ANIMAL EXPERIMENTATION: LESSONS FROM HUMAN EXPERIMENTATION

By
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Conventional wisdom tells us that animal experimentation is a relevant precursor to human experimentation. The failings of human experimentation to protect human subjects, however, raise serious questions as to the safety and appropriateness of experimentation on animals. The federal government and medical community, since World War II, have used the Nuremberg Code and the federal "Common Rule" to determine how to conduct human experimentation ethically. Due to political or economic factors, government entities, hospitals, researchers, and pharmaceutical companies have continued to conduct human experimentation without the informed consent of their subjects. These human experiments have often achieved meaningless—or worse—devastating results. Because safeguards have failed with human experimentation, the federal and local governments, in conjunction with animal advocacy organizations, should take a series of concrete steps to eliminate an experimenter's ability to cause pain, suffering, and unnecessary death to animals.

I. INTRODUCTION: PRINCIPLE AND EXPERIENCE

The experience gleaned from human experimentation is directly relevant in assessing the need for and propriety of animal experimen-

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tation. Usually it is thought the reverse is true: that animal experimentation is relevant as a precursor to human experimentation. However, the point of this article is that the failings and failures of experimentation on humans cast substantial doubt on the necessity for, or appropriateness of, experimentation on animals.

Those interested in animal rights, and in protecting animals, tend to believe that animal experimentation is never justifiable.[1] Their belief is founded on precepts and principles that allow for little qualification or compromise. It is not a view that I share. In my view from the world of bioethics, experimentation on animals might be justified to save human life.[2] It is also justified to learn more about the lives of animals, quite possibly to save their lives.[3] Concern is highest when animal lives are at risk, but much experimentation on animals poses little imposition on their lives or physical well-being.[4] For example, most recently, the press has given much attention to experimentation with sheep to determine what percentage engaged in same-sex behav-

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[1] Some animal rights advocates oppose any and all human use of animals. *See* Cass R. Sunstein, *Introduction: What Are Animal Rights?*, in *Animal Rights: Current Debates and New Directions* 3, 5 (Cass R. Sunstein & Martha C. Nussbaum eds., Oxford U. Press 2004) [hereinafter *Animal Rights*] (observing how animal rights advocates "invoke the Kantian idea that human beings should be treated as ends, not means—[and] extend the idea to animals, so as to challenge a wide range of current practices"). The modern animal rights movement also draws inspiration from several philosophers, including Peter Singer and Tom Regan. *See generally* Peter Singer, *Animal Liberation* 1 (Random H. rev. ed. 1990) (proposing that human beings are not superior nor more valuable than other animals by claiming "all animals to be equal"); Tom Regan, *The Case for Animal Rights* (U. of Cal. Press 1983) (proposing that animals have inherent value and, therefore, rights).

[2] For example, animal experimentation has led to advances in antibiotics, vaccines, blood transfusions, insulin, and anesthetics. Currently, animal researchers are focusing on cures for AIDS, Alzheimer's disease, cystic fibrosis, cancer, and Parkinson's disease. *See* Ellen Frankel Paul, *Introduction*, in *Why Animal Experimentation Matters: The Use of Animals in Medical Research* 4–5 (Ellen Frankel Paul & Jeffrey Paul eds., Soc. Phil. Policy Found. 2001) [hereinafter *Why Animal Experimentation Matters*]. The debate about the utility of animal experimentation and its cruelty and abuses is very nicely captured in the novel *The Lighthouse*, by the English author P.D. James. P.D. James, *The Lighthouse*, 71–75 (Random H. 2006).

[3] *Why Experimentation Matters*, *supra* n. 2, at 6–7 (describing discoveries in human advances that have also improved the lives of animals, "including medicines for diabetes, pacemakers for heart irregularities, hip and joint replacements for degenerative conditions, chemotherapy for cancer, and vaccines against rabies."); *see also* Found. for Biomedical Research, *Animal Research 101: A primer on the need for animals in scientific and medical research*, http://www.fbresearch.org/Education/pdf/AR101.pdf (accessed Nov. 17, 2007) (noting how advances in "reproductive techniques are [also] helping to preserve and protect threatened and endangered species").

[4] The Foundation for Biomedical Research concludes that "[t]he vast majority of biomedical research does not result in significant discomfort or distress to research animals." *Id.* A 2006 United States Department of Agriculture (USDA) Annual Inspection Report shows that fifty seven percent of all research procedures with animals involved no pain. U.S. Dept. of Agric., *FY 2006 AWA Inspections*, http://www.aphis.usda.gov/animal_welfare/downloads/awreports/awreport2006.pdf (accessed Nov. 17, 2007).

ior.[5] Such observational experimentation may tell us a good deal not only about sheep, but also ourselves.[6] There would seem little to which to object in such undertakings.[7]

Experimentation on humans, and the sale and consumption of pharmaceuticals for humans, under present Food and Drug Administration (FDA) regulations, must often—if not always—be preceded by animal experimentation to demonstrate safety and efficacy.[8] In these experiments, the animals not only may die, but also may be put to death intentionally.[9] There is a good deal of literature to the effect that

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[5] *See* Sandi Doughton, *Born Gay? How Biology May Drive Orientation*, http://archives.seattletimes.nwsource.com/html/localnews/2002340883_gayscience19m.html (June 19, 2005) (discussing how the results of an Oregon State University (OSU) experiment on "male-oriented" sheep "adds to a growing body of research that bolsters biological explanations for sexual orientation across species"); John Schwartz, *Of Gay Sheep, Modern Science and the Perils of Bad Publicity*, N.Y. Times A1 (Jan. 25, 2007) (illustrating the "distortion and vituperation that can result when science meets the global news cycle"); William Saletan, *Brokeback Mutton*, Wash Post B02 (Feb. 4, 2007) (available at http://www.washingtonpost.com/wp-dyn/content/article/2007/02/02/AR2007020201462_pf.html) (exploring the possible political and ethical ramifications of research that suggests sexual preference is biologically determined).

[6] According to Dr. Charles Roselli, a researcher at Or. Health & Sci. U. (OHSU), such research "strongly suggests that sexual preference is biologically determined in animals, and possibly in humans." Dr. Roselli discovered through his research with sheep that the "sexually dimorphic nucleus"—a densely packed cluster of nerve cells in the brain that regulates sex hormone secretion—in a male-oriented ram is more similar in shape to a ewe's than that of a female-oriented ram and that gay men's brains may similarly resemble those of women. Oregon Health & Science University Press Release, *Biology Behind Homosexuality in Sheep, Study Confirms: OHSU Researchers Show Brain Anatomy, Hormone Production May Be Cause*, http://www.ohsu.edu/news/2004/030504sheep.html (March 5, 2004) [hereinafter *Roselli*].

