
TUFTS CENTER FOR ANIMALS & PUBLIC POLICY NEWSLETTER

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FROM THE DIRECTOR

During 1989, Tufts School of Veterinary Medicine developed a strategic plan to guide the development of the school through the next decade and into the 21st century. (In fact, all the veterinary schools in the country were doing the same under the guidance of the Pew Charitable Trusts health sciences program.) The school identified policy questions dealing with animal-related controversies as an emerging issue that would be of importance to veterinary medicine and veterinary education and, when the time came to submit a program proposal to the Pew Trusts for phase IV of the Pew program, the Dean decided to submit a proposal that would focus on Animals and Society, and asked me to coordinate its preparation. The Pew Trusts approved the proposal and we received a three-year grant of \$200,000 to develop a national curriculum and education program on Animals and Society. This program is to be managed by the Tufts Center for Animals and Public Policy.

We proposed developing about 60 lecture hours of curricular materials and an in-house education program that would reach out to other veterinary educators as well as to practicing veterinarians, veterinary students and other interested individuals. The curriculum materials would cover all aspects of the Animals in Society topic from a broad multidisciplinary perspective and would consist of lecture notes, support readings, slides and other audio-visual materials. These would be made available to interested faculty at other veterinary schools so that they could develop

their own courses. These materials would also provide the core for both general and specialized educational programs that we will run here at Tufts School of Veterinary Medicine. These educational programs will range from one day symposia to one week courses to summer institutes. In addition, we hope to develop a graduate degree program. While there are no precedents for a Masters degree in "Animals and Public Policy", we are receiving a steady trickle of enquiries about possible graduate work and believe that such a degree could be useful in a variety of possible careers, in general science, in zoology, in animal control, in wildlife management, etc.

We hope to have our first summer institute during the summer of 1991. In the meantime, we have started a search for a project co-ordinator and will be developing several questionnaires to evaluate the range and depth of current knowledge and experience on these issues as well as to identify potential audiences. We plan to survey a wide range of veterinary students, veterinary faculty, and veterinary practitioners and will be bringing in specialists in curriculum planning and development to help.

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A key aspect of the proposal, as defined by Pew, was that it should outline how the project would be supported in the years after the Pew seed funding ended. We plan to seek support from a variety of sources including subscriptions, sales of materials, grants from sponsoring organizations, and fees from the educational programs.

We believe the project has great potential and wanted to let our readership know of this new program. If you have ideas or suggestions that you believe would make the program more interesting and successful, we would be happy to hear them.

Andrew N. Rowan

SEMINAR REVIEWS

Biotechnology

A seminar was held on February 9, 1990, "Biotechnology, Patents, and Public Perception: A Perspective from Europe." The speakers included, Reid Adler, Esq., director of the Office of Technology Transfer of the National Institutes of Health; Paul T. Clark, Esq., of Fish & Richardson, Boston, Massachusetts; Irene Ores, Esq., patent attorney for the Pasteur Institute, Paris, France; and Joyce Tait, Ph.D., Open University of the United Kingdom.

Mr. Clark, who prepared the patent application for what has become known as the "Harvard Mouse", began by describing the current unwillingness of the European Patent Office (EPO) to grant Harvard's patent. According to Clark the EPO explained that they refused to grant the patent for two reasons. Article 53a of the European Patent Convention says that patents cannot be granted for inventions whose exploitation would be contrary to public order or morality. Clark noted that in the words of the Office, "The idea of the patenting of higher organisms has encountered severe criticism for ethical and economic reasons." However, this reason for rejection was ultimately with-

drawn after the Office concluded, "The patent law is not the right legislative tool for regulating such problems." According to Clark, the second reason for rejection is based on another provision of the law, Article 53b which prohibits the patenting of "plant and animal varieties." Mr. Clark noted that this law was written in 1962, and he argued that the term "variety" is significant in that it implies that the law was not meant to prohibit the patenting of all animals or the term variety would not have been included.

