we want to do with it." Transgenesis also may conflict with some people's religious beliefs regarding the crossing of species and the need to respect animals.

Others question the motives behind the need to genetically engineer animals. They wonder why it must be done, and whether it is simply so companies can increase profits and/or agricultural production. These individuals believe that GE animals should be created only if a compelling need exists, and we should not use animals in a purely instrumental way (i.e., simply for our own wants and needs) or for frivolous purposes. At the same time, some suggest it is unethical to stifle or stop a technology that has the potential to save human lives.

Other critics of animal biotechnology focus on the consequences of transgenesis and cloning. One participant said that one of the obvious ethical concerns is that transgenesis and cloning could result in undue pain and suffering for animals. For example, cloning, for the first generation anyway, requires animals to undergo invasive surgical procedures, and a high percentage of attempted clones are lost through miscarriage or early death. Also, some cloned animals have been shown to have significant developmental problems. One participant argued that it was important not to generalize about these problems, because transgenic catfish and carp have been developed without the use of invasive methods and they have not had any deformities, nor have their survival rates differed from their non-transgenic counterparts. Another potential consequence mentioned was that the genetic engineering of species that can escape into the wild could have detrimental impacts not just on individual animals, but on whole species and/or ecosystems.



In the process of summarizing the ethical and moral concerns, workshop participants also delved into why these concerns exist—what the reasons are behind them. Several people pointed out that the public does not understand the processes of transgenesis and cloning; these are very complex technologies that are difficult for the layperson to grasp. Because the technologies are complex, and also because they are new and unfamiliar, they make people uncomfortable. New technologies often meet with skepticism and resistance. ("When artificial insemination was introduced into the dairy industry after World War II," said one participant, "people thought it would be the demise of the species.") At the same time, it was noted that polls show that people who know something about biotechnology are not necessarily more accepting of it.

Others said that some of the concerns can also be explained by the fact that the general public still does not understand much about the breeding techniques that have been used for years in conventional agriculture. If people used the right comparators, it was said, they would see that transgenesis and cloning are just the next steps in the continuum of reproductive technologies. Also, people do not understand how animals are treated in conventional production agriculture, and if they did, they would see that animals used in agricultural biotech research are treated the same as or better than those in conventional agriculture. As one person put it, "The range of possible harms to animals due to human intervention is almost endless, and biotechnology does not increase that in any material way." Another person noted that the kinds of questions being raised about animal biotechnology-the framework being used to assess it-were not that different than those raised about industrial animal agriculture in general. "The ethical litmus test is," one person said, "are we reducing animal suffering and pain? Are we providing the animal with the freedoms it needs?"

Some of the concerns about animal biotechnology may also stem from the fact that biotechnology allows scientists to do things that they have not been able to do before, and to accomplish them faster. One participant questioned whether the development of the technology is outpacing the development of normative ethical behaviors regarding its use. "Has the right groundwork been laid?" he asked. "Have the right kinds of discussions taken place that would establish normative behaviors against which you could then gauge immoral or unethical behavior?" A related point that some raised is that we have no public forum in the U.S. for discussing and addressing these concerns. Also, we live in a multi-ethnic, multi-religious society, and we have no way to reconcile our diverse ethical viewpoints. Thus the concerns escalate rather than being discussed and handled. Finally, one person said he felt some of the concerns were due to the fact that the science of genomics has shown us that we are not as different from animals as we have thought in the past. Perhaps the knowledge of that, he said, simply makes us uncomfortable.

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COMPARISON OF TRADITIONAL BREEDING TECHNOLOGIES TO TRANSGENESIS AND CLONING

On the second day, participants discussed whether transgenesis and cloning are significantly different than other modern breeding technologies used in agriculture. Most people seemed to agree that there are both similarities and differences. Transgenesis is unique, some participants said, because it allows genes from any source to be put into an animal, so the range of possible changes to an animal and the possible products resulting from those changes is much greater (e.g., spider silk proteins produced in goat's milk). Also, transgenesis increases the efficiency and speed of the selection of traits. It is a way of selectively manipulating one small aspect of the genome. It is also seen by some as involving higher risks than traditional breeding. "If you have a more powerful bag of tools," said one participant, "you can extrapolate that you will create more powerful problems."