[7] While observation was a critical component to the five-year research conducted on sexual preference in sheep, the discovery involving the "sexually dimorphic nucleus"—mentioned Roselli, *supra*, n. 6—was a result of dissections performed on sheep's brains. *See* Shalin Gala, *The PETA Files: PETA's Open Letter in Response to OSU and OHSU's "Gay Sheep" Experiments*, http://blog.peta.org/archives/2007/01/peta_sets_the_r_1.php (Jan. 26, 2007) (questioning the health benefits and scrutinizing the lethal outcome—the dissection of sheep's brains—of the sheep experiments); *see also* Schwartz, *supra* n. 5 (noting that the "researchers acknowledge that the sheep are killed in the course of the research so their brain structure can be analyzed, but they say they follow animal welfare guidelines to prevent suffering").

[8] 21 C.F.R. § 312.23(a)(8) (2007).

[9] David J. Wolfson & Mariann Sullivan report that "[a]lthough exact numbers are difficult to ascertain, it is believed that the number of animals killed in research in the United States ranges from 20–60 million per year." David J. Wolfson & Mariann Sullivan, *Foxes in the Hen House: Animals, Agribusiness, and the Law: A Modern American Fable*, in *Animal Rights: What it is, Why it is Happening, and What it Portends for Medical Research*, *supra* n. 1, at 226; *see also* Jerrold Tannenbaum, *The Paradigm Shift Toward Animal Happiness*, in *Why Animal Experimentation Matters*, *supra* n. 2, at 100 (noting how "[t]he primacy in the current regulatory approach of avoiding unnecessary research-animal 'pain' is strikingly illustrated by how the killing of animals is treated. Nothing in the [Animal Welfare Act] or in the [Public Health Service] policies states or suggests that there is a problem or issue raised by the killing of animals. . . . The focus of current laws and regulations then, is on avoiding or minimizing research-animal

this is almost never scientifically necessary.[10] Perhaps this is so; I remain unconvinced. In my view, the death of animals but never their "abuse" may be justified in experiments which themselves are justified by human necessity.[11]

I have made this point in other writings.[12] What I wish to add at this time is a consideration borne out of the mistakes and abuses evidenced in human experimentation over the past few decades.[13] That consideration is simply that the safeguards surrounding human experimentation have proven untrustworthy, as have the experimenters themselves.[14] This is particularly true in dealing with those human

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pain, suffering, distress, and discomfort—not on preserving the lives of research animals").

[10] While it is widely believed that animal experimentation is necessary for medical progress, "according to some national statistics, nearly two-thirds of all animal research has little or nothing to do with curing human diseases or advancing human medicine." PETA, *Animal Experiments: Overview*, http://www.peta.org/mc/factsheet_display.asp?ID=126 (accessed Nov. 17, 2007); *see e.g.* Columbia U. Cruelty, *Introduction*, http://www.columbiacruelty.com/introduction.asp (accessed Nov. 17, 2007) (documenting a PETA investigation that revealed the grotesque abuse of animals in laboratories at Columbia University, where baboons were subjected to invasive surgeries and left "to suffer and die in their cages without any painkillers," and monkeys were forced to endure surgical procedures in which metal pipes were implanted into their skulls "for the sole purpose of inducing stress to study the connection between stress and women's menstrual cycles"); Physicians Committee for Responsible Medicine, *Animal Experimentation Issues, Understanding Research Charities' Comments about Animal Experimentation Programs*, http://www.pcrm.org/resch/anexp/understanding_claims.html (accessed Nov. 17, 2007) (revealing an experiment funded by the March of Dimes that "involved killing and comparing the brains of normal cats, kittens, cats who had one eye sewn shut for at least a year, and cats who were reared in complete darkness. By the March of Dimes' own admission, no clinically relevant advances came from this study, yet March of Dimes' spokespersons continue to claim its researchers use animals only when 'necessary'").

[11] For example, "[a]nimal models can help clarify many aspects of a disease or medical condition by providing a means of systematically studying the circumstances necessary to produce impairments observed in humans, and by providing the possibility for assessing the effectiveness of potential interventions, treatments, and cures." Stuart Zola, *Basic Research, Applied Research, Animal Ethics, and an Animal Model of Human Amnesia*, in *Why Animal Experimentation Matters*, *supra* n. 2, at 86.

[12] *See e.g.* Arthur B. LaFrance, *Bioethics and Animal Experimentation*, 2 Animal L. 157, 159 (1996).

[13] *See Grimes v. Kennedy Krieger*, 782 A.2d 807, 812, 858 (Md. 2001) (finding against the EPA, Johns Hopkins, the Kennedy Krieger Institute, and the City of Baltimore for participating in an experiment that rated the slum housing in Baltimore by lead paint presence and induced, by cash incentives, young families with children to live there).

[14] *Id. See also*, Borgna Brunner, *The Tuskegee Syphilis Experiment*, http://www.tuskegee.edu/Global/Story.asp?s=1207586 (accessed Nov. 17, 2007) (referring to a government sponsored experiment involving a group of African-American prisoners who were told they were receiving medical treatment for syphilis when, in fact, the doctors only observed what happened as their diseases progressed over time. Even after it was known that penicillin could cure syphilis they were denied treatment); *Heinrich ex rel. Heinrich v. Sweet*, 62 F. Supp. 2d 282, 290 (D. Mass. 1999) (action for damages arising out of the federal government's radiation experiments on terminally ill patients without their consent); Vera Hassner Sharav, *Harvard President Laments China Study Globe*, http://www.ahrp.org/infomail/0502/15.php (May 15, 2002) (quoting The Boston Globe)

subjects, who, like animals, are characterized by an inability to protect themselves or express their interests, as with children, the poor, the mentally and emotionally disabled, and prisoners.[15] As this essay develops, a discussion of patterns and practices of misconduct over the past decade should cause us to pause and consider whether human experimentation can ever be permissible when the capacity to give informed consent is lacking.

Such a pause, and such doubts, are particularly compelling when considering animal experimentation. Animals have no spokespeople; animals have no voice. They may not insist upon informed consent, nor can they give it. They cannot question the value of the proposed research or the need to sacrifice them. Yet their inherent value as sentient beings is indisputable. However, the safeguards set up to protect humans, although demonstrably flawed, are unavailable for animals. This essay concludes that animal experimentation, even with such safeguards, should almost never be undertaken, not because of philosophical principle, but because of pragmatic mistrust.

II. THE HUMAN FAILINGS

A. Institutions and Rules

In the most general of ways, there are several safeguards that are designed to protect the subjects of human experimentation. It is worth re-examining them to determine why they have failed to protect humans. From this we may infer lessons for animal protection.

