Options for Future Discussions
on Genetically Modified and Cloned Animals

Proceedings from a workshop sponsored by the Pew Initiative on Food and Biotechnology and Michigan State University and including the paper...

Engineering Animals: Ethical Issues and Deliberative Institutions

Prepared for the Pew Initiative on Food and Biotechnology by Sheila Jasanoff and Stefan Sperling (with Sang-Hyun Kim)

Pew Initiative on
Food and Biotechnology

MICHIGAN STATE
UNIVERSITY

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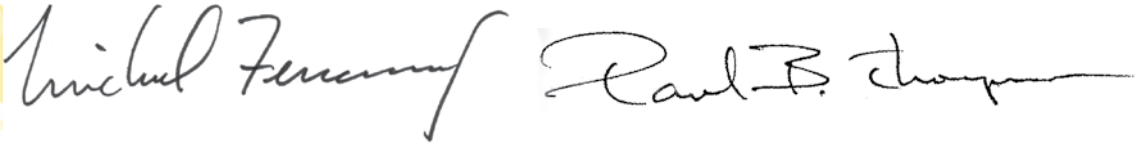
Preface

Public discussions about cloned or genetically engineered food animals have largely focused on questions about the regulatory authorities that may govern such animals. Of importance to many observers, however, are ethical issues which cannot be addressed fully at scientific conferences or during regulatory discussions. In its 2005 poll, Pew Initiative on Food and Biotechnology (PIFB) found that 53% of Americans strongly favored including ethical and moral considerations in making regulatory decisions about cloned or GM animals. At PIFB's workshop in January 2005, "Exploring the Moral and Ethical Aspects of Genetically Engineered and Cloned Animals" many participants indicated a need for additional discussions about ethics and animal biotechnology, but no institution in the U.S. appeared ready to address all the issues involved. For this reason, PIFB partnered with Michigan State University on two meetings: a one-day symposium, "Animal Biotechnology: Considering Ethical Issues,"[1] which provided an overview of the general ethical issues involved with food animal biotechnology; and a two-day workshop among experts who came together to discuss institutional options for addressing, in the future, the moral and ethical issues relating to genetically engineered or cloned animals. Attendees included representatives from the food, agricultural, and biotechnology industries, public interest groups, and academics in ethics, biology, and law. This document summarizes in brief the options discussed at the workshop.

Michigan State University saw the opportunity to work with the Pew Initiative on this project as a form of engaged scholarship in a domain that has been neglected by agriculture and food research in the past. MSU's partnership in this project is a component of an ongoing effort to re-envision the land-grant university mission under the banner of "Boldness By Design."

The Pew Initiative also commissioned a paper from Dr. Sheila Jasanoff and her colleagues at Harvard University on deliberative institutions available for discussion of the ethics of animal biotechnology. This paper was made available to workshop participants prior to the workshop and served as a basis for discussions.

We are grateful to the steering committee members for all the thought and work that went into organizing this workshop.



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1 See http://pewagbiotech.org/events/1018

Introduction

The existing laws proposed for regulating food animal biotechnology require regulators to review genetically modified animals using scientific risk assessment protocols; they do not make provisions for regulators to take ethical or moral issues into consideration in decision making. Many observers feel that the ethical and moral issues must be addressed, however—and ideally in an open, public forum or forums—since these issues are of importance to consumers. To discuss how ethical and moral issues relating to genetically engineered or cloned food animals could be addressed in the future, Pew Initiative on Food and Biotechnology[2] and Michigan State University[3] co-sponsored a two-day workshop among diverse experts.

The 35 workshop participants included representatives from federal agencies, biotech companies, food retailing companies, consumer groups, animal welfare organizations, agricultural groups, non-U.S. regulatory agenices, and universities. The workshop was held in October 2006 at the offices of The Pew Charitable Trusts in Washington, DC.

The workshop was designed as "a conversation about future conversations" about ethical and moral issues relating to genetically engineered or cloned food animals. The agenda sought to focus on *how* and *in what form should/could* such discussions continue. It was less focused on *what* should be addressed in those future conversations. The scope of discussion was limited to include food animals and food fish that are genetically engineered or cloned for food production, pharmaceutical or industrial protein production, or xenotransplantation.

Workshop organizers did not expect participants to reach consensus, given the diverse array of viewpoints present in the room, the limited time available, and the complexity of the issues. Instead, the organizers proposed the following objectives and desired outcomes:

- Explore the value/necessity and challenges of considering ethical and moral questions concerning genetically engineered and cloned food animals and developing public policy on issues with scientific and societal dimensions.
- Explore the institutional and informal approaches for considering ethical and moral questions concerning genetically engineered animals and animal clones.
- Identify the pros and cons of the potential approaches.
- Explore and understand the different views of workshop participants.
- Explore the expectations and role of government and others.
- Identify the critical factors in selecting approaches.
- Learn from each other.

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2 The Pew Initiative on Food and Biotechnology serves as an independent and objective source of information on agricultural biotechnology for the public, the media, and policymakers. Funded through a grant from The Pew Charitable Trusts to the University of Richmond, the Initiative produces reports and sponsors workshops and conferences to showcase diverse points of view on agricultural biotechnology.

3 As a respected research and teaching university, Michigan State University is committed to intellectual leadership and to excellence in both developing new knowledge and conveying that knowledge to its students and to the public. And as a pioneer land-grant institution, MSU strives to discover practical uses for theoretical knowledge, and to speed the diffusion of information to residents of the state, the nation, and the world. In fostering both research and its application, this university will continue to be a catalyst for positive intellectual, social, and technological change.

This document summarizes the workshop discussions in brief. It first covers the main issues raised during an opening panel discussion. It then includes a paraphrased summary of a presentation by Dr. Sheila Jasanoff of Harvard University, which was given to complement a paper she and her colleagues had prepared in advance for participants (see page 27 for the paper). The third section describes the primary institutional options mentioned by the group for taking up ethical and moral issues relating to genetically engineered or cloned animals in the future.

SECTION 1

Discussion of Challenges and Opportunities

THE WORKSHOP OPENED with seven panelists discussing briefly the challenges and opportunities involved in having conversations about the ethical and moral aspects of genetically engineered or cloned food animals. The seven panelists included Autumn Fiester, University of Pennsylvania; Carol Tucker Foreman, Consumer Federation of America; John Matheson, Food and Drug Administration (FDA); Mimi Riley, University of Virginia; Andrew Rowan, Humane Society of the United States; Ron Stotish, AquaBounty; and Leah Wilkinson, National Cattlemen's Beef Association. The key points they raised, along with points raised by other participants in a group discussion following the panelists' opening remarks, are summarized in this section.

The challenges of addressing ethical issues were discussed first. One primary challenge, according to several participants, is that the mandate of FDA is purely science-based. FDA is charged with implementing the Federal Food, Drug, and Cosmetics Act (FFDCA), which does not address issues such as consumer choice, right-to-know, values, beliefs, or religious preferences. While most see this as a key strength of the regulatory system, it also means that ethical and moral issues cannot be considered by FDA in the context of making regulatory decisions about whether to allow the marketing of the products of animal biotechnology. In particular, FDA cannot address any ethical questions regarding whether a given technology should be commercialized or not; their decision is based solely on whether a product meets the FFDCA's standards.

Another general challenge mentioned was the widely diverging views and values held by interested parties. Disagreements exist about what even constitutes an "ethical issue," as well as about how to weigh those issues once they are on the table. For example, some people believe that risk assessments are intrinsically value-laden, while others do not. Participants said the issues regarding cloning and genetically engineered food animals have become more politicized and polarized in recent years.

Several people said it would be a challenge to get a comprehensive set of interests represented at the table during any conversation about the ethics of genetically engineered or cloned food animals. It was also suggested that some key parties were missing from the workshop discussion, such as specific religious interests.

The sheer challenge of discussing ethical issues was also mentioned. Ethical discussions can involve complex topics, such as "the culture divide," "the fear of the monstrous," and "the commodification of nature." The difficulty of having experts "talk past each other" was also mentioned as a perennial problem. There's an inherent tension between ethics and regulation, because ethics is about questions, not answers, while regulation is about answers, not questions. Furthermore, some regulatory agencies operate under statutorily imposed deadlines, whereas ethical discussions—which often take a long time due to their complexity—may not finish until after regulatory decisions are made.

Another challenge mentioned was the difficulty in deciding what would be included or excluded from discussions. Some of the ethical issues that arise in relation to genetically engineered or cloned food animals are not specific to the field of animal biotechnology, but rather have their basis

in public concerns about industrial agriculture. It will also be demanding to keep future discussions focused on the application of biotechnology in animal agriculture and the food system and avoid a focus largely on research bioethics, where much past work has already been done.

Despite all of the challenges mentioned, a number of participants also saw opportunities for taking up ethical issues relating to genetically engineered or cloned food animals. Some participants felt the timing is right to have such discussions, because no cloned or transgenic animals are yet on the market. Looking at and addressing the range of concerns the public might raise about such animals, prior to commercialization of products from them, might ensure public acceptance of the products once they do come to market. Another opportunity mentioned was that the public seems to be increasingly concerned about the safety of the food supply and might welcome discussions on ethical issues relating to the food system. It was suggested that such a conversation could be framed in the context of sustainability or stewardship through a product's lifecycle, which is a concept of increasing importance to food companies.

The panelists were also asked if there was a strong need for new ethical discussions relating to genetically engineered or cloned food animals. Most of the panelists seemed to agree there was such a need. They pointed out that while some existing bodies address ethics with regard to laboratory animals, no institution addresses these issues with regard to food animals. Furthermore, no institution is currently able to comprehensively address what technologies should or should not be pursued, which some panelists felt would be important for increasing public trust in the food supply and the technology.

In addition to new discussions, several participants pointed out that, at present, ethical discussions are taking place particularly within biotech companies and universities and within the agriculture industry.

Finally, participants cautioned that although additional ethical discussions may be worthwhile, strongly held diverse views are unlikely ever to converge, and decisions will continue to be made through representative democracy.

SECTION 2

Presentation by Sheila Jasanoff, Ph.D.

DR. SHEILA JASANOFF gave a presentation to workshop participants on the role of deliberative institutions in addressing ethical issues raised by animal biotechnology. Dr. Jasanoff is Pforzheimer Professor of Science and Technology Studies at the John F. Kennedy School of Government at Harvard University. Dr. Jasanoff's presentation summarized the paper she and her colleagues wrote for the Pew Initiative, which was made available to participants before the workshop.[4] The following is a paraphrased summary of her talk.

The Pew Initiative was quite clear that we should look at the ways institutions take up the problem of deliberation. That has been a tacit theme in this morning's discussion as well. Deliberation happens inside formal institutions, or informal ones, so you have to think about what those institutions are.

The first point I wanted to make, which is not actually in the paper, is that while we may be talking about biotechnology today—and a slim aspect of biotechnology at that—there's a much broader discussion going on in society about three things. The first is democracy and the nature of democracy in a globalizing, increasingly complex world. We are much more confronted today with the need to be together in the same room with other cultures than we have been in the past. At the same time we are confronted by the conception that our institutions are no longer quite coping with all the dimensions of democracy. There's a tag phrase that has crept into many democratic discussions—"the democratic deficit." It refers to the fact that, in many established democratic nations, many people are questioning whether the institutions are functioning well or not. So, people are worried about democratic institutions in general.

The second background issue is that people are worried about technology in general, even as they see the promise of it. The promise and the fear are correlative. And the feelings are not the same for all technologies. Most people like mobile phones, but not nuclear power plants. Most people have ambivalent reactions to biotechnology, writ large. But they worry generally about technologies and what they do in our lives, how they are regulated, and how democratic institutions that were set up two hundred years ago are coping with them. So, that is another set of concerns.

The third ingredient is one that hasn't been talked about much, and that is the place of the citizen against this backdrop of general worries about democracy and technology. Our governing institutions have developed a general worry about us as citizens, and whether we are capable of understanding the challenges of governing ourselves, and of understanding technology. So, people are worried about institutions, even as institutions are worried about people. The form this takes is a desire to educate people about technology, because it is believed that they don't know enough to make sense of technologically based products and developments. As we have seen, FDA and others have this idea of informing the public as a very important part of what they do. This feeling is often called the "the deficit model of the public," and it's the correlative to the democratic deficit. So, that's another important background factor to keep in mind.

As I was contemplating how to write this report, it became clear that we could not compare institutions without a matrix of outputs against which to evaluate them. After all, how do you judge whether the Environmental Protection Agency is doing better or worse than the Humane Society? There has to be some sort of criteria. Thus the issues that hang people up—namely, the actual ethical issues and concerns relating

4 See page 27.

to animal biotechnology—had to come into the analysis in some way. That is what accounts for the first part of the paper. We had to create a map of the kinds of issues that an institution might be able to take on board. Without that, we couldn't evaluate whether institutions are addressing them or not. So the first part of the paper was meant to be a general, conceptual map that summarizes the ethical debates. It is not meant to be an exhaustive list of all the concerns ever expressed, but I think it is basically an accurate summary.

In producing that map, it became clear there is good news and bad news. The good news is that lots of people think they are "in the deliberative game" with regard to ethics and animal biotechnology. People do care about it. Wherever we turn, lots of institutions have taken on animal biotechnology and ethics issues in some way, even if it is not directly in their mandate. NGOs and governmental organizations seem to think they should address these sorts of issues. The bad news is that people are not talking about the same things, they are not talking to each other, and no one is taking on all of the issues. So, at the institutional level, the news is not wholly encouraging.

Let's look at Table 1, which summarizes what we found about the structure and mandates of deliberative institutions. The first column contains the various institutional types. We began with the most formal, national, and representative bodies and worked our way down. We then identified one representative institution of each type. This was difficult to do, and it certainly does not result in an encyclopedia of different institutions. But it does result in a list of significant and major examples of each type.

In this study, we looked at the U.S., the United Kingdom, and Canada. At the most democratic level, if you will, is Congress and Parliament. The representative institution we analyzed at that level was the now-defunct Office of Technology Assessment. The next level includes national commissions, and there we looked at two recent presidential ethics commissions. At the executive branch level, we looked at U.S. and Canadian examples of advisory committees. For courts, we compared the U.S. and Canada, which was interesting because they have essentially the same laws but have had different resulting legal decisions. We next looked at independent professional organizations—specifically, the National Academies of Science in the U.S. and the Nuffield Council in Britain. In the academic world, we looked at institutional review board (IRB) mechanisms. And finally we looked at two types of nongovernmental organizations (NGOs)—those based inside industry and those outside of industry.

