

BIOETHICS AND ANIMAL EXPERIMENTATION

By
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I teach bioethics and have an enduring interest in that area of the law as it relates to animals. What I want to do is discuss bioethics briefly, attempting to relate it to the topic of animal experimentation. There is a good deal of literature on the ethics of experimentation, including much literature on human experimentation. What can we learn from that literature with respect to animal experimentation?

In the history of human experimentation, there are a number of important documents. Today, there are Department of Health and Human Services regulations.¹ In 1975, the World Medical Association promulgated the Declaration of Helsinki II—an international protocol guiding medical doctors in biomedical research involving human subjects.²

Before that, there was an earlier Helsinki declaration, and earlier still, there was the Nuremberg Convention of 1947.³ The Nuremberg Code was not actually an international code, so much as it was the judgment of the Allied military tribunal trying Nazi doctors for their experimentation on human beings in the concentration camps. Jews, Gypsies, Poles, and other peoples were experimented on and frequently killed in the process. Today's federal regulations, as well as a number of protocols developed by professional groups,⁴ originated in the Nuremberg Code and the Helsinki Declarations.

The Nuremberg Code included three important concepts that require highlighting. First, free and voluntary consent is an essential prerequisite for human experimentation.⁵ Second, no experimentation should be undertaken if death is the probable or anticipated result.⁶ Third, unnecessary suffering, psychological or physical, is to be avoided.⁷

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¹ Basic Department of Health and Human Services Policy for Protection of Human Research Subjects, 45 C.F.R. §§ 46.101-46.117 (1990).

² Declaration of Helsinki II, *reprinted in* THE NAZI DOCTORS AND THE NUREMBERG CODE app. 3, at 333. (George J. Annas & Michael A. Grodin eds., 1992).

³ Nuremberg Code, *reprinted in* GEORGE J. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA app. I, at 279 (1977).

⁴ *See, e.g.,* AMERICAN MEDICAL ASSOCIATION GUIDELINES FOR CLINICAL INVESTIGATION, *reprinted in* GEORGE J. ANNAS, ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA app. III, at 285 (1977).

⁵ ANNAS, *supra* note 3, at 279.

⁶ *Id.* at 280.

⁷ *Id.*

The second Helsinki Declaration established seven factors to govern human experimentation. First, human experimentation should always be conducted according to sound scientific principles.⁸ Second, the design of the experimentation should be set in advance, and a protocol filed with an independent body.⁹ Third, experimentation should be conducted only by scientifically trained people.¹⁰ Fourth, the risk must be proportionate to the benefit.¹¹ Fifth, concern for the subject should prevail over scientific concerns.¹² Sixth, the effect on the integrity, privacy and psychology of the subject should be minimized.¹³ Seventh, the subjects must be advised of the procedure's alternatives and risks, and experimentation should proceed only after informed consent is obtained.¹⁴

Unlike the Nuremberg Code, the Helsinki Declaration weighs and balances interests throughout. It balances the concern of the individual against the benefits of the society. For example, experiments should be set up by qualified scientific personnel, but they do not necessarily have to be administered by those same personnel. Notice also that informed consent came last in the Declaration of Helsinki II. In the Nuremberg Code, it came first.¹⁵ Not only was it first, but the court said it was absolutely essential that the free and unfettered consent of the participants be obtained and included a paragraph elaborating on that theme.¹⁶

So, the Helsinki Declaration II is quite different from the Nuremberg Code. Politically, that was almost essential because, by the mid-1970s, the reaction against human experimentation had already begun to diminish, and the importance of advancing human experimentation, as a commercial or scientific enterprise, had become very much established. The principle of protecting human rights diminished in significance. I suspect that the Declaration is followed very closely by human experimenters throughout this country.

In 1966, Henry Beecher published an article in the *New England Journal of Medicine*¹⁷ which many thought was extraordinarily courageous. Dr. Beecher reviewed existing medical research studies on human beings, and analyzed whether they conformed to the Nuremberg Code or the principles that would later be reflected in the Helsinki Declaration II. His conclusion was that perhaps a quarter of the experimentation going on in the country in the 1960s was unethical — maybe even more. These were studies that had been funded extensively, conducted scientifically, and published in respected journals. Beecher concluded that these experi-

⁸ THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 2, at 334.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at 335.

¹⁵ ANNAS, *supra* note 3, at 279.

¹⁶ *Id.*

¹⁷ Henry Beecher, *Ethics and Clinical Research*, 274 NEW ENGLAND JOURNAL OF MEDICINE 1354 (1966).

mentations on humans were unethical by clearly accepted standards. He found that standards governing experimentation on humans were widely ignored. It would be nice to think that, thirty years later, in the 1990s, the government is our friend, and things are much better. I am not convinced that is true. If my pessimism is correct as to humans, the question becomes: What can we say about the condition of animals in experiments today?