We long ago left behind the Nazi experimentations of the 1930s and 1940s, but we still rely upon the Nuremberg Code and its restrictions: that human experimentation without voluntary and informed consent is impermissible, that only necessary experimentation is permissible, and that experimentation resulting in death, as an outcome, is impermissible.[16] Other aspects of the Nuremberg Code were so re-

(Harvard School of Public Health admitting it conducted genetic experiments on residents of China without their consent in the late 1990s).

[15] These groups are deemed to be at risk as research subjects simply because of certain characteristics of the group. "For example, children may be considered to be at risk simply because . . . they may be unduly influenced by any adult figure . . . to consent to something that may not be in their best interest." Dennis M. Maloney, *Protection of Human Research Subjects: A Practical Guide to Federal Laws and Regulations* 311 (Plenum Press 1984). Similarly, the nature of incarceration makes it easier for researchers "to obtain consent by taking unfair advantage of [prisoners] who may be in no position to refuse to cooperate." *Id.* Concerns regarding the mentally disabled in human experimentation are even more numerous than with other groups. This is due to the fact that this population combines the problems of diminished capacity to consent—as is seen in children—as well as restrictions on normal freedoms—such as the restrictions in movement that prisoners experience. *Id.* at 380.

[16] Naomi Baumslag, *Murderous Medicine: Nazi Doctors, Human Experimentation, and Typhus* 162 (Praeger 2005) (quoting *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Principles. 1, 2, and 5 (D.C., U.S. Govt. Printing Off., 1949). The Nuremberg Code is a set of principles established to guide human experimentation. The principles are a result of the Nuremberg trials at

strictive, for example, imposing personal responsibility on every person involved in the experimentation, that in 1964 the experimentation community adopted the principles developed at the Helsinki Convention, which substantially relaxed the limits on experimentation, substituting instead a requirement of elaborate process and protocol.[17]

By the 1980s, the principles from both the Nuremberg Code and Helsinki I were incorporated into federal government administrative regulations, which applied to most government agencies and departments involved with human experimentation.[18] As a result, there exists what is referred to as the Common Rule, which are the requirements for the protection of human subjects of experimentation funded by federal agencies.[19] However, it will become evident that the strictures of the Common Rule are often both unenforced and unenforceable.

One reason the federal government rules are important is because the National Institutes of Health (NIH) is a major source of funding for human and animal experimentation.[20] Other government agencies,

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the end of World War II and are not actually an international code but are a judgment by the Allied military tribunal in response to the inhumane Nazi human experimentation carried out during the war by German physicians. The charges against the physicians centered on human experimentation with non-consenting prisoners—including "studies" on the limits of human tolerance to freezing temperatures and inoculation of subjects with infectious disease pathogens.

17 Sharon Perley et al., *The Nuremberg Code: An International Overview*, in *The Nazi Doctors and the Nuremberg Code* 149, 158 (George J. Annas & Michael A. Grodin, eds., Oxford U. Press 1992) [hereinafter *The Nazi Doctors and the Nuremburg Code*]. The requirement of informed, voluntary consent—the first principle in the Nuremberg Code—is much less prevalent in the Declaration of Helsinki I, which provides that in cases where the research subject is legally or physically unable to provide consent, the consent of the legal guardian is sufficient. World Med. Ass'n, *World Med. Ass'n Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* ¶ 24 (1964) [hereinafter Helsinki I] (available at http://www.wma.net/e/policy/pdf/17c.pdf) (accessed Nov. 26, 2007).

18 45 C.F.R. § 46.101 (2006).

19 56 Fed. Reg. 28002, 28004-28012 (June 18, 1991) (subpart A of 45 C.F.R. § 46.101 is what is generally referred to as the Common Rule. Sixteen federal agencies have adopted these regulations governing research with human subjects). The Center for Disease Control and the National Institutes of Health have since adopted the Common Rule regulations. Natl. Sci. Found., *Frequently Asked Questions and Vingettes*, http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp (accessed Nov. 17, 2007). As a condition of receipt of federal funds for human-based research, an institution is required to sign an assurance to the effect that *all* research will be conducted in compliance with the Common Rule, and not merely federally funded research. 45 C.F.R. § 46.103(a) (2005) (emphasis added).

20 Natl. Insts. of Health, *About NIH*, http://www.nih.gov/about/ (last updated July 18, 2007). The National Institutes of Health (NIH) is a part of the U.S. Department of Health and Human Services and is the primary federal agency that conducts and supports medical research. NIH is composed of twenty seven institutes and centers, providing financial support to researchers in every state and worldwide. In 2006, NIH received $27,887,512,000 in Congressional appropriations and distributed $22,310,009,600—eighty percent—in research grants. Natl. Insts. of Health, *Budget*, http://www.nih.gov/about/budget.htm (last updated May 16, 2007).

such as the Environmental Protection Agency (EPA) and the United States Department of Agriculture (USDA), are also sources of funding for such experimentation.[21] The NIH grants funds for human experimentation to institutions, such as medical schools or the science departments of universities, usually on a competitive grant basis following a two-tiered system of peer review.[22]

Because research funds support faculty, schools are substantially dependent on agency funding.[23] Yet the schools are supposed to police themselves and the researchers are supposed to make sure that they behave responsibly, humanely, and ethically.[24] The conflict of interest is self-evident. Particularly with medical schools and hospitals, advance approval clothes an application or grant, which is entrusted to an Institutional Review Board (IRB).[25] Conduct in a specific case is reviewed by an Institutional Ethics Committee (IEC).[26] Yet these

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21 The EPA, through its National Center for Environmental Research's (NCER) Science to Achieve Results (STAR) program, funds research grants and graduate fellowships in numerous environmental science and engineering disciplines through a competitive solicitation process and independent peer review. In addition, through this same competitive process, NCER periodically establishes large research centers in specific areas of national concern including children's health and hazardous substances. U.S. Envtl. Protec. Agency, *Basic Information*, http://www.epa.gov/ncer/about/ (last updated Aug. 29, 2007). USDA provides funds to researchers to focus on national issues related to agriculture, the environment, human health and well being, and communities. U.S. Dept. of Agric., *Research Grants and Agreements*, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?navid=RESEARCH_GRANTS&parentnav=RESEARCH_SCIENCE&navtype=RT (accessed Nov. 17, 2007).

22 Dept. of Health and Human Servs., *Peer Process Review*, http://grants.nih.gov/grants/peer_review_process.htm (last updated July 31, 2007) (NIH policy mandates that peer review ensure objectivity, fairness, and "maximum competition." As such, a group of primarily non-federal scientists in relevant disciplines carries out the initial peer review. The second level of review is performed by Institute and Center National Advisory Councils or Boards, composed of scientific and lay members chosen for their expertise. Applications must be favorably recommended by groups in both levels of review to receive funding).