The EPO did grant a patent on a transgenic tobacco plant, finding that the new plant was not a plant variety. Thus there seems to be inconsistency between the EPO's treatment of transgenic plants and transgenic animals. The European legal situation has also been complicated by a recent draft directive issued by the Commission of the European Economic Community. The Commission recommended that the laws of all member countries permit the patenting of transgenic animals. If the draft becomes official, it will have the force of law in all member countries. However, because the EPO is not a country, it would not be bound by such a directive and could continue to refuse a patent for transgenic animals. Mr. Clark added that this conflict is likely to be addressed in the near future.

Public perception of animal patenting in Europe was also examined by Clark. He showed clips from European television as a medium for assessing the public's mood. First, four farmers aired their reactions, not only to questions about animal patents but also to genetic manipulation. Their responses reflected several fears concerning perceived trespasses against nature. Second, two CEOs from British biotechnology companies expressed their views. Not surprisingly, they were pro-patenting of animals. One argued that European companies needed patenting to remain competitive with the U.S. and Japan, and the other CEO cited the benefits from the patent systems of discouraging secrecy and promoting disclosure. The last viewpoint expressed was by an officer of a farm animal welfare group called Compassion in World

Farming. The commentator was outraged at the thought of patenting animals.

Clark argued that the views expressed seem quite similar to the types of arguments raised against genetic engineering on the American side of the Atlantic: violation of the sanctity of Nature, dread of the unknown, and concern at indifference toward the rights of animals. The arguments in favor of patenting include international competitive future encouraged by patenting and the public disclosure.

Professor Tait focused on risk regulation. She argued that we are feeling the social effects of petrochemical industry pollution from the 1950's, 1960's and 1970's. Regulations were put in place as problems occurred, and this reactive pattern raised public concerns about "better living through chemistry." Wildlife, according to Tait, has not fully recovered. With the advent of biotechnology, a serious attempt was made to learn from the mistakes of the recent past. The thinking has been to anticipate the potential hazards to people and environment and try to regulate in advance. This is a pro-active regulatory system.

America and Europe differ in their approaches to the regulation of biotechnology with the Europeans taking a process-based approach while the Americans focus on products. In Europe, anything developed by the process of genetic manipulation should be regulated. In America, it is argued that a pesticide produced by genetically engineered microorganisms is no different from a chemically-based process just because it was developed through biotechnology. Therefore it is the product that calls for regulation not the process. Tait suggested that big businesses can cope with a process-based approach but this will be difficult for smaller companies, and may create an entry barrier for small start-up ventures. Therefore, it may paradoxically be in the interests of larger companies to support process-based regulation.

Professor Tait introduced a new regulatory issue, called the fourth hurdle approach. Industry has in the past, had to demonstrate

quality, safety, and efficacy before products could be introduced in the marketplace. It is now suggested that "need" should also be considered. For example, bovine somatotropin (BST) is being introduced at a time when, according to Tait, there is over-production of milk in Europe. It could be argued that the introduction of BST is unnecessary.

Tait concluded by noting that potential risks accompany biotechnology particularly the release of genetically engineered organisms into the wider environments. Matters can get out of hand she warned. Microorganisms can not be easily controlled and there is the potential for the contamination of natural populations by the unintentional transfer of novel genetic material or the disruption of ecosystems. It is easy to count cows in a pasture, but not so simple with microorganisms. While people are trying to anticipate reasonable risks and develop appropriate regulations, increasing competition between companies and countries is putting pressure on regulatory agencies to expedite the development of regulations and to come up with a more rapid appraisal of new products. The pressures could lead to the abandonment of efforts to develop a pro-active risk approach.

Madame Ores, a distinguished patent attorney practicing in Paris since 1955, began her presentation by observing that in 1980, the Chakrabarty decision recognized the patentability of living matter in the USA. Prior to the Chakrabarty decision, plants were granted patents or patent-like protection in the context of either the 1930 Plant Patent Act or the Plant Variety Protection Act of 1970. Following the Chakrabarty decision the Patent and Trademark Office (PTO) granted patents for plants obtained or modified by genetic engineering. In 1988, the first patent protecting a non-human transgenic mammal was awarded to Philip Leder and Timothy Stewart for what has become known as the "Harvard Mouse."