TABLE 1

Structure and Mandates of Deliberative Institutions

(United States, UK, Canada)

	Authorization	Organization	Objectives	Products
Legislative advisory body (OTA)	National law	Political governing board; independent expert staff	Weigh policy alternatives; inform Congress of options	Reports, background papers
National Ethics Commissions (NBAC, PCB)	Presidential order	Appointed experts and stakeholders	Conduct ethical assessments	Reports, meetings and transcripts
Executive agency/ advisory committee (ELSI, GE3LS, CCAC)	National law or policy; agency decision	Appointed experts and stakeholders	Review state of science and ethics; commission research	Guidelines, regulations, consensus exercises
Court	Constitution	Appointed judiciary	Interpret the law	Judicial decisions
Independent professional organization (NAS/NRC; Nuffield)	Public charter or not-for-profit trust	Membership by invitation	Offer impartial, high-quality information and advice	Reports, recommendations
University committee, IRB	Research policy or law	Disciplinary scientists, lay experts	Review merits of research proposals	Decisions to approve, deny, modify
Industry non-governmental organization (BIO)	Voluntary	Selected experts	Identify and advocate for industry positions	Reports, educational materials
Non-industry non-governmental organization (NEAVS, Uncage)	Voluntary	Membership organization	Represent and advocate for pro-animal interests	Campaigns, educational and promotional publications

We felt it was important to think about the relationship between these deliberative forums and decision-making mechanisms. When FDA makes a decision, for example, things happen. In other institutions, that is not the case. So, we looked at the source of authority for each of these types of bodies. As we move down the chart from national bodies to NGOs, the source of authority moves from specific, well-organized, and formal to voluntary and informal. So, there are very different levels of authority. Keep in mind, by the way, that a legislative advisory body is not necessarily more democratic than a public interest group. Truly democratic institutions can take a variety of forms and can be formal or informal.

We also looked at the different managerial organizations of each type of institution. The role of expertise turned out to be an important dimension of difference. We asked, to what extent are these bodies relying on experts to determine how values get taken into account into decision making? I've done a lot of work on risk assessment. Risk assessment is a value-laden exercise; there is empirical evidence to show that. What was interesting here was to discover whether risk discussions were deemed as debates by experts (whether laden with values explicitly or not), or whether they were seen as something everyone has a right to talk about in whatever language they feel is suitable. Expertise is a mediating presence in institutions, and institutions vary in how they use it.

The objectives of each institution vary as well. The key is the link to policy. Do people in these institutions just talk in a vacuum, or do decision makers have to take their views into account? For example, if it's an agency, does it have to obey the Administrative Procedures Act and actually respond to the recommendations of its advisory body?

And finally, the work products of these institutions are important. Most organizations produce formal reports and work products. The less formal institutions may use other means. These latter institutions are often explicitly in the business of trying to change people's minds, by whatever means is effective. I was interested to hear someone this morning mention the idea of molding people's opinions via slogans on T-shirts. T-shirts would not work as an argumentative strategy within the World Trade Organization. Only some groups are "allowed" to use T-shirts as a mind-changing, deliberative device, though such a device can be effective.

Now, let's look at Table 2. Admittedly, digitizing data as we have done here is a crude way to capture a complex set of issues. But we couldn't evaluate institutional performance without attempting something

TABLE 2

Deliberative Institutions and Ethical Frames
(United States, UK, Canada)

Ethical Frame / Type of Institution	Animal Welfare		Risk		Moral Order	
	Pain and Suffering	Costs/ Benefits	Risks to Health	Risks to Environment	Mechanization	Unnatural Creation
Legislative advisory body		X	X	X		
National ethics commission	X	?	X	X	X	X
Executive agency/ advisory committee	X	X	X	X		
Court			X	X	X	?
Independent science organization: NAS	X	X	X	X		
Independent ethics organization: Nuffield Council	X	?	X	X	X	X
University committee, IRB	X	X (in science)	X	X		
Industry non-governmental organization	X	X (mainly benefits)	X	X		
Non-industry non-governmental organization	X	X	X	X	X	X

like this. The types of organizations in the left column are the same as in Table 1. Across the top we have types of issues addressed, categorized generally into animal welfare issues, risk issues, and "moral order" issues. The "Xs" in the table mean that in those bodies those issues arise and are addressed in a way worthy of mention.

It is possible to discern some broad patterns from this table. One that is interesting is that the moral order issues—things like how animals fit into the ways of life that we value—come up very unevenly across institutions. The non-industry NGOs most often raise the largest spectrum of concerns, including all of the moral order concerns. This cannot be said of industry NGOs, and we have an explanation for why this is so. Industry NGOs tend to view technology developments as natural extensions of things humans have already been doing. If you believe we've been doing something for years and now we are only using different means, then by definition you don't address the moral order questions, because you think they have been answered in advance. The non-industry NGOs, by contrast, want to see a sharper break. They see a new set of issues arising due to what they view as a radical differentiation between the new technology and the old. So, I think that's why there are Xs in the moral order category for the non-industry NGOs but not the industry NGOs.

Notice too, however, that legislative advisory bodies, executive agencies, independent science organizations, and university IRBs are not considering the moral order questions either. The explanation there is a little different, and I'll talk more about that in a moment.

I wanted to point first to the case studies we included in the paper (these case studies can be found starting on page 27). The institutions that Pew and we gravitated toward were those in English-speaking, common-law countries. But because I worked on this paper with colleagues from Germany and South Korea—and because Germany represents a civil law tradition and South Korea is a rising economic power—it seemed logical to look at Germany and South Korea as comparative case examples.

In those short case studies, we sought to describe the politics of animal bioethics and biotechnology in those countries. In Germany there is an effort to bring animals clearly and explicitly into the same moral order as humans. In South Korea, by contrast, the discussions are very issue-specific; they are driven by international debate about the eating of dog meat. Germany's legal basis is the constitution, so the animal ethics debate there involves constitutional politics. In fact, Germany has become one of the few constitutional democracies in Europe that has put an obligation toward animals into the constitution. In South Korea, as for us here in the U.S., the issues remain largely statutory.

In terms of deliberative style, the Germans focus less on who is at the table and more on the quality of the reasoning and the decision that is produced. Germans are interested in the input end of a deliberative process because they are worried about what those inputs will produce. We are interested in the input end simply because we want to make sure all stakeholders are represented. That was evident here this morning; several people expressed concern about who is not at the table and perhaps should be. That's an illustration of our political culture. And it's in contrast to many other countries, including Germany, though South Korea is somewhat like us in that regard.

We've talked some about language this morning. I want to introduce the term discourse, which is more the analysts' word. Institutional discourse is a bit more than just language. It's a formally codified way of talking that you have to "buy into" to be in an institution in the first place. Some ethical concerns are ruled out of bounds by some formal institutional discourse. For example, most American intellectual property lawyers think intellectual property law has nothing to do with values. They believe it is a technical domain with clear standards of proof. But why? In Europe, certain things are not patented due to ethics concerns. In France, for example, things contrary to "public order" or "public morality" are not patented. The American standard is that things have to be "useful," and we tend not to regard horribly violent things as useful. A bioterror agent, for example, is not seen as useful and so couldn't be patented. But it's not rejected because it's unethical. So, the notion that there's something intrinsic in patent law that rules values out of bounds is something American lawyers learn, and that I learned in law school as well. I had to become a different kind of scholar to recognize that as something I had been trained to think. That's what I mean when I say that some things are ruled out of bounds by institutional discourse.

It was interesting to discover that the highly political and scientific institutions were happy to recognize that ethical issues exist, but they do not want to probe them or understand where they come from. The OTA, for example, when it existed, was extraordinarily good at bringing diverse people to the table and identifying the range of issues. But the OTA did not look at the philosophical bases behind the different opinions, as the Nuffield Commission in England does.

Also, the identification of issues does not go hand in hand with resolving those issues. Institutions often want to delegate ethical issues out to someone else in society. Many formal government institutions, in particular, have a strong sense of what is not within their domain, in part because they have to operate within specific laws. They may want society or some other organization to think about certain issues, but they are quick to say, "not us."

That brings us to analytic observations. Institutions are places where issues get framed—places where we develop a particular way of looking at issues. That is both their strength and their weakness. Formal languages and discourse are boundary-setting devices (in terms of what gets addressed), and they act as entry barriers, because you have to speak the language of the institution in order to get into it. We are not in a society where just anybody can speak the law, for instance. It used to be that you didn't have to be a lawyer to be on the Supreme Court, but that's no longer the case. We now want more professionalization in our institutions. Why? In part because extreme fuzziness isn't consistent with providing reasons that everyone can follow. Analysis, almost by definition, implies a narrowing of the field of reason, in that it excludes everything that cannot be talked about in reasoning, rational language. So values, unless they can be shoehorned into the language of reason, are going to be kept out. And emotions are also going to be kept out. For example, there's been a debate about whether the "yuck" reaction is a good basis for making policy decisions. The law says that's not a good way to make decisions, because it's subjective. How do I know your "yuck" reaction is the same as mine? If I don't, how can I reason with you? So, public values are kept out of institutions that are trying to do reasoned analysis.

Since paradoxes are a place to start from if one wants to get to a solution, let's look at the democracy paradox.

- Everyone agrees that decisions should be generally representative of the people. Also, if the people believe something is fundamentally wrong, we agree we should not go ahead and do it. Representative bodies are supposed to take the temperature of public values and act accordingly, right?

- At the same time, everyone agrees that decisions should not be arbitrary or capricious. That's the last thing we want. We believe decisions should be based on things we can all evaluate, and should be transparent.

- And how do you get there? Everyone agrees that decisions by those in power should be "reasoned." Reasoning is an absolutely essential part of American democracy. We expect our leaders to have valid reasons for their actions.

- So, one challenge for institutions is how to deal with views and values that are not themselves "reasoned." How do you bring into the mix opinions that are based on feelings, beliefs, values, and so forth?

This paradox is not exclusive to this issue or this country, and potential solutions do exist. One is "bridging." If powerful and effective institutions get that way by drawing tight boundaries around themselves, how do you get at the issues that fall into the gaps between them? Bridge-building is the metaphor. How? A report by the National Academies of Science argued that risk assessment and risk management have drifted too far apart, and it recommended "analytic-deliberative approaches" as a solution. That's a different set of procedures, but it hasn't been widely implemented. It's difficult and expensive.

Another idea is bridging between the public and the private domain. It is a little strange to say that the public domain ought to express the private, but then that which is most private—such as emotions and

beliefs—cannot ever be allowed into the public domain because all public discourse must be based on reason. It's also strange that the lobby is our only model for bridging the public and the private. What should these bridging institutions be doing? They should not be decision focused, and they should be long-term in operation. (Though I know decisions have to be made, and I don't mean to minimize that fact.)

I want to put before you the political-theoretical idea of "essentially contested concepts." These are terms for which you cannot ever get to a fixed or permanent definition. A good example is "democracy." The value of democracy lies almost essentially in the fact that we cannot ever get it pinned down. What was democracy in America in 1776 would be considered the ultimate in injustice today. For one thing, I as a woman would not be able to vote. Other essentially contested concepts might be "natural" and "unnatural." Part of the value of a society that is at once innovative and moral is to keep alive all the time the discussion about what is morality and what is counted as moral. Not many bodies even try to do that, unless it's attached to a decision. So part of the institutional mechanism challenge is to create institutions that pick up those conversations and think very deeply about how to link the conversations to the decisions.

As a footnote to that, consensus building is then not the issue. Acceptance ought not be the criterion for deciding what is good. If people passively agree to accept genetically modified foods, as they have done in this country, even though opinion surveys show they don't know what they are eating, that isn't a very good argument for proving public acceptance of it.

Finally, therefore, patience is an important skill in a democratic society, and I think most of our institutions are not geared to the virtues of patience. How do you value patience in a society in which earning money 10 years from now is not as valuable as earning money tomorrow? So another analytic take on institutions would be to look at where patience is seen as a virtue and practiced.

Well, that's a rapid-fire overview of our thinking on these issues. Let me turn to Stefan to see if I've left out anything important.

DR. JASANOFF'S COLLEAGUE, Stefan Sperling, added that perhaps their most interesting results came in looking at the differences across international cultures. "The language people use to persuade themselves and others of the rightness of their own moral standards differs across cultures," Sperling said. The interesting question for him was: "How do you engage those different cultures and different perspectives in such a way as to not just affirm your own ways of seeing? One way is to learn to listen—not only to people who are like us, but those who are very different."

Following the presentation, participants delved into a discussion of some of the issues raised. Several participants commented on the content of the report itself, in the vein of noting issues or institutions that could have been included. For instance, some advisory committees have addressed moral order questions, though the examples listed in the paper had not. Jasanoff agreed, and noted that the charter, organizational form, and authority of advisory committees can differ. She said those most closely tied to the mission of their sponsoring agency may be constrained in the same ways the agency itself is constrained.

Another participant asked Jasanoff why she had not looked at Congressional hearings and party platform negotiations as venues for discussing ethical issues. She said those forums tend to be issue-specific and respond to particular political demands, so they were not included. Another person noted that Jasanoff looked at institutions that have dealt with biotechnology, but not those that have dealt only with food or agriculture; the participant suggested that the latter may be venues in which biotech ethics could be addressed in the future. Another participant said one risk that should be included is the risk to society and social order—for example, the risk to commercial interests and/or farmers.

The "yuck factor" was also discussed. One participant argued that the "yuck" feeling is useful—that it is a warning from our intuition that we should think carefully about something. He said that everyone has different views on what is reasonable and rational. Jasanoff said, "The issue is not whether or not we should listen to our "yuck" intuitions, but that in institutions where reasoned argument is the norm, it is not acceptable to invoke the "yuck factor" to justify a decision. We cannot be guided by individual, subjective statements about what is disgusting." She continued, "The danger of operating according to some feeling of disgust is that it can be used to justify discriminatory, marginalizing, and stigmatizing decisions. In short, in this country it is seen as dangerous to not be able to have a reasoned explanation for your beliefs."

In response to a question about how and when to begin ethical discussions, Jasanoff noted that ethical and policy discussions often take place simultaneously—and often with the ethicists unaware that a policy decision is about to be, or has been, made. The implication was that ethics discussions should begin as early as possible and that participants should seek ways for their discussions to inform policy decisions.

SECTION 3

Institutional Options for Addressing Ethical Issues

DURING THE REMAINDER of the workshop, participants talked in small- and large-group settings about existing and potential institutional structures for addressing the moral and ethical issues related to genetically engineered or cloned food animals. The main structures they discussed included university and industry ethics committees, university "benchside consultations," federal advisory committees, and quasi-autonomous nongovernmental organizations (QUANGOs). Participants also talked about the education of future ethicists, as well as some of the general attributes needed for any kind of institutional structure. Each of these topics is summarized in brief in this section.