23 Matt Hanson, *Raises Aren't Universal*, Daily Tar Heel (Chapel Hill, N.C.), http://media.www.dailytarheel.com/media/storage/paper885/news/2003/11/11/Investigative/Raises.Arent.Universal-1356224.shtml) (Nov. 11, 2003) (describing how shrinking state funding in North Carolina is forcing academic departments at the University of North Carolina-Chapel Hill to use other sources—such as federal research grants—to make up the difference).

24 *See infra* n. 25 (discussing institutional review boards).

25 *See* Maloney, *supra*, n. 15, at 47 (the primary purpose of the institutional review board (IRB) is to protect the rights and welfare of human research subjects. An IRB is a group of professionals and laypersons at an institution such as a university, hospital, or private research center who review, modify, and approve or reject certain types of research. Approval by an IRB for a research grant proposal is required by the Department of Health and Human Services (HHS) before it will allocate funds to an institution for a research grant or contract. According to Dennis M. Maloney, "HHS usually will not even review a request for grant funds, much less approve it, unless IRB approval already has been obtained by the grant's principal investigator"); *see also Grimes*, 782 A.2d at 812–14 (for an example of an IRB-approved grant and a general discussion of IRB roles).

26 *See* Am. Acad. of Pediatrics, Comm. on Bioethics, *Policy Statement: Institutional Ethics Committee*, 107 Pediatrics 205 (2001) (available at http://aappolicy

agencies of the institutions are themselves dependent for funding upon approval of the very research under scrutiny.

It is quite likely that a good deal of human experimentation in the present decade escapes much of the oversight of both federal agencies and medical institutions for the simple reason that it takes place in doctors' offices. The testing of pharmaceutical products prior to introduction to the market was formerly undertaken in clinical trials within hospitals and medical schools.[27] In the past decade, more than two-thirds of such clinical trials have been moved to doctors' offices.[28] The reasons are obvious: less capital expense, easier access to a broader patient base, reduced economic incentives, and perhaps most important, patient confidence in the conductor of the experiment.[29] As with experimentation within institutions, the conflict of interest is obvious: the patient comes to the physician for treatment, not experimentation, yet may be subject to both.[30] Indeed, the patient may find the physician is more motivated by the financial rewards of recommending a particular pharmaceutical than the clinical benefits of choosing among established, effective remedies.

It gets worse. Though most commentators agree that the federal regulations and the institutional oversight bodies are not nearly as effective as they should be,[31] they do constitute constraints on experimentation. As noted, this has led to moving experimentation to doctors' offices.[32] More significantly, attempts to escape these constraints have also led to moving experimentation overseas.[33] During the 1990s, a series of articles in the New England Journal of Medicine

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.aappublications.org/cgi/content/full/pediatrics;107/1/205) (accessed Nov. 17, 2007) (explaining an IEC's role in resolving "conflicts about treatment decisions through case consultation, provid[ing] a forum for discussion of policies relating to institutional ethics, and educat[ing] their health care communities about ethical concepts") (accessed Nov. 17, 2007).

27 Liz Kowalczyk, *Drug Trials Branch From Teaching Hospitals Suburban Doctors Answer Call To Help*, Boston Globe C1 (Aug. 15, 2000) (available at 2000 WLNR 2288286) (stating that "teaching hospitals . . . once conducted 80 percent of all clinical trials paid for by industry").

28 *Id.* (highlighting the effort of hospitals in Boston and other U.S. cities to move clinical "trials testing new drugs out to doctors' offices in the suburbs").

29 *Id.* (citing a desire "to improve relationships between academic and community physicians . . . [as well as] to gain access to thousands of potential trial participants" as a reason for moving clinical trials to doctors' offices).

30 *See generally id.* (illustrating the story of a patient who regularly ignored "missives" from Boston teaching hospitals asking him to participate in human research but agreed to participate in an experiment when approached by his family doctor). Most recently, as to the dangers thereby posed, *see* Eric G. Campbell, *Doctors and Drug Companies—Scrutinizing Influential Relationships*, 357 New Eng. J. Med. 1796 (Nov. 1, 2007).

31 Ralph Snyderman & Edward W. Holmes, *Oversight Mechanisms for Clinical Research*, 287 Science 5453, 595 (Jan. 28, 2000) (available at http://www.sciencemag.org/cgi/content/summary/287/5453/595).

32 Kowalczyk, *supra* n. 27.

33 *See* Joe Stephens, *Panel Faults Pfizer in '96 Clinical Trial in Nigeria*, Wash. Post A01 (May 7, 2006) (available at 2006 WLNR 7810126) (based on a Nigerian report that

debated the use of pregnant African women infected with Human Immunodeficiency Virus (HIV) to determine the efficacy of short-term HIV treatment by Zidovudine (AZT).[34] The reason was that the experiments were being conducted under terms that are not permissible in the United States.[35] Those who have seen the movie *The Constant Gardener* will understand the issues.[36]

Finally, human experimentation is shot through with politics, which impacts less which experiments are conducted as which experiments are precluded. Over the past few years, the news media have reported on restrictions imposed on the use of fetal tissue and the sale of the abortifacient, RU-486.[37] Politics plays an obvious role in promoting some kinds of experimentation and experimental practices; it also plays an important role in precluding important medical research.[38] The profit motive of the medical-industrial complex plays a similarly powerful role, as demonstrated by the unavailability of so-called orphan drugs,[39] compared to the present lobbying effort by the manufacturer of a newly developed vaccine, designed to prevent cervical

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Pfizer illegally gave an experimental drug to children, without their or their parents' consent, and which resulted in numerous deaths).

34 Peter Lurie, *Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries*, 337 New Eng. J. Med. 853 (Sept. 18, 1997); M. H. Merson, *Ethics of Placebo-Controlled Trials of Zidovudine to Prevent the Perinatal Transmission of HIV in the Third World*, 338 New Eng. J. Med. 836 (Mar. 19, 1998) (debating Lurie's reasoning in 1997 article, includes Lurie's reply).

35 *See* David D. Ho, *It's AIDS, Not Tuskegee*, 150 Time 13, 83 (Sept. 29, 1997)

> ("[trying] to find an [affordable] AZT regimen . . . African researchers sought sponsorship from U.S. health agencies and launched a number of scientific studies in which some [pregnant] mothers were given short treatments with AZT and some, for the purpose of comparison, received a placebo. It is the inclusion of these placebo groups that critics find objectionable. Giving a sugar pill to an AIDS patient is considered ethically unacceptable in the U.S. To give one to a pregnant African, Dr. Angell writes, shows a 'callous disregard of [a patient's] welfare for the sake of research goals'").

36 *The Constant Gardener* (Focus Features 2005) (motion picture).