Likewise cloning is unique, some participants said, because it involves more interventions such as C-sections and embryo transfer and currently creates more adverse effects, such as aborted fetuses. There is also greater predictability regarding the characteristics of the animal created than with conventional breeding.

At the same time, participants said, transgenesis and cloning are not that different from current technologies, but in fact are just the next step on the continuum of existing breeding technologies. "We created our domestic species using traditional animal breeding," said one participant. "Most of those species do not exist in the wild. So, I don't see what makes biotech unique and different from what we've always done." Others agreed, saying too that the risks involved in transgenesis and cloning are not of a different kind than those found in other assisted reproduction technologies. Some of the changes achieved through transgenesis might be achieved through traditional breeding and natural mutations. And the latter can happen quickly as well, so the pace of change also is not that different. "Is it morally right to change a pig by conventional means but not through biotechnology?" one participant asked. "It's the same thing."

The pace of change later became a key point of discussion. Participants expressed differing views on whether the pace of change made possible by transgenesis and cloning raises ethical concerns in and of itself. Some said the speed of change is not an issue in the context of determining the ethical nature or morality of the process. The fact that you could accomplish something over generations or over a single event is not relevant, they argued. Rather, it is the nature of the change, and the results of it, that are important. Others disagreed, saying that speed does have the potential to raise moral and ethical issues. Traditional husbandry practices changed things slowly, they said, while with biotechnology, things change quickly. A process could be well along before a mistake or a harm to an animal is identified and could be remedied.

But another person pointed out that while the number of generations it takes to see a trait expressed may be faster using transgenesis and cloning, the time to market may not be different than with conventional breeding techniques. Animals produced via transgenesis and cloning still require years of research and development before they become marketable.

This led to some further discussion about whether the processes of biotechnology are of particular ethical concern, or whether we should be judging only the outcomes or products of that technology. At present we are using "process" as a filter through which to assess activities that is, anything produced using transgenesis or cloning gets a more careful look than animals produced via traditional techniques. Some participants said it is unnecessary and unfair to single out biotechnology for greater scrutiny. Others said it may be unnecessary but is not necessarily unfair. "If the only way to get legitimate ethical issues discussed is to exploit a false concern," one participant said, "I think it's perfectly acceptable to do that." Others said it was simply difficult to determine what other filter would be more appropriate.

THE CONCEPTS OF SPECIES INTEGRITY AND ANIMAL TELOS

Participants also discussed on the second day whether transgenesis can adversely affect the "integrity" of a species. Several voiced the idea that "species" is a human construct, borne out of a human desire to categorize things and to define ourselves in relation to others. Some felt, therefore, that the concept of "species integrity" is meaningless. Others said that while the concept may not have a strong scientific basis, it may provide a way to discuss and assess when and if transgenesis has gone "too far" in changing an animal.

In assessing whether biotechnology has gone too far, one participant said, genotypic and phenotypic changes must be considered, and the phenotypic ones are perhaps more important. "If it looks like a duck and walks like a duck and quacks like a duck," he said, "it is a duck... even if it carries a transgene." Another said it is difficult to define when biotech has gone too far, but, to paraphrase what Supreme Court Justice Potter Stewart famously said about pornography, "we'll know it when we see it." It was pointed out that animals recognize their own kind in the wild, and that transgenesis has probably gone too far if animals do not recognize their genetically engineered cousins. Also, participants indicated that there was more concern about preserving the integrity of wild animal species than that of farm animals. It was pointed out that cross-breeding and hybridization do occur in the wild, but that the resulting animals are generally sterile.

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"We go forward without having a public dialogue on ethical issues at our peril and at the peril of the technology."