University and Industry Ethics Committees

Institutional animal care and use committees (IACUCs) were mentioned a number of times as settings in which ethical discussions *currently* take place. IACUCs are set up by institutions, such as universities or private companies, that use laboratory animals in the conduct of federally funded research or instruction. Institutions not receiving federal funding may also establish IACUCs as a matter of institutional policy. IACUCs oversee and evaluate an institution's animal care and use program. These committees focus on issues of pain and suffering relating to animals used in laboratories.

Several issues regarding the limitations of IACUCs were raised. The narrow scope of IACUCs' deliberations limits discussion of the broader ethical issues that many would like to see discussed. Additionally, there is little consistency across IACUCs with regard to how they make decisions and how effective they are. Some may have robust debates on tough issues, while another may appear to simply "rubber stamp" what leaders at the institution have already decided. The deliberations of IACUCs are generally not transparent to outside observers, and the Committees do not provide information about what they have approved or disapproved and why, raising issues of credibility and public trust. It was noted that, for private companies, opening deliberations of their ethics committee to public review would be difficult because they often discuss confidential business information.

Participants proposed several ideas for addressing some of the concerns about IACUCs. Participants noted that some companies and universities have set up ethics committees that play the role of IACUCs but also focus on broader social and ethical issues, or they have committees wholly separate from IACUCs that take on the broader issues. Several argued that the scope of all IACUCs ought to be broadened beyond just pain and suffering to include deliberation on broader social and ethical issues. Such a broadening of focus would be difficult, however, because any significant change in their scope or organization would require a change in the federal law that governs them.

Another idea was to establish a national accreditation body that would oversee IACUCs. Such a body would set guidelines or principles for each committee, akin to ISO standards. Accreditation, then, would provide accountability and give the public more confidence that ethical issues were being addressed properly.

A final suggestion was to create institutional ethics committees (separate from IACUCs) that would look broadly at the ethical, legal, moral, and social issues relating to proposed and on-going research that could affect the food supply. The members of such a committee could include the chief researcher from the company or university, an "ELSI-type" person (one specializing in ethical, legal, or social issues), a community member, a medical field representative, a nutritionist, a farmer or other agricultural person, and an NGO representative.

Benchside Consultations

"Benchside consultations" were raised as a means through which some ethical issues are beginning to be addressed in research, primarily in the university setting. Benchside consultations are the practice of having professional bioethics colleagues review and discuss the ethics of a proposed research project. One participant gave the example of a Stanford University professor who conferred with his fellow researchers before using biotechnology techniques to insert human cells into a mouse brain. His colleagues raised important ethical questions, and as a result he decided to terminate the project.

Benchside consultations are gaining currency in academic circles because they offer several advantages to research institutions. They are much quicker and more efficient than holding a large public deliberation process. They allow key ethical questions to be anticipated early in the planning stage of research and addressed before a researcher has invested much time or money to the project. The scope of benchside consultations may also be open to a broad range of issues, depending on how widely the researcher and his colleagues wish to carry their ethical considerations.

While many participants saw benchside consultations as having merit and recommended that they be expanded to all universities and companies in which research is conducted, others viewed them more skeptically. They saw the consultations as less democratic because they offer no open, public discussion, with representation limited to a small group of potentially likeminded scientists. Second, benchside consultations are voluntary, with the decision of whether to request one left to the researcher involved. Concern was also raised that, as university budgets tighten, benchside consultations may not override the potential financial incentives that exist to undertake commercially focused research that may raise larger ethical questions.

Suggestions for improving benchside consultations included involving professors and researchers across the university, augmenting the group with a person from the community, and developing standards and funding for such consultations through the Land Grant University system.

Federal Advisory Committees

Participants also addressed the concept of advisory committees as a way to explore the larger societal and ethical issues relating to genetically engineered or cloned food animals. Advisory committees are typically set up by federal agencies, and they ideally include a broadly diverse and representative set of interested parties. They issue reports or recommendations to the agency, which the agency may then choose to accept or not. A current example is the Advisory Committee on Biotechnology and 21st Century Agriculture, which was set up by the U.S. Department of Agriculture.

Participants noted several limitations of advisory committees. One concern was that advisory committees may be set up just for "show," such that they have no influence and/or may be expected to simply "rubber stamp" decisions made by the agency. Additionally, the committee's membership

may not reflect the full diversity of views. Finally, the mandate of an advisory committee is generally determined by the sponsoring agency and so reflects the priorities and biases of the administration then in power.

Nevertheless, in its report-out to the larger group, one small group recommended that FDA convene an advisory committee to address the ethical, social, moral, and legal questions involved in the cloning and genetic engineering of food animals.

QUANGOs

The concept of a "quasi-autonomous nongovernmental organization," or QUANGO, was first raised in the full-group setting and then discussed further in one of the small groups. QUANGOs were said to be national, multi-stakeholder bodies that are largely independent of government but funded by and accountable to government. They are similar to advisory groups, yet are more independent, autonomous, and longer-lasting (sometimes even permanent). Examples noted include the Danish Ethical Council for Animals, the Farm Animal Welfare Council in Britain, and the Health Effects Institute in New Zealand. Advantages of a QUANGO can include increased legitimacy and credibility and the ability to take on as broad or as narrow a scope of discussion as necessary.

One of the small groups recommended the formation of a slightly different version of a QUANGO, one that would receive funding from government and other organizations. The group envisioned that this QUANGO would discuss principles and frameworks regarding broad social and ethical issues relating to genetically engineered or cloned food animals. It would serve as a source of information and recommendations, they said, and could influence policy and actions. It could develop guidance for researchers and product developers (including "best practices"), as well as education and outreach materials for the public. It could also take public input into consideration and serve as an "honest broker" or mediator on controversial issues. The small-group participants said they also envisioned that this QUANGO would be highly visible, transparent, and credible. They felt it would help to increase public trust in the technology and in the food supply, as it would be seen to deliberate seriously and resolve key issues. One challenge, they said, would be to find the right balance between independence and accountability.

After the small group presented this concept, workshop participants discussed it in some detail. Several said they were intrigued by the idea and felt it should be explored further. Others argued that it would have little authority if too far removed from government. Many agreed with the small group's assessment that the QUANGO should address the broadest ethical questions relating to food animal biotechnology. Some suggested that the QUANGO be utilized to review products, providing an assessment of their safety and ethical soundness. It was hoped that if the organization had a diverse and well-respected membership, the public would be reassured by their assessments. Such assessments could also help to limit the liability of industry because it could set standards for their work.

Participants also had suggestions regarding the inner workings of the QUANGO. With regard to the QUANGO's agenda, the organization's members would develop the agenda as well as taking issues brought to it by the government or others. To engage the larger public, the QUANGO could solicit public input on key topics of concern; the success of the QUANGO, however, would not depend upon public enthusiasm or support. Though the organization's written materials would be available to the public, the QUANGO's primary usefulness for the public would likely be the reassurance to the public that some organization was examining the ethical issues involved. Funding for the QUANGO could be set up like that of the Health Effects Institute in New Zealand, which is funded 50/50 by the government and the auto industry. To avoid any real or perceived conflicts of interest, however, it was suggested that the organization should be either strictly government-funded or have a broad diversity of funding.

The Education of Future Food and Agricultural Ethicists

At several points in the discussion, the dearth of ethicists with food and agricultural training was mentioned. As interest in ethical issues related to food and agriculture has grown, so has the number of ethicists examining those issues. Many, however, come from a bioethics background. Without some background training in agriculture, they may not ask questions that relate to the history, purposes, and future of agriculture, and its structure.

Participants suggested that significant capacity needs to be built in the area of ethics with a food or agricultural focus and additional funding should be sought to educate students from diverse fields in ethical issues. Such education could result in the future in richer discussions about ethical issues by a more informed and educated set of experts.

General Attributes

Throughout these conversations, it was noted by many participants that no "silver bullet" exists. That is, no single institution—whether it be an established or future venue—could readily take on all of the relevant ethics questions. Instead, ethics discussions will likely, and should, take place in numerous types of institutions by a wide variety of people. The goal, then, is to ensure that each institutional structure for addressing ethics does the best job it can do, and that all issues are covered in one way or another in a manner that engenders public trust and confidence.

To that end, participants discussed the two primary attributes that all ethical discussions must have—and be seen to have—legitimacy and credibility. Participants argued that legitimacy and credibility are needed to increase public trust in the food supply and the processes of genetic engineering and cloning, and to help the public feel confident that all important ethical issues are being addressed.

In order to be seen as legitimate and credible, those who take part in ethical discussions must be free of conflicts of interest. Restricting the involvement of those with a financial conflict-of-interest would be one step, but non-economic conflicts of interest may also exist. It was noted that "conflicts of commitment" may exist where academics choose to sit on an industry ethics committee to keep up-to-date on emerging issues, which, in turn, may inform their future research and writing. Such a person may be unlikely to raise particularly challenging ethical concerns to the company's research.

Another key element of legitimacy mentioned is appropriate representation. Often, the same two or three people are always chosen to represent each particular viewpoint, and discussions then devolve into the "dueling of experts." Broader participation may be needed, such as having several people represent each major interest. While this might result in larger committees or organizations, it would also result in richer discussions.

Finally, participants noted that other key elements of legitimacy and credibility include transparency, accountability, funding, and reporting structure.

Conclusion

THERE ARE A NUMBER of options available for future discussions of food animal biotechnology and ethics. The scope of such discussions and the extent to which broad participation is sought will determine what type of deliberative institution will be appropriate. In some cases, it may be possible to alter slightly existing institutions, such as IACUCs, to satisfy calls for increased transparency. In other cases, it would be necessary to establish entirely new forums to address wide-ranging topics, broad public participation, and openness.

The devil will be in the details of any attempt to address ethical issues and animal biotechnology. Decisions about who will participate, the scope of the discussion, the product and the authority of the discussion, and the amount of transparency involved will not be easy. Finding funding for such discussions may also prove difficult, particularly because the perceived legitimacy of the discussions may vary with the degree to which the benefactor is viewed as controlling the discussions.

APPENDIX A

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Engineering Animals:
Ethical Issues and Deliberative Institutions*

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Introduction: From Welfare to Ethics

The first industrial revolution of the 18th and 19th centuries increased the distance between humans and animals, producing an urban culture in which domesticated animals became household pets, wild animals inhabited zoos, and farm animals were seen mainly as disembodied parts in supermarket refrigerator cases. The second, high-tech revolution of the 20th century arguably has brought animals back into human consciousness with a long-forgotten immediacy. Genetic sciences and technologies today seem intent on restoring a closer communion between animals and humans than was previously imagined, enabling forms of co-existence, and even commingling, in which lines between species are increasingly blurred. Efforts to map and sequence the genes of various species have revealed surprising degrees of commonality between humans and creatures we considered well removed from us on the evolutionary tree. Chimpanzees and humans share nearly 99 percent of their genes in common. Only a few hundred of those genes may account for all the differences between these two species.[1] Humans share some 90 percent of their genes with rodents and 60 percent with chickens.[2]

With the aid of new genetic technologies, animals today are called upon to serve humanity in many roles, some familiar but ratcheted up in intensity, some unprecedented: as surrogates for humans in biomedical research; as model systems for detecting environmental hazards, observing disease progression, or testing therapies; as factories for producing scarce hormones and proteins that humans need; as more efficient or nutritious sources of food; and as sites for investigating the frontiers of reproductive and developmental biology and the nature of consciousness. Cows have been modified to secrete human breast milk protein; pigs re-engineered to make their hearts available as safe replacements for worn-out human ones; and monkeys to test the regenerative potential of human embryonic stem cells.[3] These new uses are creating an animals-R-us™ world, in which animals seem increasingly to function as surrogates for, even as extensions of, humanity.

At the same time, contradicting the growth of "likeness," the ways in which we use animals have changed dramatically. The human ability to manipulate animal genomes, in particular, has brought into question the very notion of animals as lodged in nature, possessing moral autonomy, and having entitlements that protect them, in some respects, against unrestricted instrumental use. Some animal manipulations in the genetic era seem only to extend age-old animal breeding practices by new scientific means. Principally, these aim to make existing strains and species more productive, palatable, or nutritious as sources of food. But these modifications, often designed to produce rapid increases in size or yield, may have unexpected and potentially harmful consequences—to the animal itself or to the environment. Treated with genetically modified bovine growth hormone, dairy cattle can increase their milk yield by as much as 40 percent, but they also are more prone to side-effects such as leg and hoof disease and mastitis. Transgenic fish, such as salmon engineered to grow up to five times faster than normal, may threaten the existence of native wild species.[4] Pigs have become arthritic and deformed under the weight of growth spurred by the insertion of a gene for human growth hormone.[5]

Genetic manipulation also raises moral questions beyond those of health or environmental risk. The birth of the cloned sheep, Dolly, in Scotland in 1996 crystallized this problem. An exact copy of an adult ewe, produced from a single cell of the "mother," Dolly prompted worldwide reflection on the

ethical limits of cloning. Though her early death was a matter of concern, her own welfare proved to be of secondary importance in comparison with that wider debate. Harvard University's oncomouse, genetically modified to make it more susceptible to cancer, gave rise to controversy about the appropriate limits on patenting higher animals. And Alba, the famous "green fluorescent protein" bunny imagined by the Brazilian-born artist Eduardo Kac as a work of biological art, and realized in a French laboratory through the insertion of a jellyfish gene into a white rabbit embryo, spurred discussion on whether animal genetic modification (GM) of no economic or medical use to humans should be permitted under any circumstances.

Both movements in the human-animal relationship—those that emphasize the similarities between humans and animals, and those that enable the extension or intensification of human dominion over animals—raise ethical quandaries for animal biotechnology. Under pressure from both sides, the framework of "animal welfare" that regulates human responsibility toward animals no longer seems adequate. Questions have arisen about the institutional capacity of contemporary societies to identify and deliberate on the novel ethical questions raised by humans' increasing ability to make genetic modifications in animals.

This paper addresses the issue of institutional capacity in four parts.

- First, we map the major ethical concerns that have arisen in connection with animal biotechnology, identifying six salient areas of debate and the positions or principles that have developed around each.
- Second, we review the spectrum of deliberative institutions that have taken on board some or all of these ethical issues; and we describe, using examples from three common-law jurisdictions (Britain, Canada, and the United States), varied institutional mechanisms for addressing ethical problems through principles, guidelines, and recommended practices.
- Third, we draw conclusions about the influence of particular institutional designs on the capacity to frame and debate the ethics of animal genetic engineering.
- Fourth, in the appendices to this report, we offer two brief country case studies—of Germany and South Korea—to illustrate how two other advanced industrial nations, neither subscribing to the common-law framework, have grappled with the ethical problems of animals in relation to modern biotechnology.