37 *See generally* Nicholas Wade, *Scientists Divided on Limit of Federal Stem Cell Money*, 150 N.Y. Times A16 (Aug. 16, 2001) (explaining how scientists conduct stem-cell research and the impact of federal laws limiting access to stem cells); *see* Jonathan D. Rockoff, *FDA is urged to halt sale of RU-486; Conservatives point to 4 deaths possibly linked to abortion pill*, Balt. Sun 1A (Nov. 27. 2005) (available at 2005 WLNR 19202573) (describing the controversy over the use of RU-486 and attempts by both the pills' advocates and opponents to influence the FDA's decision on the drug's availability).

38 Rockoff, *supra* n. 37.

39 Forbes.com, *AstraZeneca's Zactima Designated "Orphan Drug" by US Regulators*, http://www.forbes.com/home/feeds/afx/2005/10/31/afx2308452.html (Oct. 31, 2005) (describing an orphan drug and its limited target population); Stephen Heuser, *Shire Drug Gets FDA Approval*, http://www.boston.com/business/healthcare/articles/2006/07/25/shire_drug_gets_fda_approval/ (accessed Nov. 17, 2007); Pub. L. No. 97-414, 96 Stat. 2049 (1983) (the "Orphan Drug Act" provided tax incentives for pharmaceutical companies to create drugs for diseases affecting a very small percentage of the population, as the lack of patients needing the drugs would otherwise make the development cost prohibitive).

cancer, to require mandatory vaccination of all young girls.[40] Such mandatory vaccination would cost parents hundreds of dollars and would yield billions in profits to the manufacturer.[41]

B. Cases in Point

We should now consider several cases to illustrate some of the concerns above. Then we will consider their implications for animal experimentation.

The Nazi doctors were tried at Nuremburg at the end of World War II for conducting experiments on prisoners.[42] The experiments were conducted without consent and often led to death.[43] Moreover, they held little potential for benefiting the human subjects. The methodology was often brutal in the extreme, exposing subjects to lethal gases or freezing temperatures.[44]

It is important to make three observations. First, the experiments were not conducted by crazed, aberrant crackpots. Rather, most of the experiments were conducted by some of the finest minds of German medicine.[45] Indeed, it is fair to say that the Nazi experiments were

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[40] Linda A. Johnson, *Merck Suspends Lobbying for Vaccine*, Wash. Post (available at http://www.washingtonpost.com/wp-dyn/content/article/2007/02/21/AR2007022101359.html) (Feb. 21, 2007) (announcing Merck's decision to end its nationwide lobbying effort to have states mandate that girls be given vaccine to prevent the sexually transmitted virus that causes cervical cancer).

[41] *Id.*

[42] *The Nazi Doctors and the Nuremberg Code*, *supra* n. 17, at 3–4.

[43] *See Judgment and Aftermath*, in *The Nazi Doctors and the Nuremberg Code*, *supra* n. 17, at 104 ("In every single instance appearing in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers. In no case was the experimental subject at liberty of his own free choice to withdraw from any experiment. . . . All of the experiments were conducted with unnecessary suffering and injury and but very little, if any, precautions were taken to protect or safeguard the human subjects from the possibilities of injury, disability, or death. In every one of the experiments the subjects experienced extreme pain or torture, and in most of them they suffered permanent injury, mutilation, or death").

[44] *Id.* at 97–98 (describing brutal experiments conducted at Dachau concentration camp—purportedly to investigate the most effective means of treating persons who had been severely chilled or frozen for the German Air Force—"where subjects were forced to remain in a tank of ice water for periods up to three hours" and "kept naked outdoors for many hours at temperatures below freezing." At Sachsenhausen, Natzweiler, and other concentration camps, wounds deliberately inflicted on the prisoners were infected with Lost gas—commonly known as mustard gas).

[45] *See* Telford Taylor, *Opening Statement of the Prosecution, December 9, 1946*, in *The Nazi Doctors and the Nuremberg Code*, *supra* n. 17, at 87 (in his opening statement for the prosecution of the Nazi Doctors, Dr. Telford Taylor—chief prosecutor—recounted the achievements of *some* of the physicians on trial: "[the] 20 physicians in the dock range from leaders of German scientific medicine, with excellent international reputations, down to the dregs of the German medical profession. . . . Outstanding men of science, distinguished for their scientific ability in Germany and abroad, are the defendants [Paul] Rostock and [Gerhard] Rose. Both exemplify, in their training and practice alike, the highest traditions of German medicine. Rostock headed the Department of Surgery at the University of Berlin and served as dean of its medical school. Rose stud-

consistent with, even the product of, the public health principles of European medicine developed since the 1890s and, in some degree, still current today in the United States in the 21st century.[46] Second, the judgment at Nuremberg was not a product of the medical community and its deliberations but, instead, of a criminal tribunal passing its judgment on the misconduct of scientists, with a clear view towards protecting future generations from such experimenters.[47] Thirdly, with you and me clearly in mind, the Tribunal at Nuremberg laid down uncompromising principles: there shall be no experimentation without informed consent; every person involved in the experiment is individually responsible for his or her ethical conduct; experimentation shall be intended for the benefit of those who are subjects; and—finally—death is not an option.[48]

After Nuremberg, it would seem that principles guiding experimenters would be clear. And yet, every decade brings more instances of failure to abide by those principles. In the early 1950s, the United States undertook its first multi-center, double-blind medical experimentation.[49] The objective was to determine whether high oxygen for

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ied under the famous surgeon, Enderlen, at Heidelberg and then became a distinguished specialist in the fields of public health and tropical diseases. [Siegfried] Handloser and [Oskar] Schroeder are outstanding medical administrators. Both of them made their careers in military medicine and reached the peak of their profession. Five more defendants are much younger men who are nevertheless already known as the possessors of considerable scientific ability, or capacity in medical administration. These include defendants Karl Brandt, [Siegfried] Ruff, [Wilhelm] Beiglboeck, [Konrad] Schaefer, and [Hermann] Becker-Freyseng").

[46] In 1883 Sir Francis Galton—cousin of Charles Darwin—introduced the term eugenics, the proposed improvement of the human species through controlled breeding. "The concept expanded on Social Darwinism to include a more proactive approach to improving the species, manipulating the natural selection process" by eliminating characteristics judged to be undesirable. "The United States was at the forefront of the eugenics movement, and a national program included forced sterilizations, segregation laws, and marital restriction. The Carnegie Institute even established a laboratory at Cold Spring Harbor, New York, where scientists plotted the systematic removal of non-Nordic people." Baumslag, *supra* n. 16, at 36–37.

[47] By including the Nuremberg Code in their final legal judgment, the tribunal hoped to enforce ethical standards by holding researchers accountable. Separated from the legal judgment, the Code would serve only as an ethical framework to guide human experimentation and would have no greater force than earlier ethical codes. As one commentator observed,

> It is possible that the judges at Nuremberg incorporated the Nuremberg Code as part of their legal judgment to ensure its place in common law. It was their hope and vision that, once established in international criminal law, this Code would be widely disseminated and, if followed, would guard against future atrocities. Furthermore, while punishment for violation of ethical codes might be unclear, punishment for violation of international law would have clarity and force.