To begin with, it is helpful to sort out the standards concerning human experimentation which may also apply to animal experimentation. There are four principles I think should be the same for animal experimentation. First, the conditions under which experiments may be conducted on animals should be scientifically sound and decided upon in advance. Second, the conditions should be humane, regardless of whether we are dealing with white mice, baboons, fish, dogs or cats. Third, there should be no needless cruelty. Some experimentation is going to be necessarily cruel, but there should be no needless cruelty. Anything that is nonessential to the experiment itself should be avoided. Fourth, the personnel conducting the experiments should be the personnel who set up the experiment. They should be responsible for the protocol, have the qualifications which got the experiment funded, and be institutionally approved.

Protocol under the Nuremberg Code was quite clear: every person involved in human experimentation was responsible for the ethical quality of that experimentation — every person.¹⁸ There could be no defense in only taking orders under the Nuremberg code. Under the Helsinki Declarations, individual irresponsibility is no defense either. Monitoring must take place to enforce individual responsibility.¹⁹ That monitoring may be through the host institution, through the governmental funding agency, or by local law enforcement agencies.

Next, which of the principles in human codes might not apply to animal experimentation? There are four areas that might not apply. One is the requirement of informed consent. However we define the quality of human persons and try to distinguish those from nonhumans, one of the differentiating qualities is the ability to give consent. There is a grey area in the world of bioethics that gets us into trouble with people of limited intelligence, competence, or options. However, even under the most loosely acceptable categorization, one of the qualities of animals is that they would not be able to give the kind of consent that the Nuremberg and Helsinki Codes would require.

Second, the goals of the experimentation would be quite different with respect to animals from humans, because both the Nuremberg and Helsinki Codes and all of the federal regulations contemplate that prior to human experimentation, there should be animal experimentation. If it is necessary for animals to die so that we live, that is an acceptable predicate for most codes concerning experimentation on humans. Nobody is asking the animals how they feel about that, and that is a second clear difference.

¹⁸ ANNAS, *supra* note 3, at 279.

¹⁹ THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 2, at 334.

Third, with almost all the human experimentation codes, death is an unacceptable alternative. For example, this becomes an important operating principle when we are dealing with prisoners who are facing death sentences. Similarly, when we are dealing with subjects facing death through disease — AIDS, for example — human experimentation codes do not permit those people to consent to experimentation protocols which contemplate their death. This is not true for animals.

Finally, a significant difference, and the subject of much controversy, is that the human experimentation codes contemplate that the experiment should not interfere with, or destroy, the integrity of the subject, the psychology of the subject, or the identity of the subject. However, a good deal of animal experimentation has, in fact, that precise objective. Indeed, there are certain experimental animals, rats, for example, who are standardized across generations precisely to standardize experimental results! I can think of four cases from my bioethics course where the end point of the experiment is essentially to create a new life form.²⁰ It would not be possible under the human experimentation protocols to have experiments leading to a different identity, a different integrity, or a different life form.

In discussing animal experimentation, we should start with an equitable code as a basis. There are four differences to be sure: (1) no requirement of consent; (2) the balancing of the individual participants' interests versus society's interests; (3) the risk of death; and (4) the possibility or indeed, the objective of changing identity, integrity or the composition of the participants. A purist "animal rights" ideologue would object to these differences, and would argue that humans and animals should be treated identically. It may be doubted that this is ethically necessary or defensible. If ethics implies fidelity to nature or to community (they are not the same), the fact is, that destruction of others is the rule — not a violation of the rule. Communities do prey on each other, death and destruction are part of the order of things. Limits exist chiefly because of obligations which we have towards each other, that is, towards those who are members of our community — broadly and fairly defined.

We should care about animals, not because they are part of the human community, but because they contribute to it. Moreover, part of their contribution is the giving of love, and receiving it in turn. Kindness and care are due animals for these reasons and because we ennoble ourselves when we respect those around us.²¹

²⁰ *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Foundation on Economic Trends v. Bowen*, 722 F. Supp. 787 (D.D.C. 1989); *Genentech, Inc. v. Bowen*, 676 F. Supp. 301 (D.D.C. 1987).

²¹ The author is greatly indebted to the two seminal books in the area, TOM REGAN, *THE CASE FOR ANIMAL RIGHTS* (1983) and PETER SINGER, *ANIMAL LIBERATION* (1975). While disagreeing with the authors in significant ways, I can only recommend their works with the highest praise.