Ethical Concerns and Positions

GENETIC ENGINEERING HAS extended and drastically altered humans' ability to change the lives of animals, but the associated ethical questions and concerns are neither entirely novel nor entirely unprecedented from a policy standpoint. Our aim in what follows is to flag both new dimensions of older concerns and novel concerns that reflect specific possibilities opened up by genetic sciences and technologies. We identify three sets of recurring issues: (1) questions about the health and well-being of animals themselves, traditionally grouped under the heading of *animal welfare*; (2) questions about perturbations in nature and the environment, generally addressed under the rubric of *risk*; and (3) new questions about ontology and the disruption of the *moral order*, popularly referred to as *playing God*.

Animal Welfare

The principle that we should not inflict unnecessary or excessive pain on animals has long been established in Western culture. Since the foundation of the first Society for the Prevention of Cruelty to Animals (SPCA, later RSPCA) in London in 1824, other local and national groups with similar aims have sprung up throughout the world. Their missions include responses to reports of cruelty, care of stray animals and animals in distress, and campaigns for higher standards of treatment in private homes, agriculture, business, industry, and research. Efforts by individual entrepreneurs and private groups culminated in many instances in national legislation. The passage of the 1911 Protection of Animals Act in Britain and the 1966 Animal Welfare Act, covering non-farm animals, in the United States represent widening legislative efforts to prevent unnecessary suffering to animals in research, business, and agriculture, as well as in commercial enterprises that display animals, such as circuses, aquariums, or zoos.

Concerns expressed under the heading of animal welfare include pain and suffering in the first instance, but they also include the balance, or lack thereof, between the purposes of animal use and the consequences for the animal. Tacitly or explicitly, any weighing of purposes against consequences requires policymakers and the public to take sides between different philosophical theories for animal protection, most notably, between utilitarianism and approaches (e.g., the capabilities approach[6]) that may absolutely protect some aspects of an animal's existence against human intervention.

PAIN AND SUFFERING

The earliest goals of animal protection focused almost entirely on physical harm and distress. Britain's RSPCA, for example, was founded by social reformers wishing to prevent cruel treatment of farm animals and horses used in transporting goods or people. Flogging and beating, baiting, and inhumane conditions of housing and transport figured prominently among early concerns and are still alive today. More recently, attention has also turned to animal consciousness and sociality, seen as worth protecting in their own right, so that humane treatment now encompasses such issues

as whether animals are kept in conditions that occasion fear or other psychic distress, and whether they are granted or deprived opportunities to associate with others of their own kind.

An interesting debate, in this regard, has arisen around the use of cloning to preserve endangered species. Where populations are small, preservation efforts may require a controversial resort to interspecies cloning, typically by transferring nuclei from the scarce species to the enucleated oocytes of a related species. Producing exact copies of each existing endangered animal is an alternative, with the justification that twinning the population in the present generation is more likely to increase genetic variation in the long run, fostering an increase in biodiversity. Such interventions are controversial because they violate intuitive ideas of what is natural, in reproduction for example, for the ostensibly greater good of preserving an endangered part of nature.

WEIGHING BURDENS AND BENEFITS

Animal welfare laws laid the basis for certain kinds of standard-setting that are, by now, deemed reasonably uncontroversial: for example, specifying the size of cages or containers for transport, the frequency of feeding and watering, and the levels of hygiene in animal care facilities. Other features of humane treatment, however, remain harder to pin down to standard measures and require regulatory authorities to weigh various factors on a case-by-case basis.

The balancing approach has come to prevail in decisions regarding the number and kinds of animals used in research. In 1958, the Universities Federation for Animal Welfare commissioned two authors, William Russell and Rex Burch, to write a report on baseline principles for using animals in research.[7] Russell and Burch proposed three criteria—*replacement, reduction, and refinement*—which they designated as the "three R's," analogous to the "three R's" of basic literacy (reading, writing, and 'rithmetic). Their formula caught on. We will see below that the "three R's" approach has been widely adopted, in the United States and internationally, as a basis for justifying animal use in research.

Russell and Burch defined the three R's as follows:

> Replacement means the substitution for conscious living higher animals of insentient material. Reduction means reduction in the numbers of animals used to obtain information of a given amount and precision. Refinement means any decrease in the incidence or severity of inhumane procedures applied to those animals which still have to be used.[8]

The idea of replacement implicitly recognizes a greater need to protect conscious, hence presumably more human-like, animals than animals of a lower order. Reduction reflects a bias against wasteful and unnecessary destruction of animal lives; at the limit, this principle supports the use of computer models, where feasible, in place of any living animals. And refinement speaks to the firmly established value of preventing, or minimizing, inhumanity in the form of cruelty to animals.

Risk

Like any other modern technological development, animal biotechnology has been assessed within the framework of risk, the dominant conceptual framework developed in the 20th century to protect societies against the potentially harmful consequences of their own ingenuity. Two types of risk have drawn particular attention: the risk of disease transmission from animal hosts to humans; and the risk of uncontrolled proliferation of genetically modified species, with resulting losses in biodiversity.

RISKS TO HEALTH

The most feared pattern of disease transmission from animals to humans involves a pathogen that is evolutionarily adapted to be harmless in the host but becomes infectious upon transfer to a different species. In worst-case scenarios, a transfer to a single individual not only infects the recipient, but causes secondary infections in those who come into contact with the infected person, producing a public health disaster of unpredictable dimensions. Technological manipulation of animals in the broadest sense, including not only GM but other forms of industrial intervention, is associated with two major pathways of concern.

One pathway involves transplantation, a matter of growing interest as technologies of xenotransplantation make progress.[9] Risks to transplant recipients are dealt with through standard medical procedures of informed consent. Risks to third parties who may be infected through contact with the treated individual, or intergenerationally from parent to offspring through reproduction, are not so easily accommodated within this framework, which rests on an ethical relationship between the physician and the patient. Procedures for consulting with and obtaining consent from wider communities at risk remain as yet in their infancy.[10]

A second pathway leads through the food chain. "Mad cow" disease, detected in Britain in the mid-1980s, is the paradigm case of a food-borne illness arising from industrial agriculture and commodification of animals. In that case, meat and bone marrow meal fed to beef cattle resulted in the transfer of an infectious protein called a prion across the species barrier from sheep to cows to humans and other animals. The effects on cattle were devastating, with nearly two hundred thousand cows infected before the epidemic was finally controlled. By 2006, as many as 150 people in Britain had died of variant-CJD (Creutzfeld-Jakob Disease), as the human disease came to be known; given the long incubation period of the disease, up to 50 years, more deaths are almost certainly to be expected. The British beef industry suffered losses in the billions of pounds.[11]

In 1989, a governmental committee formed to investigate the BSE epidemic (years before the identification of the human variant) concluded: "We note that this disease appears to have resulted from unnatural feeding practices as found in modern agriculture. We question the wisdom of methods which may expose susceptible species of animals to pathogens and ask for this general issue to be addressed."[12] That observation reflected and reinforced a growing public aversion to industrial agriculture, which many see as "unnatural" and hence unethical. Particularly in Britain, but also in other Western nations, that perception still affects public attitudes toward food produced through genetic modification of animals. In the United States, the organic foods movement firmly rejected the notion that food produced through genetic modification could carry the "organic" label; and European publics have successfully demanded that GM foods be labeled as such.

RISKS TO THE ENVIRONMENT

From the moment that genetic engineering entered the toolkit of agricultural science and technology in the 1980s, there has been concern that GM plants and animals might either enjoy an evolutionary advantage, and so outcompete natural species, or cause devastating side effects on non-target species. In either case, there would be a loss of biodiversity, with potentially grave consequences for long-term sustainability in agriculture and food production.

Containment of GM crops and plants has proved difficult to achieve. In August 2006, for example, the U.S. Environment Protection Agency disclosed that an as yet unapproved GM grass species bred for use on golf courses had escaped almost 4 kilometers beyond the experimental plots in which it was planted.[13] Similar "escapes" have been reported with crop plants such as corn, rice, and sugar cane. One episode that a report for the Pew Initiative on Food and Biotechnology described as a

"seminal event" in American public responses to agricultural biotechnology was the discovery of a genetically engineered corn variety, trade-named StarLink™, in the human food supply.[14] StarLink™ had been approved only for use in animal feed, and its migration into products such as tortillas and corn chips signaled not merely a massive regulatory failure but also the pragmatic difficulty of maintaining a workable segregation between GM and non-GM food products.

Similar concerns have arisen around the emerging industry in GM fish. A widely cited Purdue University study of 1999[15] gave rise to an ongoing scientific debate about the possible ecological consequences of GM fish escaping into the wild. Even fish engineered to be sterile, it was feared, might spread transgenes to other species. Scientists have analyzed the possible harmful consequences of such dispersal using the familiar discourse of risk assessment. In particular, the Purdue scientists William Muir and Rick Howard defined *risk* as the probability that a transgene would spread into a natural population, and *hazard* as the probability of ecological consequences, ranging from disruption to species extinction.

Moral Disruption: Playing God

While scientists have focused on the physical and biological risks of creating novel organisms, public concern about the genetic revolution has included from the start additional worries about disruptions in the natural order. For some religious groups, genetic interventions also imply the disruption of a divinely ordained moral order—with humanity taking over powers previously thought to be god's alone. Jeremy Rifkin, the influential critic of biotechnology, entitled one of his early works, *Who Should Play God?*[16]; and even the historian of science Horace Judson, celebrating the birth of genetic engineering, chose a title with religious overtones, *The Eighth Day of Creation*.[17] In the context of animal biotechnology, worries about upsetting the moral (and hence also natural) order cluster around two principal issues: converting animals into machines for human use and benefit; and creating new entities that cross species lines and, at the limit, put into question morally significant distinctions between humans and other animals.

ANIMALS OR MACHINES?

A cartoon circulated during the height of the public debate surrounding recombinant bovine growth hormone (rBGH) in the United States illustrated the unease that many feel about instrumentalizing animals beyond a point. It showed an rBGH-treated cow with an enormously elongated body, fitted out with multiple udders, all heavy with milk. The animal in the picture had effectively turned into a machine for industrial use. Implicitly, the image criticized the reduction of complex, natural beings to single-purpose, utilitarian objects. The cow, the cartoon implied, was meant to be something more than a milk-yielding machine; exaggerating this single property took away from the animal's intrinsic worth and made it something less than a sentient being. These kinds of fears build upon older concerns with industrial agriculture, whose large scale, loss of connection to nature, and impersonal systems of management and control have long provided a dystopic vision for supporters of organic agriculture. *The Meatrix*, a popular web-based Flash movie, cites as the major the problems of factory farming: animal cruelty, antibiotic resistant germs, massive pollution, and destroyed communities.[18]

Survey results suggest that animal cloning, the technology of producing some or many identical copies of a single ancestor, arouses ethical concerns for many people, although it is unclear whether these concerns are tied to possible health risks or the objection to mechanizing animals.[19] Many survey respondents are concerned about the safety of foods derived from cloned animals. On the other hand, cloning has been seen as a boon to some who have lost a beloved pet and can afford

the means of cloning it.[20] Ethical worries about the loss of identity and autonomy through genetic replication remain primarily focused, to date, on human cloning.[21]

Concerns about the transformation of animal life to mechanical functions have arisen particularly within the framework of patent law. Western intellectual property law rewards useful invention, that is, bringing new and beneficial things into the world. In the past quarter century, the category of "patentable subject matter" has expanded to include living organisms. In that process, the line dividing living organisms from non-living matter has been rendered less distinct. Despite periodic expressions of public unease,[22] U.S. patent legislation and jurisprudence have not sought to redraw that line. American patent law does not maintain a sharp distinction between animate and inanimate inventions, nor between non-human higher animals (e.g., vertebrates or animals possessing consciousness) and other forms of animal life. We see below that Canadian patent law has developed differently in this regard.

UNNATURAL CREATION

A second focal point for moral questioning is the crossing of species barriers through recombinant genetic techniques. The prospect of trans-species gene transfers offends some people's dietary prohibitions and preferences—for example, the insertion of fish genes into vegetables, or the widely rumored insertion of pig genes into tomatoes, which could cause problems for vegetarian and kosher eaters, respectively. Going beyond dietary concerns, for many people the creation of genetic combinations that could never have occurred in nature raises ethical questions. The resulting constructs are seen as sufficiently unnatural to trigger feelings of disquiet and rejection.[23]

Animal biotechnology also induces uneasy public responses through the production of chimeras. In classical mythology, a chimera was a fearsome creature composed of the physical parts of several different animals, such as a lion, a goat, and a snake. In modern biology, the term is used to refer to an organism that contains genetic material from two non-identical individuals, including individuals from more than one species. Examples of chimeras include human embryos containing non-human genes and non-human embryos containing human genes. Laboratory-produced genetic crosses are hard to classify and raise new ethical questions about the degree of similarity between species (when does a chimp become human?), the permissible limits of interference with categories established in nature, and the possible unintended consequences of such experiments.

Deliberative Institutions

THE ETHICAL DIMENSIONS of human-animal relations have been addressed and deliberated within a wide variety of institutions: public (i.e., governmental), quasi-public (i.e., having some public accountability), and private (i.e., non-governmental). These differ in their organization and objectives, their strategies and resources, and their links to policymaking. Together, they play a crucial role in integrating major advances in science and technology with the basic beliefs and values of a democratic society. Indeed, the often inchoate moral opinions or intuitions held by citizens could not be incorporated into policy without mediating institutions that provide the forums, the procedures, the discourses, and the analytic frameworks that make ethical debates possible in the public domain. This section discusses the major types of institutions that have been active in formulating and addressing the ethics of animal biotechnology, and illustrates how each works with specific examples.

Legislative Advisory Bodies

In democratic nations, legislatures often seek advice from experts on technical matters, and increasingly also on ethical issues connected with advances in science and technology. Institutional mechanisms for seeking such advice vary both within and among nations, and may include some or all of the following: specially designated legislative support agencies; standing committees; ad hoc commissions; hearings or inquiries; and oversight proceedings. Experts appointed to advise the legislature generally are called upon to weigh various options for lawmakers, usually at a time when legislative proposals are still fluid. However, practices for responding to expert recommendations differ enormously across political systems, ranging from fairly rapid uptake of expert advice into legislation in Germany or Britain to much less certain and sporadic responses in the United States.

In 1972, the U.S. Congress established an innovative agency, the Office of Technology Assessment (OTA), to provide on-going technical support for legislative decisions involving science and technology. It was the smallest of four technical agencies supporting Congress, but its aim was to offset what many saw as an unfair advantage in technical information enjoyed by the executive branch as a whole. As the first body of its kind in the West, OTA served as a model for a number of other nations (e.g., Britain, Germany, Netherlands) before it was abolished in 1995. During its 23 years of existence, OTA issued about 50 reports a year, each taking between 18 months and two years to complete.