While the U.S. PTO now is willing to grant patents for transgenic animals, the situation is very different in Europe. Originally, patent protection was granted under the different laws of individual countries in Europe.

However, with the advent of the EEC, it was clear that harmonization of these laws was necessary. The Strasbourg International Convention of 1963 aimed at providing common rules for intellectual property protection for the six members of the EEC. This was followed by the Munich Convention on European Patents of 1973 which came into force in 1978. This established common rules and the EPO. According to the Munich Convention, the contracting countries are not bound to provide for the grant of patents for inventions whose publication or use would be contrary to "public order" or "morality" nor for the grant of patents for "plant varieties or animal breeds." However, under the European Patent Convention (EPC), microorganisms (protists) are patentable. Thus, there was no bar to patenting life, *per se*.

Madame Ores stressed that the plant and animal variety clauses appeared to exclude both plants and animals from patentability. However, the EPO's Board of Appeals decided in 1983 that a patent claim for plant material was acceptable. Five years later, in 1988 the Board decided that claims for hybrid seeds are allowable (in *Re "Hybrid Plants" for Lubrizol Genetics, Inc.*). In this case, the Board decided that the modification did not involve "essentially biological processes for the production of plants or animals" and that Lubrizol Genetics had developed a process for improving efficiency and yield that contained important technical (i.e., non-biological) processes. Madame Ores suggested that these decisions raised the possibility that the EPO Board of Appeals might build similar case-law (using "essentially biological" versus "non-biological" as the discriminating line) in favor of the patentability of animal breeds.

The ferment over the patentability of living matter is now the subject of a proposed European Commission Directive on the Legal protection of biotechnological inventions. This Directive would establish harmonized and clear standards for protecting biotechnology inventions. However, the Directive would likely be strongly opposed by the Greens. Since biotechnology involves living organ-

isms, one cannot avoid the ethical issues. These issues include concerns regarding animals merely as objects, about the possible escape into the wild of transgenic animals, and about the disruption of evolution. However, Madame Ores argued that the EPC is not the appropriate focus for such discussions. From the perspective of the EPO, there should be a clear distinction between the protection of inventions and ethics.

Madame Ores concluded with the thoughts that a balance has to be found between science, ethics and the law. The content of research should not be regulated, but any attack to the dignity or to the liberty of man should be avoided by appropriate laws based on a sound ethical framework. The ethical balance regarding biotechnology should include both short-term and long-term benefits for humanity.

Mr. Adler began his talk by describing the role of the National Institute of Health's (NIH) Office of Technology Transfer (OTT) which is responsible for the central development of technology transfer policies and mechanisms at NIH and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) to complement the Federal Technology Transfer Act of 1986.

The activities of the OTT have been developed in order to respond effectively to the growing and diverse demands for technology transfer activities on the part of NIH, ADAMHA and the Center for Disease Control (CDC). The activities include a technology management program for NIH, management of the NIH/ADAMHA/CDC patent portfolio and involvement in license negotiations. The OTT is also involved in the yearly industry collaboration forum and in-house technology transfer training. Adler noted that NIH is the largest biomedical research institute in the world, and their mission is to enhance public health and study disease.

NIH is keenly interested in developments in Europe regarding patent law as it affects technology transfer, international collaborative research initiatives, marketing efforts, various bilateral science and technology

agreements, and intellectual property rights. The intellectual property rights are a major trade issue within the General Agreement on Trade and Tariffs (GATT) talks. The issue of reciprocity of rights throughout Europe is a key question for the biotechnology industry which is currently grappling with some of the issues raised by intellectual property rights. Adler went on to say NIH tends to favor animal patents because patenting is viewed as attracting investment funds to support further research.