This conversation led to a discussion of animal "telos," a concept used by Dr. Bernie Rollin in his talk and in his writings on the subject. The term was adopted from Aristotle and refers to an animal's fundamental nature. The question is, is it ethically acceptable to change the telos of an animal through transgenesis? (An example would be to create chickens that have a high tolerance for living in small cages.) Rollin and others believe it is important that we respect the telos of an animal—that we meet the needs that matter to the animal—but that it is ethically acceptable to change an animal's telos so long as we meet the new needs of that animal and the changes do not cause suffering. Others said that if biotechnology changes an animal's telos, that may be an indication that we have gone too far in changing that animal.

DECISION-MAKING ABOUT ANIMAL WELFARE AND ETHICAL ISSUES

On the final day of the workshop, participants talked about how ethical and moral concerns relating to animal biotechnology can be best addressed and considered in the United States, given that the regulatory system focuses on science-based questions relating to health and safety.

Participants first discussed why ethical and moral issues need to be addressed at all, particularly by the general public. One response was that companies will need broad public acceptance of the products of animal biotechnology in order to sell those products and recoup their R&D investments. Also, a lack of public understanding and acceptance could have implications beyond just the food system; it could affect the public's view regarding the development of human drugs through biotechnology and the science of genomics as a whole. One person said, too, that the presentations and discussions during this workshop revealed clearly that more dialogue is necessary—that it would be useful for all parties to listen to and learn more about each others' views.

It was also pointed out, however, that the public's lack of understanding of the technology—and of ethical frameworks—makes their participation in any dialogue problematic. Several participants pointed to polls that reveal that the public does not understand that all food contains DNA and that the fruits and vegetables they eat are hybrid varieties. Also, one participant said, "There are many people who don't even know what their own religious traditions teach and believe about our proper relationship to animals." Others argued that the public has a right to be involved in an open dialogue about this technology and what is being done with it, no matter how difficult such dialogue would be. One participant put it this way: "We go forward without having a public dialogue on ethical issues at our peril and at the peril of the technology." It was suggested by several participants that knowledge about ethical issues relating to animal welfare must be better emphasized in the schools. Agriculture students and animal science students must study ethics and animal welfare issues in college, they said, and they must recognize that science is not value-free.

Participants talked about how ethical and moral considerations are sometimes addressed in existing forums such as Institutional Animal Care and Use Committees (IACUCs). Companies and universities that use laboratory animals in research must set up an IACUC to oversee and evaluate the organizations' animal care and use program, and these committees must have a minimum of one member not affiliated with the institution. This member might be someone from the Humane Society, for instance, or from a patient advocacy organization. IACUCs can potentially address ethical and moral issues relating to the use of animals in research. Other existing decision-making forums where ethical issues may be taken up include within private companies and universities as they make decisions about what research to pursue and how to conduct it; within companies' scientific advisory committees; at the National Institutes of Health, in the course of its grant-making process; and at the grassroots level in local communities.

Workshop participants discussed a number of options for how ethical and moral issues for transgenic and cloned animals could be more openly and comprehensively addressed in the future. Many agreed that there should be a place to talk about ethical issues that is separate from any discussion about the safety of the technology. One idea was to strengthen the role of IACUCs in taking on ethical and moral issues. It was suggested, for example, that the many IACUCs come together and standardize the norms being used to assess animal welfare and ethical issues, and to develop overarching principles or guidelines that would hold researchers at universities and companies to higher standards of animal care. Also, individual IACUCs could each hold a meeting once a year to look at "bigger picture" issues, including ethical concerns.

Some felt that more also needs to be done to educate and listen to the public regarding the ethics of animal biotechnology. Because IACUCs and scientific advisory boards are controlled by the institutions they serve, it was argued, a neutral, impartial forum should be established in which the public can play an active and participatory role. Such a forum could develop broad principles (not regulations or strict guide-lines) that could then be used by researchers and companies to help them make ethically appropriate decisions. The United Kingdom's Banner Commission and various presidentially appointed commissions in the United States were mentioned as appropriate models for such a forum. It could be sponsored by a government body, or by a private foundation or professional association.