Two principles governed all of the agency's work: political balance and broad consultation.[24] To secure the former, OTA was governed by the Technology Assessment Board (TAB), a 12-member body comprising six Senators and six Representatives, evenly divided between the two major parties. Further, OTA was eminently accessible: reports could be requested by any congressional committee, or the TAB, or the OTA director. OTA also famously sought to incorporate a breadth of views into its reports, using for this purpose a 10-member, multi-stakeholder, advisory council, multipartite review panels for each report, and wide solicitation of views and written inputs from experts. To maintain its reputation for non-partisan advice, OTA preferred to lay out a spectrum of policy options and their implications, rather than present Congress with a single preferred course of action. This approach guarded the agency against charges of politicization, but it also prevented OTA from resolving, and sometimes even clearly articulating, conflicts over fundamental policy objectives.

From the early 1980s onward, OTA issued a number of reports on biotechnology.[25] They covered a range of issues, from the state of the art in different sectors of the biotech industry to public perceptions of genetic engineering to the position of the U.S. industry in the global political economy. Ethics figured repeatedly in assessments done by the OTA over more than a decade, but no consistent methodological approach or philosophical positions can be discerned in the agency's reports. Perhaps predictably, given OTA's reluctance to be identified too closely with partisan political viewpoints, its reports set out divergent, even contradictory, understandings of a problem, without seeking to reduce them to definitive conclusions.

For example, a 1981 OTA report contained a chapter on advances in reproductive biology that plainly conceptualized animals as useful objects, needing "improvement" to make them still more beneficial to humans. Animals were described in utilitarian language, as part of "the physical capital used on the farm," and selecting animals for desired characteristics was said to enhance "the efficiency of the information contained within each cell."[26]

Yet the same report also contained a chapter on genetics and society that identified challenges to "deeply held social values" from our "increasing control over the inherited characteristics of living things." The public, the report indicated, feared a slippery slope by which manipulation of lesser animals would inevitably lead to manipulation of humans. Whereas earlier chapters in the report had analogized genetic improvement to the use of fertilizers or pesticides to improve soil quality, this chapter noted that genetics raises special concerns:

> The idea that research in genetics may lead some day to the ability to direct human evolution has caused particularly strong reactions. One reason is that such capability brings with it responsibility for retaining the genetic integrity of people and of the species as a whole, a responsibility formerly entrusted to forces other than man.[27]

On the whole, the OTA reports on biotechnology set forth a reasonably accurate, if broad-brush, picture of issues and attitudes without probing too deeply into their causes or consequences. Thus, in one of a series of background papers on "new developments" completed in the late 1980s, OTA surveyed public perceptions of biotechnology. The overall tone was upbeat, noting that people did not "appear to be concerned about the morality of genetic engineering of plants and animals" but only about specific applications.[28] Closer reading indicates that OTA's respondents reacted more negatively to animal manipulation than to medical uses of genetic manipulation, with 37 percent saying they strongly approved of making farm animals more productive, and only 27 percent of making larger game fish.

In keeping with the U.S. tendency to treat patenting as a technical rather than ethical matter,[29] a background paper on life patents devoted only two paragraphs to ethical considerations. The report refrained from delving too deeply into the reasons for contradictory moral intuitions regarding patents on life, dismissing many of the arguments as "speculative, relying on factual assertions that have yet to occur or be proven."[30] Such arguments, the report writers concluded, were not likely to be reconciled with those of persons holding equally strong countervailing beliefs.

National Ethics Committees

Over the past decade or so, U.S. presidents have established several highly visible bioethics forums in order to foster discussion on controversial developments in biotechnology. Most notable are the National Bioethics Advisory Council (NBAC), established by President Bill Clinton in 1995 (charter expired on October 3, 2001); and the President's Council on Bioethics (PCB), appointed by President George W. Bush in 2001, and renewed in 2003 and 2005.

NBAC consisted of 15 to 20 experts who overwhelmingly came from academic backgrounds, either from medical schools or from bioethics or life science departments. A small number came from the biotech industry. NBAC initially investigated the protection of human research subjects, but just days after news of the cloned sheep Dolly broke in 1997, President Clinton asked NBAC to deliver a report on the ethics of human cloning. NBAC's 1997 *Report on Human Cloning*[31] specifically excludes the issue of animal cloning. It mentions the Roslin Institute's cloning of Dolly by the method of somatic nuclear cell transfer (SNCT) merely to explain the scientific technique itself. The report recommends legislation prohibiting creating a child by somatic cell nuclear transfer in such a way as *not* to interfere with research on cloning animals. Animal cloning, the report concludes, "does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees."[32]

The report explicitly recognizes the value of animal cloning research and recommends its continued pursuit, while also ensuring the genetic diversity of animals in order to prevent adverse long-term consequences.[33] The report also approves the creation of transgenic animals, and it endorses research on animal systems to assess the viability of creating animals that can serve as organ donors for humans. Its recommendations are phrased so as not to impede research involving the cloning of human cells or DNA, which are standard procedures in molecular biology.

The President's Council on Bioethics, established by executive order on November 28, 2001, serves to "advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology." The Council was created during a heated debate over the future of research on human embryonic stem cells, and its mandate, its composition, and the treatment of individual appointments all proved to be controversial. Commentators on the PCB pointed out that its composition favored conservative outcomes. In his opening speech to the PCB, President Bush reminded the Council that "the other thing is that I have spoken clearly on cloning. I just don't think it's right." The Council devoted its very first session to the ethics of human cloning. The cloning of animals was discussed in a background paper, which was referred to only in passing during the Council's discussion.

On October 16, 2003, the PCB devoted 90 minutes to a session called "Toward a 'Richer Bioethics': Chimeras and the Boundaries of the Human." Given that chimeras of goats and sheep seemed to make chimeras of humans and non-human primates thinkable, Chairman Leon Kass's initial guiding questions were whether we should care, or perhaps even worry, about breaches of the human-animal divide, and how we know when a moral line has been crossed. For Kass, who is also an interpreter of classical mythology, "it is not so much that science has raised new questions, but that it makes these old questions now urgent and very timely."[34] In the subsequent probing of moral intuitions, it became clear that most council members were not opposed to chimeras in principle, so long as they were treated with the appropriate respect. The main goal of this exploratory session was to debate whether the Council should hold further sessions on the human-animal divide, given the disquiet voiced by the public in various forms. In the end Chairman Kass encouraged council members to submit additional views and recommendations in writing, and left open the possibility that further action could be taken.

The method of sampling committee members' intuitions makes the Council a place where future scenarios are imagined, but in some critics' view this also opens the way to speculation, divorced from any likely scientific reality. It also suggests that agenda-setting within the Council need not bear any obvious relation to expressed or implicit public concerns.

Executive Agencies and Advisory Committees

While the broad outlines of national policy are laid down by law, it falls to the agencies in the executive branch to implement the law's mandates in detail, and it is in this more technical phase of policymaking that ethical issues are often raised and deliberated. Institutional means of factoring public values into genetic research and development policy have been in place in the United States since the 1970s. The best known of these are aimed at reviewing proposals on their ethical as well as scientific merits, and at assessing in advance the risks of misusing genetic information. As adjuncts of the research enterprise, these mechanisms tend to have a built-in bias in favor of promoting science, albeit under safeguards that guard against irresponsible research and misuse of information.

In 1974, the National Institutes of Health (NIH), the agency primarily responsible for funding biomedical research, established a Recombinant DNA Advisory Committee (RAC) to help ensure the safety of experiments with the new techniques of genetic engineering. Initially composed of 12 biomedical scientists, RAC's membership was soon broadened to 21, so as to include ethicists, laypersons, and members of patient groups, as well as other disciplines. One of RAC's early responsibilities was to draft the 1976 *NIH Guidelines for Research Involving Recombinant DNA Molecules*. Currently, RAC is positioned within NIH's Office of Biotechnology Activities and is responsible for securing that safe and ethical conduct of NIH-funded human gene therapy experiments.

The launch of the Human Genome Project (HGP) in 1989 brought with it another institutionalized mechanism for considering the ethical aspects of biotechnology. This was the Ethical, Legal, and Social Issues (ELSI) program, jointly administered by the National Human Genome Research Institute and the Department of Energy. ELSI used from 3 to 5 percent of the funds set aside for the HGP to examine issues arising from that program's goals, processes, products, and applications in medicine and health care.

For nearly a decade, ELSI operated under the general guidance of the ELSI Working Group, a 15-member body composed of experts and stakeholders from academic medicine, government, patient organizations, and the private sector. In 1997, following an external review of the ELSI program, the Working Group was replaced with a new body, the ELSI Research Planning and Evaluation Group (ERPEG), headed by the well-known bioethicist LeRoy Walters. In turn, ERPEG was disbanded in 2000, upon submission of its final report, and responsibilities for ELSI advice were thereafter independently administered by NIH and DOE.

As a component of the HGP, ELSI research focused primarily on questions related to the human applications of biotechnology.[35] At the same time, as the world's best-funded and most visible bioethics program, ELSI also began serving as a model for other countries. The idea of conducting systematic ethical analysis side by side with rapidly developing areas of science and technology caught on, and expanded to include topics beyond those on the U.S. ELSI research agenda.

The Canadian response deserves particular attention in the context of this report. In 2000, an independent, not-for-profit corporation, Genome Canada, was established with the mission to make Canada a world leader in selected areas of genomic and proteomic research. The organization funds not only scientific research, but also concurrent research on the social dimensions of genomics through its GE^{3}LS (Genomics, Ethics, Environment, Ethics, Law, Society) program. One objective of the program is to ensure that Canada will actively promote GE^{3}LS research as an integral part of its scientific projects. Though Genome Canada intends to work with existing bodies, such as the Canadian Council for Animal Care (CCAC), GE^{3}LS's goal is to sponsor research that goes beyond simply meeting regulatory requirements.[36]

CCAC is the agency responsible for maintaining standards for the care and use of experimental animals throughout Canada. Its scientific subcommittee develops guidelines on issues of emerging concern. In 1989, CCAC issued a statement on the Ethics of Animal Investigation, governed by the following overarching principle: "The use of animals in research, teaching, and testing is acceptable ONLY if it promises to contribute to understanding of fundamental biological principles, or to the development of knowledge that can reasonably be expected to benefit humans or animals." In keeping with this aim, CCAC requires all animal researchers to adhere to the Russell-Burch "three R's." As a Canadian agency, CCAC is particularly sensitive to national research interests, and that concern informed the agency's decision to develop a guideline for fish in 1996. The following extract illustrates the agency's approach to scientific uncertainty and to the relationship between ethics and science:

> During the development of these guidelines, questions concerning the capacity of fishes to experience any of the adverse states usually associated with pain in mammals were under debate in the scientific literature. *The CCAC subcommittee on fish adopted a precautionary approach in development of these guidelines, recognizing that fishes have the potential to experience pain and manipulations that provoke stress or avoidance/escape behavior may be causes of distress. Therefore the guidelines both support the leadership role that Canadians play in fish research, and ensure that the welfare of fishes is carefully considered, recognizing that better welfare will result in better science* [emphasis added].

In 1997, CCAC issued guidelines specifically governing the creation and use of transgenic animals, supplementing earlier general guidelines on animal care. Overall, CCAC endorsed the creation of such animals partly on the ground that they help satisfy the "three R" principles of replacement and reduction: mouse models may obviate the need to use more sentient species; animals bred with greater specificity as models (e.g., the oncomouse) may reduce the use of animals in research. Partly, also, CCAC approved the genetic modification of livestock as a possible benefit to human health. On the side of risks, the guidelines aim particularly to assure containment, thereby controlling against the possibility of unintended releases into the environment, and monitoring to detect unexpected distress or survival problems in animals created through genetic modification.

Courts

The power of courts to affect public policy derives from their institutional responsibility to interpret the law in the light of changing social circumstances. That source of authority, however, is also a constraint, since courts may not make law or policy on their own; they are restricted to formulating decisions that simply interpret what the legislature has written. Technological change has created particular challenges for courts, requiring them to construe statutory language in relation to specific fact situations that legislatures have not contemplated. An example is the patent law of the United States and Canada, whose text goes back to a 1790 U.S. statute substantially redrafted by Thomas Jefferson in 1793. The law defines patentable subject matter (i.e., what *can* be patented) as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." In 1980, the U.S. Supreme Court was asked to decide whether that language allowed the patenting of living organisms, and in the landmark case of *Diamond v. Chakrabarty*,[37] a 5-4 majority of the Court held that it did.

The *Chakrabarty* court's reasoning adopted a "but-for" logic that is commonly taught in legal education and is often used to make causal arguments, as follows: an act A causes an effect B if B would not have happened *but for* A. In *Chakrabarty*, the Court adopted a similar logic to determine what constitutes a patentable invention. Referring back to a congressional report reauthorizing the

law, the Court reaffirmed that patents may be granted on "anything under the sun that is made by man."[38] In this case, the inventor, Ananda Chakrabarty, was seeking a patent on a bacterium produced in his laboratory containing genes from several different plasmids. Since this organism could not have existed in nature without Chakrabarty's mediating ingenuity, it met the Court's test of patentability. The decision paved the way for patenting all life forms, including higher animals such as mice, pigs, and cows, some engineered to contain human genes and cells.

A Canadian Supreme Court decision of 2002, interpreting virtually the same statutory language as in the United States, shows that it is not the structure of judicial reasoning in and of itself that enforces particular interpretations of the law.[39] The case involved a patent application on a mouse genetically engineered at Harvard University to be more susceptible to cancer, and therefore of value in cancer testing. The oncomouse had received a U.S. patent in 1988, under the authority of *Chakrabarty*, and had subsequently been patented in Europe and several other industrial countries. The Canadian court, however, refused the patent claim, indicating that there was a difference in kind between micro-organisms (legally patentable in Canada) and higher animals. That distinction, the court held, needed to be evaluated by the legislature. If patents were to be granted on higher organisms, it would be up to parliament to say so explicitly.

Timing was important to the outcome in the Canadian case. By 2002, some of the Canadian jurists clearly felt that the specter of a slippery slope, possibly even leading to the commodification of humans, was more real than it had seemed to the U.S. justices in 1980. Allowing patents on higher organisms, the Canadian majority concluded, would create problems in a time when the boundary between animals and humans was becoming blurred through biomedical advances such as xenotransplantation. As Justice Bastarache wrote for the majority: "The pig receives human genes. The human receives pig organs. Where does the pig end and the human begin?" In such an environment, it was imperative for lines to be redrawn and clarified through legislative action. "In my view," Bastarache observed, "it is not an appropriate function for the courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded." [40]

For the four Canadian dissenters, who in essence followed *Chakrabarty*'s logic, classifying the oncomouse as a composition of matter was thoroughly unproblematic because every cell in its body had been changed through the addition of an oncogene ("the oncogene is everywhere in the genetically modified oncomouse, and it is this important modification that is said to give the oncomouse its commercial value"[41]). By contrast, Justice Bastarache, writing for the majority, was substantially less persuaded about the inventor's degree of control over the whole mouse. To him, it was almost common sense that altering one small bit of a complex organism's genetic code does not produce an altogether different entity, a human invention that is no longer natural.