Michael A. Grodin, *Historical Origins of the Nuremberg Code*, in *The Nazi Doctors and the Nuremberg Code*, *supra* n. 17, at 138.

[48] Baumslag, *supra* n. 16, at 162 (discussing the trial of war criminals at Nuremberg).

[49] *Burton v. Brooklyn Doctors Hosp.*, 88 A.D.2d 217 (N.Y. App. Div. First Dept. 1982).

premature infants caused blindness.[50] Early on, the conclusion was yes. Still, at Brooklyn Doctors Hospital, baby Burton was put into the experiment and given anywhere from thirty to eighty-two percent oxygen.[51] Neither his parents nor his attending physician were consulted.[52] The doctor running the experiments knew that her very own hospital had done its own investigation and concluded that eighty percent oxygen was likely too high.[53] Still, the doctor changed the standing orders of the attending physician and placed baby Burton in the experiment, subject to eighty percent oxygen.[54]

Twenty-two years later, in *Burton v. Brooklyn Doctors Hospital*, Burton sued.[55] He was blind, unable to work, subject to continuous distraction and pain. The doctors argued they were not his physicians. They also argued that they had authority from the general consent form his parents had signed. They argued that the experiments were necessary.[56] The court found otherwise.[57] Any parent reading this article will understand why. What cannot be understood is why, a decade after Nuremberg, the doctors had still not gotten the message.

Let us move to the 1970s, from Brooklyn to Cincinnati, where doctors directing the clinic at the University of Cincinnati College of Medicine exposed impoverished patients to fatal doses of radiation.[58] The point was to find out when and how radiation kills. Needless to say, this was not why people came to the clinic. The doctors defended the experiment by arguing that the patients were poor and were not paying for their treatment. Moreover, they argued the information was needed by the military.[59] The trial court, in a scathing opinion, found against the hospital and the doctors.[60] In one of the best opinions in this area, the trial court held that the Nuremberg Code is part of the common law of the United States and that the doctors in Cincinnati

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[50] *Id.* at 219–20.

[51] *Id.* at 220–21.

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *Burton*, 88 A.D.2d at 222.

[56] *Id.* at 221.

[57] *Id.* at 222–24.

[58] *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 800, 805, 811 (S.D. Ohio 1995).

[59] The experiments—funded by the Department of Defense—had the primary purpose of testing the effect of radiation on soldiers in the event they would encounter a nuclear attack. Defendant's complaint referenced a report prepared for the Department of Defense by the individual Defendants who conducted the Human Radiation Experiments during the period 1960 to 1966 indicating that the goal was "'to develop a baseline for determining how much radiation exposure was too much, and to determine how shielding could decrease the deleterious effect of the radiation,' and to determine what a single dose of whole or partial radiation could do to 'cognitive or other functions mediated through the central nervous system.'" *Id.* at 803.

[60] *Id.* at 832.

could be held to know of the Nuremberg Code and Common Rule principles.[61]

However, the Cincinnati case shows that three decades after Nuremberg, the doctors and the teaching hospital had still not gotten the message. It is even more puzzling in light of the existence, at the time, of the Common Rule, which essentially applied Nuremberg principles to all federal agencies. More puzzling still is the subsequent Report of the Advisory Committee on Human Radiation Experiments, which, while condemning the conduct of the physicians, essentially extended to them amnesty, a kind of compassion which they had not shown towards their patients.[62]

Our third case is *Grimes v. Kennedy Krieger Institute*, a decision by the highest court of the state of Maryland, rendered in 2001. There, the Maryland Court of Appeals found against the Kennedy Krieger Institute (KKI), whose contract was funded by the EPA, Johns Hopkins University, and the city of Baltimore. These were all public institutions committed to the public interest and, at least in the three former instances, of the highest reputation.[63] And yet these institutions agreed amongst themselves to rate slum housing in Baltimore by lead paint presence and induced, by cash incentives, families with young children to live there.[64] Everybody involved knew the children could get lead in their blood.[65] The parents were told they would receive continuing medical care and reports, but it is unclear whether they were told their children might be at risk of serious neurological damage and death.[66] The children were not asked for their consent and there was

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61 *Id.* at 821–22.

62 *Research Ethics and the Medical Profession: Report of the Advisory Committee on Human Radiation Experiments*, 276 J. Am. Med. Assn. 403 (1996).

63 *Grimes*, 782 A.2d at 818–20, 840.

64 *Id.* at 811–13. *See also id.* at 824–25 (describing the compensation offered to project participants: "for your time answering questions and allowing us to sketch your home we will mail you a check in the amount of $5.00. In the future we would mail you a check in the amount of $15 each time the full questionnaire is completed. The dust, soil, water, and blood samples would be tested for lead at the Kennedy Krieger Institute at no charge to you").

65 *See id.* at 812–13 (noting that the children in the research project "were encouraged to reside in households where the possibility of lead dust was known to the researcher to be likely, so that the lead dust content of their blood could be compared with the level of lead dust in the houses at periodic intervals over a two-year period. Apparently, it was anticipated that the children, who were the human subjects in the program, would, or at least might, accumulate lead in their blood from the dust, thus helping the researchers to determine the extent to which the various partial abatement methods worked").

66 The consent form indicated that the researchers would provide the parents with "specific blood-lead results," and contact them to discuss the house test results and steps they could take to reduce any risks of exposure. *Id.* at 824–25. The court adds that

> there was no complete and clear explanation in the consent agreements signed by the parents of the children that the research to be conducted was designed, at least in significant part, to measure the success of the abatement procedures by measuring the extent to which the children's blood was being contaminated. It

nothing new to be learned—except how quickly their blood would pick up lead.

But wait, there is more: in fact, the parents were not given current and accurate updates on the dust samples taken from their houses.[67] The children developed lead in their blood.[68] The parents sued.[69] The doctors argued that the children were not patients and that the parents had given consent to put the children at risk.[70] Further, KKI said, it had not created the housing with lead-based paint, which would exist regardless of experimentation.[71] The city of Baltimore argued that it could not force the slumlords to remove the paint because they would just stop renting the slums.[72] The Court of Appeals was appalled. It held that the doctors had a special relationship with the children and parents.[73] It found that existing controls and processes, such as IRBs, had failed utterly[74] and held that parents could not consent to put their children at risk.[75]

That the Courts in *Burton*, *Cincinnati*, and *Grimes* condemned the human experiments is a cause for celebration, although on reflection, it is a small cause at best. In each case, the principles of Nuremberg, Helsinki, and the Common Rule had been understood for decades. Yet, they were avoided, indeed subverted. There is an entire industry and governmental apparatus, involving billions of dollars, which resists restrictions on human experimentation.[76]

To elaborate a bit further, this past summer in Portland, Oregon, a newspaper reported that there would be public meetings to receive public comment on proposed experimentation on unconscious victims in ambulances.[77] Three years earlier, a blood substitute was tested on

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can be argued that the researchers intended that the children be the canaries in the mines but never clearly told the parents.