Center for Animals & Public Policy

"Agriculture and the Environment" was a subject covered by Carl Osborne, D.V.M., on February 23, 1990. Dr. Osborne began his talk by saying, "The health of the environment is key to human welfare, and agriculture has had the greatest impact on the environment worldwide." The key questions that arise are (1) how do you get all the people fed, and (2) how should the environment be protected?

Wherever farming takes place it is followed by a general series of events. Land is cleared and soil is washed away. The range of soil loss is from 2.5 to 25 tons per hectare per year depending on the attention to basic soil management techniques. Wildlife habitat is also destroyed. The land is plowed annually which promotes more erosion. Fertilizers, pesticides, herbicides and other products are mixed into the soil. In fact approximately 380,000 metric tons of pesticides are applied to the farmland each year. According to Osborne the American agriculture system is the best in the world in terms of yield per acre, but there are growing concerns. "The land needs stewardship" said Osborne.

There are broad, agricultural policy matters that need to be addressed. On the federal level legislative efforts to deal with a variety of concerns have resulted in the farm bill (Food and Agricultural Resources Act of 1985), the Clean Water Act and the Federal Insecticide, Fungicide and Rodenticide Act known as FIFRA. On a state and local level

other issues have surfaced. They include preservation of open space and waste management. At the federal level, a sod buster provision was attached to the 1985 farm bill. It specified that if the government pays a farmer to grow a crop, the farmer has to do it "our way" in an environmentally benign manner. The Clean Water Act dealt with the loss of wetlands due to agriculture and restricted the destruction of wetlands. The farmer had to have a conservation plan for the farm and was no longer permitted to drain wetland for agriculture.

Solutions do exist for dealing with the planning and management issues that have come to the fore. They include the federal commodity crop programs, pesticide program with revisions for FIFRA, watershed protection and funding for research. At the state and local level they can involve property taxes, land use restriction and market development. There is a natural role for veterinarians. They can be the mediating voice between the perspectives expressed by the agricultural groups and the various environmental groups. Veterinarians are acutely aware of the significance of environmental stewardship.

"Bite Worse Than Bark: Aggressive Dogs and How to Control Them"

Mike McGill (V-91) gave a talk on March 9, 1990, describing his research project on canine aggressive behavior. He developed and administered a survey to obtain some preliminary data on the occurrence of different types of aggressive behavior in dogs. During the course of the summer, he also obtained information from Animal Control Officers (ACOs) on canine aggression.

Initially, the study aimed to interview three groups of owners of aggressive dogs. The first group of owners were those who were sufficiently concerned to contact Dr. Amy Marder, a veterinarian whose practice focus is animal behavior. The second group owned dogs that were quarantined for biting. The third group, owners of aggressive dogs given up to shelters, had too few subjects to compare

with the other two. It was suggested that owners in this last group either denied the aggression or were afraid of liability issues. Thus the data were obtained from the first two groups. Group II consisted of 21 owners whose dogs were quarantined for biting. Group I consisted of 16 owners whose dogs were seen by Dr. Marder for behavior problems.

There are approximately 55 million dogs in the USA of those about 15-20% pass through the shelters each year. Of those 10 million, about 60-80% are killed by the shelter, many because of behavior problems. Aggression is the main behavior problem that results in a dog being brought to a shelter.

When the survey responses were evaluated, information suggested that the most common types of aggressive behavior reported for Group II were fear biting and territorial aggression. For Group I, the responses indicated that dominance and fear aggression were the behaviors most commonly reported. Other findings from the survey results indicate that the effects of castration as a modifier of behavior for aggression driven by fear may not be that successful. As shown by others, aggression is more prevalent in males.

The approach taken to aggressive dogs by ACOs was reviewed by McGill. ACOs throughout Massachusetts are taught to stress five approaches when dealing with aggression. These include: (1) enforcing licensing and leash control laws, (2) encourage owners to neuter male dogs, (3) change the dog's behavior with the help of animal behavior experts, (4) educate people about changing the behavior of potential victims, and (5) eliminate seriously aggressive dogs by euthanasia.