The analysis is instructive, both as a philosophical text and because of its contrast with the linear reasoning employed by the *Chakrabarty* court:

> Although some in society may hold the view that higher life forms are mere "composition[s] of matter", the phrase does not fit well with common understandings of human and animal life. Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed. A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer. *The fact that it has this predisposition to cancer that makes it valuable to humans does not mean that the mouse, along with other animal life forms, can be defined solely with reference to the genetic matter of which it is composed*. The fact that animal life forms have

> numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere "composition[s] of matter". It is a phrase that seems inadequate as a description of a higher life form [emphasis added].[42]

In this way, the Canadian court rejected the logic that had, in the United States, rendered irrelevant whether the container of a patentable genetic trait is a mouse or a micro-organism.

Independent Professional Organizations

Independent scientific and ethical bodies, often drawn from professional elites, have made significant, and in some cases authoritative, contributions to thinking about biotechnological research with animals. Scientific societies such as the U.S. National Academy of Sciences or Britain's Royal Society involve themselves in ethical matters both from a sense of responsibility for the products of science and technology, and from a desire to protect the scientific community against real or imagined charges of lack of concern for public safety, or abuses of human or animal experimental subjects in research.

The National Academy of Sciences, founded in 1863, is one of the oldest and most respected scientific societies in the world. Through its various operating arms, most importantly the National Research Council, the NAS seeks to live up to its self-characterization as "advisers to the nation on science, engineering, and medicine." The Academy's reputation rests on the quality of its scientific findings, and concern to safeguard that reputation dominates the framing, conduct, and review of all Academy studies. Study committees are constituted in a balanced fashion so as to be free from obvious partisan leanings, each committee member is subjected to a public declaration of possible conflicts of interest, and extraordinary care is taken to ensure thorough and critical peer review of all Academy publications.

The 2002 report on animal biotechnology reflects the Academy's primary focus on science and scientific credibility.[43] In what is perceived as a morally contested field, the study sought to limit itself to just those issues that could be addressed on the basis of science. Significantly, ethical concerns received only fleeting mention toward the end of a chapter dealing with scientific uncertainty, policy context, institutional capacity, and social implications. Even then, the report observed that ethical concerns can neither be resolved completely through scientific debate nor separated cleanly from scientific concerns. Therefore, the report concluded, "a strong case can be made that the ethical assumptions underlying a research initiative or the application of a technology should be made explicit."[44]

By contrast, Britain's Nuffield Council on Bioethics offers a rare example of a private body conducting ethical deliberations with significant influence on public policy thinking, if not outcomes. The Nuffield Foundation established this body in 1991, in response to a perceived need for high-level ethical deliberation on issues arising from the life sciences, and after it became clear that the U.K. government would not go the way of the United States, France, or other European countries in appointing a national ethics commission, with official responsibility to inform and advise the government. Funding for the Council comes from the parent foundation, the Medical Research Council, and the Wellcome Trust, Britain's largest private funder of biomedical research. The Council's 15 members represent the intellectual and professional elite and are selected from relevant fields, including law, philosophy, anthropology, science, and theology.

Between 2003–2005, the Council addressed issues of research ethics involving animals.[45] The authors rejected the idea that the moral status of animals can be distinguished from that of humans through a single ordering principle (e.g., the clear-line view; the moral sliding scale view; the moral

equality view[46]). Instead, the report identified five separate morally relevant features that may have implications for the treatment of animals in research:

- sentience
- higher cognitive capacities
- capacity to flourish
- sociability
- possession of a life.[47]

The report made a number of recommendations mainly aimed at improving the conditions in which animals are used for research. While there were significant philosophical differences within the group—ranging from overall acceptance of the benefits of animal research to opposition to research on sentient animals—the report did not dwell on these differences. Instead, without attributing agreement to all members of the group, the report sought to make recommendations that all members accepted as valid contributions, clarifying important points in the debate. Through this working agreement, the Council split off potentially contentious positions on animal rights from a strong consensus that steps should be taken to improve the lot of experimental animals.

University Committees/IRBs

As the primary sites of ground-breaking research in the life sciences, universities are often also on the frontlines of ethically questionable research. It is in the academic research context that new biological entities are often created (e.g., the oncomouse or human embryonic stem cells), raising questions about the moral status of things not previously encountered in the world. Universities, acting alone or in consortia (as in the case of the Russell-Burch study), are responsible both for examining the ethical issues surrounding new developments and for assuring ongoing adherence to regulatory requirements and principles of care in research involving animals. The former responsibility is addressed by ad hoc committees, while the latter is channeled through standing committees for animal care and welfare. Both types of bodies have taken on board particular questions related to animal biotechnology.

Ethical aspects of research on the frontiers of biotechnology are sometimes addressed almost by chance. A recent example is the recommendation developed by several Stanford professors, led by Henry Greely at Stanford Law School, about Irving Weissman's research involving the transplantation of human nerve cells into mouse brains.[48] Weissman's ultimate object is to produce a mouse model as a platform for drug testing and other research on human brain cells, but without using actual human subjects. Greely took on the task of ethical evaluation at Weissman's request and called on four additional faculty members to help him. The deliberations of this hastily put together committee touched on some of the deepest philosophical questions about human consciousness. The group had to consider the relationship between the architecture of the human brain and the biological materials it is composed of, the likely results of transposing human neurons into the architecture of a mouse brain, the signs that might indicate mouse-like or non-mouse-like developments in the mouse brain, and the actions that would be appropriate if experimental mice began displaying non-mouse cognitive functions. In effect, a self-appointed group of five highly accomplished academics took up the challenge of addressing one of philosophy's most enduring questions; what is the nature of human sentience, and how does it differ from that of non-humans? In the process they also established ethical principles for a frontier area of animal biotechnology at one of the nation's premier research universities.

Institutional Review Boards (IRBs) at all research universities review proposed studies for conformity with ethical requirements. IRBs also ensure sustained attention to the welfare of animals used in scientific experiments. If a study involves animal subjects, the researcher has to obtain approval from the local IRB, which reviews the study protocol to ensure that it meets applicable criteria for the care and ethical use of animals. IRBs make threshold decisions about what counts as an animal in the first place, and non-vertebrates are typically excluded from the view. The reviewers' primary concern is to make sure that the researcher not only complies with regulatory requirements, but has also thought through what to do if research animals escape, become diseased, or show signs of unusual or unexpected distress. In general the legitimacy of a proposal depends on its being adequately grounded in the relevant scientific literature. Researchers typically have to demonstrate that study results will advance human knowledge and not impose unnecessary or undue burdens on the animal subjects.

Some IRBs require special approval for studies that involve transgenic animals. At MIT, for instance, the IRB approval process for research involving transgenics calls for a high degree of specificity, on-going monitoring, and reporting of any unexpected results. The application form also stresses the need for explicit, scientifically grounded euthanasia criteria.

Industry Non-Governmental Organizations

In recent years, many biotechnology companies have developed an in-house ethics capability to respond to perceived public concerns about genetic research, including controversial areas of research involving animals, chimeras, human embryos, and stem cells. As a trade association representing (and lobbying for) more than a thousand biotech companies in the United States and 33 other nations, the Washington-based Biotechnology Industry Organization (BIO), formed in 1993, deserves special attention.[49] BIO's standing, board-of-directors level Bioethics Committee, composed of employees of BIO members, is committed to socially responsible uses of biotechnology, including principles that provide guidance going beyond legal requirements. Through quarterly meetings, as well as ad hoc meetings of committees and working groups, the Bioethics Committee addresses issues of current concern to members and the public.

Interestingly, BIO assimilates its concern for ethics to that of the molecular biologists who organized the Asilomar conference leading to the first controls on biotechnology. A segment on ethics in BIO's Guide to Biotechnology seamlessly segues from Asilomar and the formation of RAC within NIH to the birth and advance of the biotech industry:

> During the early 1980s, as the biotechnology industry moved from basic research into product development, the RAC assumed the responsibility of formulating safety standards for industrial manufacturing using recombinant organisms and reviewed proposals voluntarily submitted by companies such as Genentech and Eli Lilly.[50]

BIO thus represents its own thinking about bioethics as a continuation of the "thoughtful, responsible and very public introduction of and discussion" about biotechnology initiated by the academic scientific community.[51]

Among the key points on animals used in research, BIO states: "Animals enhanced or bred through biotechnology techniques eat, drink and behave similarly to their conventional counterparts."[52] BIO's statement of ethical principles for the use of animals in research flags six major principles: humane treatment; judicious use (essentially a restatement of the "three R's"); high standards of care; regulatory oversight; increased public awareness (i.e., of the benefits of research involving animals); and open discussion of ethical considerations.

Non-Industry Non-Governmental Organizations

Non-governmental organizations (NGOs) play an extremely prominent part in framing ethical debates about animals, including issues specific to animal biotechnology. On the whole, these groups represent a more comprehensive view both about the category "animals of concern" and of the ethical issues about which we as moral beings ought to be concerned. For example, American Humane Association, an organization devoted to the humane treatment of animals in film-making, insisted that rubber flies be swatted, instead of real ones, in the 2003 version of the Western, Monte Walsh.[53] Two NGOs are considered here to illustrate the range of concerns expressed by animal rights and animal welfare groups. Both are membership organizations, funded by public donations and are run as not-for-profit bodies.

The New England Anti-Vivisection Society (NEAVS) was founded in Boston in 1895. The society was in part a reaction against scientific medicine and its vivisection laboratories established by institutions like Harvard University in the final decades of the 19th century. As the society's website states, its goal from the beginning was "to expose and oppose secret or painful experiments upon living animals, lunatics, paupers or criminals." The society's members believed that once citizens were educated about the animals' plight, they would demand laws to prohibit vivisection. The society began to flourish in the second decade of the 20th century, publishing a journal that advanced its aim to educate the public. Today NEAVS is actively involved in the protection of animals, and its educational initiatives and publications continue to expose the cruel and inhumane treatment of animals.

NEAVS's understanding of appropriate treatment goes beyond traditional standards of animal welfare to incorporate something resembling a concept of animal dignity. In its campaign against industrialized chicken farming, for example, NEAVS cites the *Baltimore Sun* reporter Robert Burruss's horrific vision of headless chickens serving as egg factories, being kept alive on industrial-size heart-lung machines. The Society also takes issue with the suggestion that chickens bred to be blind might not mind being cooped up in close quarters as much as chickens with ordinary sight.[54] Running through the Society's campaign on chickens is a concern to protect the place of animals in a perceived moral order that grants even chickens a right not to be overproduced, objectified, or manipulated beyond natural limits for purposes of human consumption.

The British anti-vivisection society Uncaged defines itself as much by its style of intervening on behalf of animals as by its choice of campaign targets. Representing itself as a holistic organization, Uncaged stresses that it "operate[s] at every level, from grassroots protests to motions in Parliament, through to participation in academic discourse."[55] As illustration, Uncaged calls attention to its web-based publication, *Diaries of Despair*, which documents alleged abuses of animals in xeno-transplantation experiments conducted at the Huntingdon Life Sciences laboratories.[56] The organization represents itself as working in the public interest, in the tradition of investigative journalism, uncovering evidence that a government-industry-university coalition sought to keep secret. It is perhaps not far-fetched to see in Uncaged's activities an emerging form of virtual global citizenship on behalf of hitherto unrepresented animal rights.

Conclusions

OUR REVIEW OF institutional approaches to ethical deliberation around animal biotechnology, including GM animals produced for food, suggests that the last few years have seen an intensification and spread of ethical concerns across Western (as well as non-Western, see Appendix 2) societies. Table 1 provides an overview of the main institutional types, along with their sources of authority, their organization, their objectives, and their products. Table 2 gives a rough indication of which issues each type of institution sees as central to its mission. The following preliminary conclusions emerge from this survey:

- The ethics of animal use is a pervasive concern in contemporary society, cutting across all sectors: government, industry, academia, and the public. Older concerns for animal welfare have expanded to include newer concerns about the disruption or infringement of the moral order.
- Genetic sciences and technologies have raised new ethical concerns, arising from the possibilities of intensifying industrial practices in agriculture, reducing diversity, and creating new entities that cross species lines.
- Frequently expressed ethical concerns arise both from a growing perception of the genetic and moral likeness between human and non-human animals, and a growing sense of unlikeness arising from new possibilities for manipulating animal genomes, designing them, and making them function more like utilitarian objects.
- The nature of deliberative institutions affects the range and kinds of ethical issues that can be raised, because institutions inevitably exclude some matters from debate, specify the languages or discourses in which issues may be raised, and delimit the scope of allowable participation by citizens and laypersons. A few further generalizations emerge from our survey:
    - Ethics committees and NGOs address a broader spectrum of issues than scientific and regulatory ones.
    - Formal institutional discourses (e.g., law, science) effectively rule some ethical issues out of bounds, especially those relating to animals in the moral order.
    - Political and scientific bodies do not probe the foundations of competing ethical positions, but prefer to delegate this responsibility.
    - Identification of issues does not necessarily go hand in hand with resolving them (e.g., OTA; courts, through their inability to make law).
- A comparison of institutions responsible for animal bioethics in the United States, Britain, Canada, Germany, and South Korea suggests that culture may play as important a role, or even a more important role, than institutional forms in shaping ethical debates around animal biotechnology. The contrast between the U.S. and Canadian court cases on animal patenting offers one illustration. Equally, examples from varied countries suggest that background traditions of public reasoning and public participation may significantly affect the range of issues that are considered in legal and policy debates. In particular, the extent to which questions regarding animal biotechnology and the moral order have been broached in public appears to reflect

cultural differences in drawing boundaries between science, ethics, and related concerns such as economics and the environment. On the whole, U.S. institutions appear to draw the sharpest boundaries at all levels of decisionmaking (legislatures, agencies, courts, and other deliberative bodies). Arguably, this tendency prevents meaningful negotiation between publics, especially animal rights groups, and experts.

- Ethical deliberations no longer take place exclusively in the formal institutions of government, such as legislatures, regulatory agencies, or courts. Increasingly, the internet is providing an independent forum for airing ethical concerns. This new, virtual space possesses unique properties as an arena for public debate: it provides access for views, and viewers, that may be excluded from, or refuse to participate in, elite and professional forums; it permits a mixing of rational and emotive registers; it allows the use of potentially powerful visual imagery (e.g., the *Diaries of Despair* released by Uncage). The implications for bioethics, and for democracy, of this revolution in the forms and processes of communication and participation deserve deeper study.