Id. at 813. (emphasis omitted).

67 *Grimes*, 782 A.2d at 825 (explaining how results regarding dust samples that revealed "hot spots"—areas where the level of lead was higher than it might be in a completely abated house—were not furnished to tenant until more than nine months after the samples had been collected and not until after blood in the tenant's child was found to contain elevated levels of lead).

68 *Id.* at 825, 828–29.

69 *Id.* at 807.

70 *Id.* at 832.

71 *Id.* at 832.

72 *Id.* at 815 n. 6.

73 Grimes, 782 A.2d at 845–46.

74 *Id.* at 817.

75 *Id.* at 855.

76 Michael Janofsky, *E.P.A. to Bar Data from Pesticide Studies Involving Children and Pregnant Women*, N.Y. Times A22 (Sept. 7, 2005) (available at http://www.nytimes.com/2005/09/07/politics/07enviro.html).

77 Andy Dworkin, *Study Seeks OK on Patient Trials*, The Oregonian B1 (May 8, 2006) (available at http://infoweb.newsbank.com/; *path* The Oregonian, *search* Study Seeks OK on Patient Trials) (announcing four community meetings—one in each county where the study is taking place—to offer the public a chance to ask questions and share opinions about the study). OHSU is one of eleven medical centers throughout the

such victims, in place of the prevailing practice of saline solution transfusions.[78] Those experiments were discontinued when people died.[79] I sought to attend the meetings on this most recent experiment on unconscious people, went to the addresses indicated in the article, but could not find anyone in attendance.

My interest was this: if a person was unconscious, how could she or he consent to being a subject of experimentation for an unproven treatment modality? Amazingly, the answer is something called "community consent." The NIH and the FDA have agreed that human experimentation may proceed on unconscious subjects without their consent if the community has consented in meetings, even where nobody present has even the remotest prospect of being the unconscious victim of the experimentation.[80] Therefore, the protections for human subjects of experimentation are, at best, of dubious value. What, then, can or should be done to protect animals from the risks facing humans?

III. IMPLICATIONS FOR ANIMAL EXPERIMENTATION

A. The Natural Order of Things

It is dangerous to generalize too much from the preceding cases. There are hundreds of instances of human experimentation that have gone well. Still, the experience reflected in the *Burton*, *Cincinnati*, and

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United States and Canada currently taking part in an experimental study using a new type of saline solution, administered intravenously by paramedics on severely injured accident victims. The experimental fluid, hypertonic saline that contains more salt than the conventional saline solution or blood, will replace the use of traditional blood. *Id.*

78 Thomas M. Burton, *Red Flags: Amid Alarm Bells, A Blood Substitute Keeps Pumping; Ten in Trial Have Heart Attacks, but Data Aren't Published; FDA Allows a New Study: Doctors' Pleas Are Ignored,* Wall St. J. A1 (Feb. 22, 2006) (available at http://proquest.umi.com/pqdweb?index=0&did=991350801&SrchMode=I&sid=2&Fmf=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1195332317&clientId=5359) (revealing FDA's decision to allow a new study on the blood substitute PolyHeme despite an earlier clinical trial that finished with ten of eighty-one patients receiving PloyHeme suffering a heart attack within seven days—two of whom died. None of the seventy-one patients in the trial who received real blood were found to have had a heart attack).

79 *Id.* (describing an earlier 1998 trial of Baxter International's blood substitute, HemAssist, which was stopped when twenty-four of fifty-two patients given the blood substitute died, compared to eight of forty-six who received real blood).

80 In 1996, the FDA adopted a rule granting waiver from informed consent requirements for trauma patients but only under conditions specified, the first being:

> (1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

21 C.F.R. 50.24 (2007).

Grimes cases should give us pause.[81] If ever we are to protect a species from irresponsible experimentation and abuse, certainly it would be our own species. Yet experience teaches that protective mechanisms fail often enough to be a matter of profound concern.[82] For those concerned with experimentation on animals, the failings with human subjects should be profoundly troubling.

To review, the most significant protection for human subjects is the requirement of informed consent, which applies to both treatment and experimentation.[83] Yet in the *Burton*, *Cincinnati* and *Grimes* cases, informed consent was either not obtained, bypassed, or obtained fraudulently.[84] With animal subjects, of course, there simply is no capacity to give informed consent. And so those concerned with animal rights should be profoundly concerned at the absence of even this deficient protection.

The next level of protection for human subjects and experimentation is found in the processes of NIH, IRBs, and IECs, grant approval and medical institution or hospital oversight.[85] All, or most, of these are missing with animal experimentation. Grants typically require that the experimenter not abuse animals.[86] However, the terms are not carefully specified and the oversight bodies are either missing totally or are poorly staffed and poorly funded, much as they are with

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[81] *Burton*, 452 N.Y.S.2d 875; *In Re Cincinnati Radiation Litigation*, 874 F. Supp. 796; *Grimes*, 782 A.2d 807.

[82] *Burton*, 452 N.Y.S.2d at 877, 879 (hospital doctors did not warn the parents of a premature infant of the risks associated with high oxygen exposure, which resulted in the infant's blindness); *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 800, 804 (Department of Defense performed radiation experiments on patients, telling them the experiments were actually forms of cancer treatment); *Grimes*, 782 A.2d at 811–12, 818 (the federal, state, and Baltimore governments, in coordination with private companies, enticed low-income residents to be subjects of human experimentation on the effects of lead poisoning but did not adequately warn of the risks of such experimentation).

[83] *See supra* nn. 16–17 and accompanying text (discussing principles of the Nuremberg Code and the Helsinki Declaration).

[84] *Burton*, 452 N.Y.S.2d at 879, 881; *In Re Cincinnati Radiation Litigation*, 874 F. Supp. at 800, 802–04; *Grimes*, 782 A.2d at 818.

[85] *Supra* nn. 20, 25–26 and accompanying text (discussing the roles and processes of NIH, IRB, and IEC).