Statistics on the incidence of dog bites in Boston, Revere and Wellesley were provided. The dog bite incidence was about 3 bites per 1000 dogs per year in Wellesley and about three times as high in Revere and Boston where animal control programs are not properly supported and funded by the two towns.

McGuill was asked what most surprised him throughout the course of his work. He said the devotion of the owners in Group

I to their dogs, was remarkable. Many owners described extraordinary levels of commitment to their dogs in the face of serious behavior problems.

Teleconference Summary: February 22, 1990

The Center served as a link-up site for a teleconference, "Ethics of Animals in Our Lives." The conference was organized by the Center to study Human-Animal Relationships and Environments (CEN/SHARE) of the University of Minnesota. The speakers presented various ethical issues that dealt with society's use of animals to meet human needs.

Arthur L. Caplan, the director of the Center of Biomedical Ethics at the University of Minnesota set the stage by making the point that at the present time Congress gets more mail about animal research than any other topic. Caplan also mentioned his role in Peter Singer's landmark book, Animal Liberation. Caplan, as a student in search of part-time work, tracked down many of the articles collected by United Action for Animals that were later used by Singer for his book. In the course of reviewing these articles, Caplan was struck by the number of studies with flaws in their design and also the redundancy he encountered, i.e., how many times does experiment X need to be done to prove or confirm the findings of Y? These encounters stimulated Caplan to think about the nature of the relationship we have with animals. He then began to think about the range of matters involving animals used in research. What is the moral status of animals? If animals have certain intrinsic values or properties, do they confer moral standing? Do we think of animals on a moral par with humans?

In examining these questions Caplan confined his inquiry to animals used in research settings. He argued that one cannot avoid using animals in research because it is a sure road to getting information. He went on to say, "The more you learn about animals, the better you can treat them."

Caplan offered several reasons as to

why the care and handling of animals used in research has come to the fore. The thinking of the 17th century philosopher, mechanical scientist and mathematician, Rene Descartes has been very important. To Descartes, animals were regarded as mere machines without consciousness and without a soul. They were like very complicated clocks. Today, our knowledge of the biological and physiological similarities between animals and humans is well documented. For some, those similarities have raised questions about our treatment of animals, particularly in a research setting. Caplan also suggested that the rise in the animal rights movement has corresponded (or followed) an increasing interest among philosophers in these questions. Finally, Caplan noted that, since World War II, considerable public money has been spent on research on animals. "Money gets people's attention," Caplan said, and the public is therefore, more interested in how the monies are spent on animal research.

The increased visibility raises the question; what is the duty of the scientific community to listen to those that foot the bill? Caplan concluded scientists must be more accountable in how they interact with animals. While Caplan does not believe that people and animals are morally equivalent, he does argue that the moral status of animals deserves more attention and consideration than in the past.

The other speaker was Samuel B. Ross, the executive director of Green Chimneys Children's Services in New York state. Green Chimneys is an independent day and boarding school. Its activities center around a children's educational farm on 150 acres where animals and plants facilitate therapy for disadvantaged and disturbed children. Ross pointed out, "therapy means healing, and the concept is not limited to one discipline. The idea of a children's educational farm is not inconsequential."

At Green Chimneys, some of the children have been unwanted and uncared for. All of the children have special needs. They all come from a background of failure. Green Chimneys is trying "to kindle the spark within"

and to establish relationships, Ross said, "kids learn responsibility through care and concern for animals."

While at the farm, the children receive care and they receive services. They also provide service. They are the young docents who teach the people who tour the farm about the animals they are seeing. The animals are the hook that can get the children back into society. No matter how serious their handicap may be, the kids still have the opportunity to serve society in the docent role. They are able to care for and about an animal. The animals mediate a sense of belonging and a pride in ownership for the kids.