Tables

TABLE 1

Structure and Mandates of Deliberative Institutions
(United States, UK, Canada)

	Authorization	**Organization**	**Objectives**	**Products**
Legislative advisory body (OTA)	National law	Political governing board; independent expert staff	Weigh policy alternatives; inform Congress of options	Reports, background papers
National Ethics Commissions (NBAC, PCB)	Presidential order	Appointed experts and stakeholders	Conduct ethical assessments	Reports, meetings and transcripts
Executive agency/ advisory committee (ELSI, GE3LS, CCAC)	National law or policy; agency decision	Appointed experts and stakeholders	Review state of science and ethics; commission research	Guidelines, regulations, consensus exercises
Court	**Constitution**	**Appointed judiciary**	**Interpret the law**	**Judicial decisions**
Independent professional organization (NAS/NRC; Nuffield)	Public charter or not-for-profit trust	Membership by invitation	Offer impartial, high-quality information and advice	Reports, recommendations
University committee, IRB	Research policy or law	Disciplinary scientists, lay experts	Review merits of research proposals	Decisions to approve, deny, modify
Industry non-governmental organization (BIO)	Voluntary	Selected experts	Identify and advocate for industry positions	Reports, educational materials
Non-industry non-governmental organization (NEAVS, Uncage)	Voluntary	Membership organization	Represent and advocate for pro-animal interests	Campaigns, educational and promotional publications

TABLE 2

Deliberative Institutions and Ethical Frames
(United States, UK, Canada)

Ethical Frame / Type of Institution	Animal Welfare		Risk		Moral Order	
	Pain and Suffering	Costs/ Benefits	Risks to Health	Risks to Environment	Mechanization	Unnatural Creation
Legislative advisory body		X	X	X		
National ethics commission	X	?	X	X	X	X
Executive agency/ advisory committee	X	X	X	X		
Court			X	X	X	?
Independent science organization: NAS	X	X	X	X		
Independent ethics organization: Nuffield Council	X	?	X	X	X	X
University committee, IRB	X	X (in science)	X	X		
Industry non-governmental organization	X	X (mainly benefits)	X	X		
Non-industry non-governmental organization	X	X	X	X	X	X

APPENDIX 1

Animal Biotechnology and Ethics in Germany

From Welfare to Constitutional Recognition

Among European nations, Germany has long played a leading role in protecting animals. On the whole, animals have received increasing protection under German law over the past three decades. This movement reflects a growing consensus that animals, as sentient beings, have particular claims on human sympathy.

Animal welfare legislation, prohibiting the public mistreatment of animals, goes back in Germany to the late 19th century, shortly after the founding of the modern state. The issue surfaced again early in the period of Nazi rule. In early 1933, the legislature criminalized kosher slaughtering practices as animal torture, and later that year incorporated this prohibition into the *Reichstierschutzgesetz*, a sweeping law protecting animals. While reaffirming the human commitment to the care of weaker species, this legislation also furthered the state goal of hindering Jewish religious practices.

After the war, the *Reichstierschutzgesetz* remained largely intact, but the place of animals in human lives and consciousness changed. Where before animals had a visible place as working animals, changes in agricultural and research practices introduced new animal living conditions on secluded farms and in closed laboratories. When these often-atrocious living conditions came to public awareness, the Animal Protection Law (*Tierschutzgesetz*) was passed in 1972 to expand the zone of human responsibility, including the use of animals in research, and to "protect the life and well-being of animals as part of humans' responsibility for their fellow creatures." Article 1 of the law states that "no one may inflict pain, suffering, or damage on an animal without good reason" (*ohne vernünftigen Grund*).

Like most German legislation, this law was a careful compromise designed to reconcile the aims of the animal protection lobby with those of the nation's powerful pharma and agricultural industries. It also marked a transformation in the basis for animal rights—away from emotional sympathy pure and simple (e.g., for workhorses) toward a more rational, possibly scientific assessment of all animals' potential for pain or distress (including lab and farm animals).

Ever since the writing of Germany's postwar constitution in 1949, animal protection groups had called for giving animals constitutional recognition. In 1990, the German Civil Code was amended to state, in Paragraph 90a, that animals are not things, but that for legal purposes (buying, selling, etc.) they may be treated like things. While some saw this as a sufficient move toward recognizing animals as having consciousness, and hence entitlement to respect from humans, others saw a fundamental conflict between the idea that animals are "fellow creatures," as the Animal Protection Law put it, and the factual treatment of animals in research, during long-distance transport, and in general animal care.

Over the following decade, Germans continued to debate whether animal rights should receive constitutional status. The Basic Law of 1949 had protected animals only implicitly, as part of the environment, and as members of their respective species, but it did not protect animals from pain and suffering. Since basic rights may be constrained only when they collide with other basic rights, the protection of animals was constitutionally weak. The coalition of Social Democrats and Greens governing Germany at the turn of the

century moved to remedy this perceived weakness in the law. In mid-2002, the German parliament voted overwhelmingly in favor of a constitutional amendment to include the protection of animals as a goal of the state. Germany thereby became the first European nation to offer explicit constitutional protection to animals.[57] Article 20a now reads, "The state takes responsibility for protecting the natural foundations of life (*natürlichen Lebensgrundlagen*) *and animals* in the interest of future generations" [emphasis added]. The amendment did not place animal protection above the state's other basic obligations, but it made animal rights a constitutional good that (for example) courts must take into consideration when deciding on issues where basic rights are in conflict.

A test of the amendment's reach quickly came before the Constitutional Court when it was confronted with the issue of *Schächten*, or ritual slaughter, in 2002. The court decided that a Muslim butcher was permitted to slaughter sacrificial animals without anesthesia, in accordance with religious custom. The constitutionally protected freedom of religion won out in this case against the state goal of animal protection. The court was also influenced by an equal protection argument, since Jewish butchers had been granted a specific exemption from the 1972 Animal Protection Law, allowing them to slaughter animals in virtually the same way that was being denied to their Muslim counterparts.

Advisory Committees

PARLIAMENTARY INQUIRY COMMISSIONS (ENQUETE KOMMISSION)

Parliament has the constitutional power to appoint so-called inquiry commissions to help it in reaching difficult political decisions, and these can offer a forum for deliberating controversial ethical issues. Germany is normally governed by a coalition of parties, and the appointment of inquiry commissions can be a significant negotiating factor in building coalitions.

These commissions are distinctive in two ways. First, they are composed of an equal number of members of parliament and of experts from outside the domain of politics. In that sense, they represent an integration of science and politics. Second, they are multi-party commissions; they contain representatives from each party based on that party's strength in parliament. Each party then gets to appoint a proportionate number of experts of its choice and, most often, its reasoned position. The composition of inquiry commissions thus represents, in miniature, the same political make-up as parliament as a whole. Moreover, every member of an inquiry commission has an appointed substitute, in case the primary representative is unable to attend a meeting. These two features together highlight a pronounced feature of German politics, namely that in political decisions the views of all established players need to be taken into account. The insistence on substitutes in advisory committees underscores the need to make sure that all voices can be heard at all times.[58]

One particularly influential commission was the *Enquete Kommission Chancen und Risiken der Gentechnologie*. Appointed in 1986, the commission issued a report that laid the basis for Germany's Genetic Engineering Law of 1990.[59] The report illustrates the risks as well as benefits of tying public ethical deliberation to the political process. Unusually for reports of German inquiry commissions, this 1987 report contained a lengthy dissent by the Green Party, which had recently gained entry into the Bundestag. While the Green position statement brought to light fundamental value conflicts that remained latent in the U.S. political system,[60] it also prevented a reasoned consensus from developing around fundamentally contested issues. A case in point is the treatment of the possible slippery slope from animal to human genetic manipulation.

The majority report saw no particular risks to humans from then available procedures for genetic manipulation of livestock. They noted that techniques such as *in vitro* fertilization had first been tried on mouse models and then transferred to humans. In their imagination, this pathway did not set precedents for similar transposition to humans of techniques used primarily to improve the genetic make-up of livestock. Mice

may have served as models for humans in reproductive research; this did not mean, to the majority, that cows used in agricultural research would also serve as models for humans. By contrast, the Greens saw genetic manipulation in more seamless terms, arguing that animal manipulation inevitably would open up the way to manipulation of humans.[61]

NATIONAL ETHICS COUNCIL (NATIONALER ETHIKRAT)

Generally, the German executive has not sought independent ethical advice, but in 2001, amid great controversy over the ethics of stem cell research, then-Chancellor Gerhard Schröder appointed the National Ethics Council (NER), a highly visible and well-endowed committee composed of 25 well-known experts (including Christiane Nüsslein-Volhard, Germany's only recent Nobel laureate in the life sciences) and stakeholder representatives. This large, multipartite body represented almost a microcosm of German society and sought to include all possible ethical positions with regard to stem cells. Nevertheless, Schröder was widely criticized for what many saw as an attempt to sidestep, and possibly undermine, parliament's supreme authority in making decisions of national moral significance.

The NER has interpreted its mandate narrowly as including only issues involving human biology. In a radio interview of 2006, NER president, Kristiane Weber-Hassemer, stated that "we are not responsible for animal protection and also not for plants."[62]

BÜRO FÜR TECHNIKFOLGENABSCHÄTZUNG

The German Office for Technology Assessment (*Büro für Technikfolgen-Abschätzung*, or *TAB*) was appointed in 1990, on the model of the U.S. OTA, to provide information to Parliament with regard to decisions related to research and technology. Besides formulating and conducting projects that assess the consequences of technological developments, the TAB's mandate is to observe and analyze trends in science and technology, and their consequences for societal development. These research and monitoring functions are aimed at analyzing the potential of such developments, at investigating their environmental consequences, at analyzing the legal, economic and social frameworks necessary for realizing the benefits of technology, and at offering alterative courses of action for political decisionmakers.

The TAB satisfies the informational needs of Parliament, and its tasks are specified solely from the Parliamentary Committee on Education, Research, and Technology Assessment (*Ausschuss für Bildung, Forschung, und Technikfolgenabschätzung*). Between 1990 and 2006 the TAB published more than 100 reports, which varied in length from less than 50 pages to more than 300 pages. In addition the TAB has published several dozen lengthy background and discussion papers, as well as a number of books.

In 1997, TAB was asked to produce a report on animal cloning. TAB concluded that it would be too restrictive to limit the report to the technical, medical, and economic aspects of animal cloning. Instead, the report also chose to address whether animal cloning was adequately governed by law in Germany, and whether it should be subject to legal restrictions or even a ban. The report concluded that there were no principled constitutional barriers to animal cloning, and that cloning could be prohibited under the Animal Protection Law only if it caused substantial and measurable distress to the animal.

Experimental Animals

As in other industrial countries, animal research in Germany is a regulated process that requires the approval of specially constituted advisory commissions (*Tierversuchskommission*). These include lay

members as well as specialists, and applicants are accordingly instructed to present their findings in language accessible to educated laypersons.

An application form used at the Charité Hospital in Berlin includes detailed instructions for applicants. These make it clear, without using the language of "three R's," that research protocols should use vertebrates and higher animals only when research on lower animals is not possible (principle of *replacement*). The level of cerebral development is taken as a surrogate marker for the likelihood that an animal will feel pain. However, computer modeling, frequently mentioned as a substitute for animal use in the U.S. context, is not offered as an explicit alternative. Formal authorization at all points is extremely important for the legitimacy of the German IRB process. The instructions specify, for example, that anesthesia must be administered by appropriately credentialed veterinarians; and vertebrates used for research must be bred in licensed facilities.

As in other national IRB reviews, the science system itself supplies an important dimension of accountability. The need for the study, for instance, has to be justified in detail with reference to the existing scientific literature. Researchers also have to describe how the severity and extent of possible harm to the animals stands in relation to the expected gains in scientific knowledge.

Non-Governmental Organizations

Germany has a varied and highly active range of organizations dedicated to animal welfare and broader issues affecting animals. A group called "Animal Public," for example, is devoted specifically to wild animals, and it seeks to help abused circus animals or exotic pets that have become dangerous. Another group called "Pro Animale" supports efforts to establish farms for old horses and cows that would otherwise be killed. The German Animal Protection Foundation (*Deutscher Tierschutzbund*), was established in 1881 as an umbrella organization to help focus the efforts that smaller organizations make to provide animals with proper living conditions and to spare them suffering. Today it is Europe's largest, uniting 720 local animal protection organizations and more than 500 animal shelters. It has more than 800,000 members in Germany. A small Animal Protection Party has as its primary goal securing more extensive constitutional rights for animals. It stands for recognizing the inseparable unity of humans, animals, and nature, and seeks to grant animals rights that are based on the animals' needs.

Conclusions

Germany, far more than any common-law country, has sought to anchor the status of animals in the law. The preference for establishing moral order through law is now reflected in the nation's Basic Law, which recognizes an affirmative state obligation to protect animals. This can be seen as a victory for pro-animal interests in German politics, and it also reflects a political culture in which any ethical position that can be defended with reason is likely to find a positive reception. In this case, it is significant that it took ten years of deliberation to build support for a two-word constitutional amendment ("and animals"); it is also significant that support, when it crystallized, was almost unopposed.

Even the most political of German institutions, such as the legislature, appear to place a higher value on collective reason than on innovation, especially when new actions might open up gaps or unregulated spaces in the law. This tendency toward inclusiveness perhaps also explains why Germany has been more risk averse with respect to animal genetic modification than some other countries.

APPENDIX 2

Animal Biotechnology and Ethics in South Korea

(contributed by Sang-Hyun Kim)

Ethical concern about animals has developed in South Korea through repeated contact with other countries and advocates of their ethical systems. These interactions have given rise to answering activism and the formation of new social movements in Korea. Debates on animal welfare and on the implications of genetic manipulation have evolved in tandem, but as in the United States and Germany, the institutional consideration of these issues remains for the most part formally separate.

Early History: International Pressure

Until the mid-1980s, public debate on animal protection simply did not exist in South Korea (hereafter Korea). Several laws contained provisions on animal protection and related issues (e.g., the Protection and Hunting of Wild Birds and Animals Act; the Processing of Livestock Products Act), but these laws neither provided a comprehensive legal framework for animal protection nor incorporated concepts of animal rights and welfare.

Pressure from abroad forced the Korean government to pay more attention to animal issues in the 1980s. The cultural practice of eating dog meat became a particular hot button issue, attracting protest and forcing policy change. When it was decided that the 1986 Asian Games and the 1988 Olympics would be held in Seoul, the International Fund for Animal Welfare (IFAW), the World Society for the Protection of Animals (WSPA), and other animal rights groups in the West threatened the Korean government that, unless dog meat eating was banned, they would launch campaigns to boycott the games and Korean products. Fearing negative consequences, in 1984, the Ministry of Health amended the enforcement ordinance of the Food Sanitation Act, designating dog meat as "abominable" food and prohibiting its sale.