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Several other ideas were raised as ways to strengthen decision-making and dialogue around ethical issues. One is for companies to follow the example of Hematech, Dr. Robl's biotech firm, in their efforts to keep the public informed about their work and their effective use of their IACUC. Another idea is to undertake a type of public cost-benefit analysis, to enable people to discuss their views on the costs and benefits of transgenesis and cloning. A third idea is for biotech-related scientific societies to do as the Association for the Study of Animal Behavior has done: They drew up ethical guidelines for research into animal behavior, and they require that studies published in their scientific journal meet those ethical guidelines. Another option is to create a USDA regional coordinating committee on ethical issues. A committee on animal bioethics already exists, but it does not include biotech scientists. The USDA lacks sufficient funding to support these committees, however, so the creation of one would require significant encouragement and support from industry groups and others.

Finally, it was noted that it is simply incumbent on all participants—no matter the forum used—to communicate their ethical concerns clearly and comprehensively, provide as clear a factual basis as possible, and engage in discourse with other interested parties.

SECTION 4 CONCLUSION

THIS WORKSHOP OFFERED A RARE OPPORTUNITY for ethicists, biotech developers, individuals from the food and agriculture industries, animal and consumer advocates, and government officials to engage in a wide-ranging discussion of the ethical and moral questions associated with transgenesis and cloning as applied to animals. Workshop participants explored their respective views and attempted to interpret the variety of views of the U.S. public expressed in several polls on the subject. During the discussions, it became clear that the moral and ethical framework used to evaluate transgenesis and cloning is essentially the same as the framework used to evaluate other modern agricultural breeding technologies. Also, there do seem to be ethical issues relating to animal biotechnology that go beyond health and welfare and that require further consideration and dialogue. It is hoped that this report will help to foster that dialogue among a wider audience, so that discussions of these important issues will continue into the future. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY

APPENDIX A PRESENTERS' BIOGRAPHIES

HAROLD COWARD, Ph.D., FRSC

Harold Coward is Professor of History and Founding Director of the Centre for Studies in Religion and Society at the University of Victoria. He was named President of Academy II of the Royal Society of Canada for a twoyear term commencing November 2004. Dr. Coward has conducted research in Indian philosophy and religion, psychology of religion, and comparative religion. For the past 22 years he has directed interdisciplinary research centers where he pioneered bringing together the best knowledge of science, social science, and the humanities in response to major challenges facing the world. Dr. Coward has authored or coauthored 17 books, edited 33 books, and published 76 journal articles and 57 chapters in books. Dr. Coward received his Ph.D. in Religious Studies from McMaster University.

CHESTER GIPSON, Ph.D.

Chester Gipson is Deputy Administrator of Animal Care at the Animal and Plant Health Inspection Service at the U.S. Department of Agriculture. In that role, Dr. Gipson works with animal industry and animal interest groups and is responsible for the enforcement of the Animal Welfare Act. He also oversees the activities of Animal Care Headquarters in Riverdale, Maryland; the Eastern Regional Office in Raleigh, North Carolina; and the Western Regional Office in Fort Collins, Colorado. Dr. Gipson's career with the USDA has spanned more than 20 years in a variety of positions. Dr. Gipson holds a Ph.D. in Veterinary Medicine from Tuskegee University, a Master of Agriculture (Physiology) from the University of Florida, and a B.S. in Animal Science and Biology from Florida A&M University.

MICKEY GJERRIS, Ph.D.

Mickey Gjerris is Assistant Professor at the Danish Centre for Bioethics and Risk Assessment. His work centers on ethical and religious issues within biotechnology. He has edited two books on ethical and religious philosophical issues, has written numerous articles on the same subjects, and is co-founder of the Forum for Existence and Science at the University of Copenhagen. As a Ph.D. candidate he arranged two research conferences and has a wide experience in communicating biotechnological and bioethical issues to the public. Dr. Gjerris holds a Ph.D. in bioethics from the University in Copenhagen and an M.A. in Theology.

JAMES ROBL, Ph.D.

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