Ross pointed out that, while the animals and plants serve the temporary residents of Green Chimneys, he has a responsibility and is a steward for the animals and plants as well as the children. When one learns to care for a living thing, then one can grow to become a caring individual.

BIOTECHNOLOGY SEMINAR **SCHEDULE**

The Center's Biotechnology Seminar schedule is below. Space is available on a first-come first-serve basis. There is no charge to attend. However, please call in advance to register to attend (508)839-5302 x4750.

May 17, 1990

4:15-6:15 pm
Arthur M. Sackler Center
for Health Communications
Room B-08
145 Harrison Avenue
Boston, MA 02111

Monsters, Myths, and Morals of Genetic Engineering

Bernard Rollin, Ph.D.
Colorado State University
Department of Philosophy

Charles Weiner, Ph.D.
Massachusetts Institute of Technology
Program in Science, Technology & Society

Mark Ratner
Senior Editor, Bio/Technology
New York, NY

Thomas A. Shannon, Ph.D.
Worcester Polytechnic Institute
Department of Humanities

June 18, 1990

1:30 - 5:30 p.m.
Arthur M. Sackler Center
for Health Communications
DeBlois Auditorium
145 Harrison Avenue
Boston, MA 02111

**The Chakrabarty Decision:
Ten Years Later**

Robert P. Merges, Esq., Moderator
Boston University School of Law

Robert L. Dancy, Esq.
Nutter, McClennen & Fish
Boston, MA

Edward F. McKie, Jr., Esq.
Banner, Birch, McKie and Beckett
Washington, DC

Jerrold Tannenbaum, Esq.
Tufts University
School of Veterinary Medicine
Boston, MA

Harold C. Wegner, Esq.
Wegner and Bretschneider
Washington, DC

Gerry J. Elman, Esq.
Editor-in-Chief
Biotechnology Law Report
Media, PA

ANNOUNCEMENTS

Biotechnology Primer

A primer derived from the 1988-89 Biotechnology seminar series is now complete. It contains summaries from each of the seminars of the series. Please call the Center if you would like to receive a free copy. It will serve as a quick reference to identify and outline some of the emerging issues in biotechnology.

New Associates

The Center has recognized three additional associates. Mr. Mark Lynch is a well-known ornithologist who works at the Worcester Art Museum as an instructor/docent. He also hosts "Inquiry", a weekly talk show of the arts and sciences.

Nancy Milburn, Ph.D., is a professor in the Biology Department at Tufts University in Medford. Her primary research interests include insect physiology and insect neurophysiology. Professor Milburn teaches cell biology, neurobiology, insect physiology and pest management, and a course called, "Scientific Research, Creationism and the American Social Contract."

Sheldon Krimsky is associate professor or Urban and Environmental Policy at Tufts. He holds B.S. and M.S. degrees in physics, M.A. and Ph.D. degrees in philosophy and has completed post doctoral studies in economics and environmental policy. Professor Krimsky is the author of Genetic Alchemy: The Social History of the Recombinant DNA Controversy and co-author with Alonzo Plough of Environmental Hazards: Communicating Risks as a Social Process.

ANNOUNCEMENTS (CONT.)

An Appeal

The Center's activities are funded by a number of sources all of which provide monies on an annual basis, that is, funding that is never guaranteed from year-to-year. The seminars and many publications have been available to you free of charge. Please consider making a tax-deductible donation to support the Center. Your check should be made payable to Trustees of Tufts College - TCfA&PP.

Thank You!

UPCOMING EVENTS

Continuing Education Seminar

The Tufts University School of Veterinary Medicine cordially invites you to our Eighth Annual Feline Symposium to be held on Saturday, June 9, 1990 at the Administration Building on the Grafton Campus. We welcome all owners and breeders interested in these lectures.

For further information, please contact: Janice Lennon - Continuing Education Office, Tufts University School of Veterinary Medicine, 200 Westboro Road, N. Grafton, MA 01536 Tel. # (508) 839-5302 x4705.