Animal Welfare Legislation

The transition from military to civil rule in the late 1980s increased environmental awareness in Korea. With a more open political climate, civic organizations flourished, many of which took a pro-environment stance. A variety of local animal-loving clubs also came into being. In 1990, with the help of IFAW, the Korean Animal Protection Society (KAPS) was founded—the first government-registered animal protection group in Korea.

Again, international pressure spurred the government into further action. In 1988, as the Seoul Olympics approached and protests mounted from animal rights groups abroad, the Korean government promised that a new law protecting animals would soon be drafted, but inaction continued after the Olympics, and even the 1984 ban on the sale of dog meat no longer seemed to be in effect. As a result, tens of thousands protest letters continued to pour into Korean embassies in Europe and the US. In late 1989, when Korean

president Roh Tae-Woo visited the Queen of England, IFAW and other animal rights groups organized demonstrations outside Buckingham Palace, creating a public relations fiasco. Korean bureaucrats increasingly felt that animal issues could pose serious problems for the nation's trade and diplomacy. In 1991, the Ministry of Agriculture finally introduced the Animal Protection Act.

The Animal Protection Act had little impact. While prohibiting cruelty to animals, its 12 articles were quite short and vague. It had a very weak penalty provision, which was rarely enforced (only a couple of cases were reported between 1991 and 2001). Not surprisingly, IFAW and other international animal rights groups continued their campaigns against animal cruelty in Korea throughout the 1990s. The Natural Environmental Conservation Act was more detailed and comprehensive, but the Korean government was likewise reluctant to strictly implement the Act. And in 1992, the National Wildlife Federation and the World Wildlife Foundation-U.S. jointly filed a Pelly Amendment petition to impose trade sanctions against Korea for trading rhinoceros horns and tiger bones.

New Social Movements and Legislative Reform

New animal protection groups that emerged in 1999 and the early 2000s differed from the Korean Animal Protection Society (KAPS) and other animal loving clubs in salient ways. They wanted to broaden the scope of animal activism by employing the concepts of "animal rights" and "animal welfare," and by looking at not just pet/companion animals but also farm, wild and experimental animals.

A case in point was their involvement in the controversy surrounding the draft bill on bioethics. In 2001, after lengthy discussions, the Korean Bioethics Advisory Commission (KBAC) drafted the Framework Act on Bioethics. The KBAC involved some of the most vocal critics of the government's handling of biosafety and bioethics issues, and its proposal was seen as a progress by many environmental activists (although it was opposed by scientists and bio-industry and was eventually rejected by the government). The new animal rights activists regarded biotechnology as an important area of concern. These groups initially supported the KBAC's efforts in the hope that the issues of experimental animals and animal patents would be taken into consideration. Later, however, (led by the Forum Against Cruelty to Life Forms) they strongly criticized the KBAC for ignoring the rights and welfare of transgenic and disease-model animals.

In 2002, in order to alleviate negative perceptions of Korea, the Ministry of Agriculture attempted to amend the Animal Protection Act. Animal protection groups viewed these measures as a positive step, but far from sufficient. For KAPS, the most serious problem was the Ministry's attempt to introduce the definition of "pet animals." Article 2 of the amendment defined pet animals as "cats, dogs, and other animals designated by the enforcement ordinance of the Act that are raised for the purpose of companionship and emotional development." KAPS suspected that such a definition would legitimize the distinction between "pet dogs" and "food dogs," thereby opening the way for the legalization of dog meat. Also, the amended article on the prohibition of cruelty to animals still contained the phrase "without a rational reason." The KAPS feared that this would neutralize the entire article since raising and slaughtering dogs for food purpose could easily be interpreted as "rational."

The new animal groups shared the view that the Ministry's amendment might lead to the legalization of dog meat, and closely worked with the KAPS to campaign against it. However, they had a broader objective than stopping dog meat consumption, and proposed their own alternative amendment, with the following proposed changes:

- The Act should not only protect the lives and safety of animals but also ensure their welfare;
- In addition to pet/companion animals, both farm and experimental animals should also be defined in detail;

- The definition of animals should not be confined to mammals but include a range of non-mammalian vertebrate species (and even some of invertebrate cephalopods in the case of experimental animals);
- "Cruelty" should be defined as the infliction of unnecessary or avoidable pain to animals (as well as negligence about their suffering);
- The prohibition of cruelty to animals should be extended to all animals—pet/companion, farm, wild, and experimental animals;
- A national animal welfare/ethics commission should be established under the Ministry of Agriculture, and should include representatives of civic groups;
- Local governments should establish animal experiment ethics committees to monitor and approve animal experiments in the respective regions, and again should include representatives of civic groups;
- Certain animal experiments should be banned outright—for instance, the production of transgenic animals for the pet market, and smoking experiments on animals.

The two parties were not able to reach consensus, and animal rights activists condemned the Ministry for not making sufficient efforts. But the resulting, new amendment accommodated some of the requests from animal groups. For instance,

- the objective included the phrase "promotion of animal welfare";
- the duties of the government and citizens to protect animals were stipulated;
- the definition of cruelty to animals was expanded (e.g., the phrase "rational reason" was replaced by "just reason"), and types of cruelty were specified in more detail;
- the prohibition of cruelty to animals was extended to farm and experimental animals;
- ethical principles of animal experimentation were delineated;
- the establishment of animal experiment ethics committee was introduced (though at the level of research institutes);
- an inspectorate for animal protection was introduced;
- the penalty provision was strengthened.

Interestingly, criticism also came from the Ministry of Health and Social Welfare, especially the Korean Food and Drug Administration (KFDA). It was estimated that more than 5 million experimental animals were used every year in Korea, but only five research institutes were certified by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). The KFDA argued that the Ministry of Agriculture did not have sufficient technical expertise to handle the issues involving experimental animals, and that, if animal experimentation were regulated by the Animal Protection Act, it might deter the competitiveness of Korea's biomedical research. In the end, a compromise was made between the two ministries: animal experimentation would be regulated by the Animal Protection Act, but related facilities would be under the KFDA's jurisdiction. Currently, it is expected that the Ministry of Agriculture's latest amendment of the Animal Protection Act would be ratified by the National Assembly sometime later this year. But sources of controversy still remain, and it is not yet clear what will happen next.

Experimental Animals

At present, there is practically no national regulation on animal experimentation in South Korea. The Animal Protection Act (Article 10) states experiments causing pain to animals should be avoided as much as possible, and that animals in chronic pain as a result of experimentation should be put to death as quickly as painlessly as possible. No other provisions regarding experimental animals exist.

In 2001, the survey by the Korean Food and Drug Administration (KFDA)'s National Institute of Toxicological Research suggested that 40% of the universities, hospitals and research institutes conducting animal experimentation did not have related guidelines, and that only 22% had an Institutional Animal Care and Use Committee. By 2005, the KFDA estimated that more than 930 institutions used over 5 million animals a year in South Korea, but that a significant portion still did not have proper guidelines for animal experimentation. In its latest (2005) amendment of Animal Protection Act, the Ministry of Agriculture sought to strengthen the Act's Article 10. This amendment is expected to be ratified later this year and come into force sometime in 2007. The first paragraph of the amended Article 10 lays down the principles of animal experimentation, which follow the Russell-Burch "three R" tenet (replace-reduce-refine).

There is considerable overlap between these amendments and the new bill drafted by the KFDA and the KALAS. Like the 2005 amendment of Animal Protection Act, the KFDA-KALAS draft stipulates the three-R-based principles of animal experimentation (Article 6) and the establishment of the Institutional Animal Care and Use Committee (Article 7). But the latter is being more severely criticized by animal rights groups. The activists think that the KFDA is not really interested in animal rights and welfare, and see the KFDA-KALAS draft as nothing more than a deceitful attempt to evade charges of animal cruelty. The doubt is reinforced by the draft's Article 1, which prioritizes the development of the life sciences and the improvement of public health over the proper treatment of experimental animals. Animal rights activists also protest that the Article 6, which lays out the basic principles of animal experimentation, does not give any indication as to what qualifications are required for those conducting animal experiments, thereby opening the way for the expansion, not restriction, of the use of experimental animals.

In the meantime, in order to avoid potential problems for publication in international journals and patent applications (and, to a lesser extent, for publicity), a growing number of Korean universities, hospitals, and research institutes are beginning to develop and implement their own guidelines for animal experimentation. Before the early 2000s, only a handful of research institutes had rigorous standards for animal experimentation. In early 2005, South Korea National University (SNU) passed the university regulation 1471 "Policy and Regulation for the Care and Use of Laboratory Animals," along with the "Guide for the Care and Use of Laboratory Animals." As a result, the Institute of Laboratory Animal Resources (ILAR) was established as "a management department to perform operation and support of the IACUC (Institutional Animal Care and Use Committee) as well as administrative support of laboratory animal facilities." (http://ilar.snu.ac.kr/).

As the KFDA, KRICT, and SMC did earlier, SNU closely followed the U.S. model. Its policy and guideline were based on the U.S. Public Health Service's "Policy on Humane Care and Use of Laboratory Animals" and the "Guide for the Care and Use of Laboratory Animals" prepared by the U.S. National Research Council's Institute of Laboratory Animal Resources (now Institute for Laboratory Animal Research).

On the issue of animal pain/distress, SNU's Guide for the Care and Use of Laboratory Animals (I. Purpose) suggests:

> ... One of the most important aspects in the refinement of animal experiments is to minimize the pain on the laboratory animals. Termination upon the completion of experiment gives not only pain to animals, but also distress including anxiety,

> unpleasantness and despair especially to those with somewhat higher intelligence. Such a measure for pain on each laboratory animal is difficult since receptivity and expressions against pain are different for each type of the animal. However, if it were a condition for a person to feel pain, it would be the same for animals. ...

SNU adopts only a slightly modified version of the NRC animal pain/distress classifications (SNU Guide's Appendix 3. Classification of Protocols Upon the Pain on Animals):

> Classification A: Research involving plants, bacteria, protozoa, or invertebrates, but not involving vertebrate animals.
>
> Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.
>
> Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.
>
> Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.
>
> Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

As for "transgenic animals", the Guide states (IV. The Beginning and Completion of Protocols):

> Transgenic animals are considered as unique resources. Care should be taken to preserve such resources through standard genetic-management procedures, including maintenance of detailed pedigree records and genetic monitoring to verify the presence and zygosity of transgenes. Cryopreservation of fertilized embryos, ova, or spermatozoa should be considered to safeguard against alterations in transgenes over time or accidental loss of the colony. Accurate recording, with standardized nomenclature where it is available, of both the strain and substrain or of the genetic background of animals used in a research project is important. Several publications provide rules developed by international committee for standardized nomenclature of outbred rodents and rabbits, inbred rats, inbred mice and transgenic animals.

It seems that the policies and guidelines adopted (or being prepared) by other universities, hospitals, and research institutes are similar to those of SNU.

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23 See, for example, Public Perceptions of Agricultural Biotechnologies in Europe (PABE), April 29, 2002, http://www.pabe.net.

24 For more on the OTA, see Bruce Bimber, *The Politics of Expertise in Congress* (Albany: SUNY Press, 1996).

25 These reports include: Office of Technology Assessment, *Impacts of Applied Genetics: Micro-Organisms, Plants, and Animals* (1981); *Commercial Biotechnology: An International Analysis* (1984); *Biotechnology in a Global Economy* (1991), and a series of five reports entitled *New Developments in Biotechnology* (1987–1989). All these can be found at http://www.wws.princeton.edu/ota/ns20/pubs_f.html.

26 OTA, *Impacts of Applied Genetics*, p. 183.

27 Id., p. 258.

28 OTA, *Public Perceptions of Biotechnology* (1987), pp. 57-58.

29 Jasanoff, *Designs on Nature*, pp. 208-209.

30 OTA, *Patenting Life* (1989), p. 17.

31 NBAC, http://www.georgetown.edu/research/nrcbl/nbac/pubs/cloning1/cloning.pdf

32 Id., p. iv.

33 Id., pp. 24-25.

34 http://bioethics.gov/transcripts/oct03/session2.html

35 For an overview of the ELSI program's accomplishments, see ERPEG Final Report, http://www.genome.gov/10001727.

36 *The Ottawa GE³LS Workshop Report*, February 2006, http://www.genomecanada.ca/xcorporate/about/documents/GELSWorkshopReportEng.pdf.

37 *Diamond v. Chakrabarty*, 447 US 303 (1980).

38 447 U.S. 303, at 309.

39 *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* 2002 SCC 76.

40 2002 SCC 76, para. 181.

41 2002 SCC 76, paras. 68, 69, 96.

42 2002 SCC 76, para. 163.

43 National Academy of Sciences, *Animal Biotechnology: Science Based Concerns* (Washington, DC: National Academies Press, 2002).

44 Id., p. 120.

45 Nuffield Council on Bioethics, *Ethics of Research Involving Animals*, London, May 25, 2005.

46 The clear-line view holds that humans are different from non-human animals; the sliding scale view holds that there is a continuum of differences that make humans more or less like animals; the moral equality view holds that there are no morally relevant differences between humans and non-human animals.

47 Id. Chapter 3.

48 Henry T. Greely. "Defining Chimeras...and Chimeric Concerns." The American Journal of Bioethics - Volume 3, Number 3, Summer 2003, pp. 17-20. See also "Chimeras: Animal-Human Hybrids," PBS Online News Hour, August 16, 2005, http://www.pbs.org/newshour/bb/science/july-dec05/chimera_8-16.html.

49 For details on BIO, see http://www.bio.org/aboutbio/.

50 http://www.bio.org/speeches/pubs/er/ethics.asp.

51 Id.

52 http://www.bio.org/foodag/animalpoints.asp.

53 See http://twmag.com/westerns/western-animals_harmed_03_06.htm

54 http://www.neavs.org/programs/papers/birdsreasearch_7_conclusion_kdavis.htm

55 http://www.uncaged.co.uk/default.htm

56 http://www.xenodiaries.org/summary.htm

57 A provision on animal rights was also included in the European Union's (EU) constitution in 2004, but the negative Dutch and French votes in 2005 brought the process of adopting the constitution to at least a temporary halt. The Swiss constitution since 1992 includes a legally imprecise mention of the "dignity of creatures" that some view as predating developments in the EU.

58 Jasanoff, *Designs on Nature*, pp. 268-269, 289.

59 *Report of the Commission of Enquiry on "Prospects and Risks of Genetic Engineering"* (hereafter Prospects and Risks), German Bundestag, January 1987.

60 Jasanoff, *Designs on Nature*.

61 *Prospects and Risks*, p. 96b (majority position) and p. 328b (Green position).

62 Deutschland Radio Kultur, March 18, 2006.