[86] All grantees of the Public Health Service (PHS)—and subsequently, NIH—must adhere to the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* [hereinafter *Policy*]. Mandated by the Health Research Extension Act of 1985 and implemented by the Office of Laboratory Animal Welfare (OLAW), an office located at the NIH, the *Policy* provides guidelines on pre-surgical and post-surgical care; veterinary and nursing care; and the use of analgesics, tranquilizers, and anesthetics and covers all live, vertebrate animals, including rats and mice. Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820, 822, 875 (1985); Natl. Insts. of Health—Office of Protection from Research Risks (NIH–OPRR), *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (Bethesda, MD: NIH–OPRR, 1986). For a more detailed discussion of regulatory control over animal research, see Zola, *Basic Research, Applied Research, Animal Ethics, and an Animal Model of Human Amnesia* in *Why Animal Experimentation Matters*, *supra* n. 2 at 79; Jerrold Tannenbaum, *The Paradigm Shift towards Animal Happiness*, in *Why Animal Experimentation Matters*, *supra* n. 2 at 97–100; Baruch A. Brody, *Defending Animal Research*, *supra* n. 2, at 133.

humans. The *Grimes* court was particularly specific in criticizing the failings of the IECs and IRBs in permitting children to be put at risk of lead paint poisoning in the Baltimore slum housing.[87] If those systems failed to protect children, what is there to provide even minimal protection for animals?

The third level of protection for human subjects has to do with the purposes of experimentation and its outer limits. Putting a human to death is simply not permissible. By way of contrast, in animal experimentation, the subjects are regularly put to death.[88] Again, human subjects may be involved in experimentation only when no other alternative is available, and even then, when therapeutic benefits are likely. No such limitations typically exist for experimentation on animals. Finally, human experimentation must be preceded by live experiments, which do not put humans at risk; this means putting animals at risk. There is no predicate for testing on animals such as there is for testing on humans.

One other consideration bearing on animal experimentation, quite distinct from human experimentation, is the commonplace abuse of animals raised for human consumption. Hogs and chickens are regularly kept in pens, allowing them no movement, no normal association, and not even minimal freedom, and are force-fed for rapid growth and consumption.[89] Recently, in the newspapers of several large cities, the Humane Society of the United States (HSUS) complimented the Burgerville chain of restaurants for committing itself to buying only chickens that have been raised outside of confining coops or pens, which are used at factories and completely restrict the chickens from any movement toward a normal range of activities.[90] This is commendable, but it does not portend well for those concerned with animals and experimentation, because it means that, by and large, animals may be mistreated when raised for consumption. Of course, it also means the subjects may be themselves consumed

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87 *Grimes*, 782 A.2d at 812–14.

88 Steven M. Wise writes that "[t]ens of millions [of animals] are annually consumed in biomedical research." Steven M. Wise, *Animal Rights, One Step at a Time*, in *Animal Rights*, *supra* n. 1, at 19. Just one, small example is that of Dr. Roselli's experiment on sheep behavior mentioned *supra* n. 6.

89 Currently, federal law does not regulate how farm animals are kept and the majority of state anti-cruelty statutes do no apply to farm animals. Wolfson & Sullivan, *Foxes in the Hen House: Animals, Agribusiness, and the Law: A Modern American Fable*, in *Animal Rights*, *supra* n. 1, at 212.

90 *See* Puget Sound Bus. J., *Burgerville to Use Eggs from Cage-Free Chickens*, http://seattle.bizjournals.com/seattle/stories/2007/01/15/daily6.html?surround=lfn (Jan. 16, 2007) (highlighting Burgerville's decision to use cage-free eggs); see also Allan Brettman, *Burgerville Goes To Cage-Free Egg Items*, (Jan. 17, 2007) (available at http://web.ebscohost.com/ehost/detail?vid=4&hid=106&sid=05bcbac0-2cd3-4ae2-8993-06f23a72839f%40sessionmgr102) (noting Burgerville's move to cage-free eggs as emblematic of a niche it has carved in the "sustainable food practices world"); HSUS, *Burgerville Becomes the First Restaurant Chain to Renounce Battery Cage Eggs*, http://www.hsus.org/farm/news/ournews/burgerville_cage_free.html (Jan. 17, 2007, 2007) (praising Burgerville as a pioneer).

How can greater protections be justified for animals being used for experimentation, when animals used for consumption are so mistreated? Perhaps one might refer to a natural order of things, in which species routinely consume other species. Birds do it, bees do it, even educated fleas do it, and so humans may similarly be understandably engaged in consuming other animals. But unlike humans, other animals do not experiment on each other; nor, in the ordinary course, do they torture or kill for purposes other than nutrition. When we do that, we are changing and departing from the natural order.

When we change the natural order of things, we have increasingly limited the purposes and the means of doing so. In places such as Australia, New Zealand, and Hawaii, introducing non-native species has led to ecological disasters.[91] Here in the Northwest, we spend hundreds of millions of dollars to transport anadromous fish over and around the dams we have built on the Columbia River, impeding or destroying the natural life cycle of fish such as salmon.[92] Similarly, we protect species, such as the Spotted Owl, Northern Wolf, and Snail Darter from extinction by humanity's impositions on the environment.[93] Again, in Africa, for decades, humanity has attempted to pre-

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[91] The cane toad was introduced into Australia in an effort to control beetles in sugarcane fields, however, they secrete a poison through their skin and "pose a deadly temptation [as prey] to owls, pythons, and native marsupials called spotted-tailed quolls or tiger cats, which evolved without any lessons about poisonous prey." Yvonne Baskin, *A Plague of Rats and Rubbervines: The Growing Threat of Species Invasions* 91 (Island Press 2002). In 1958, a predatory wolfsnail was introduced to the Hawaiian islands in the hope of controlling populations of the alien giant African snail. Today the African snail survives while the wolfsnail has decimated more than half of forty-one species of native Hawaiian tree snails of the genus *Achatinella*, leaving the remainder in serious decline. George W. Cox, *Alien Species and Evolution: The Evolutionary Ecology of Exotic Plants, Animals, Microbes, and Interacting Native Species* 222 (Island Press 2004). In New Zealand, the brushtailed possum was introduced from Australia during the nineteenth century to establish a fur industry. Unfortunately, the possum

> developed a monstrous appetite for the island's remaining native forests. Today, every New Zealand sunset brings out roughly 70 million of them, and before dawn, another 21 tons of trees . . . have disappeared down the possums' digestive tracks. Nor is it just trees that suffer: the possum also eats the eggs and chicks of some native birds, and displaces others from their nesting sites.

Chris Bright, *Life Out of Bounds: Bioinvasion in a Borderless World* 116 (Linda Starke ed., Worldwatch Inst. 1998).

[92] The Columbia River Fish Mitigation Project was initiated in 1991 with the purpose of improving "fish survival through 'passage' dams on the Columbia/Snake Rivers." Funded through annual Congressional appropriations, the Project spent $65.9 million in 2004 alone and $638.4 million from 1997 to 2004. U.S. Army Corps of Engineers & Bonneville Power Administration, *Columbia River Fish Mitigation Project*, http://www.efw.bpa.gov/IntegratedFWP/ColumbiaRiverFishMitigationProject.pdf (accessed Nov. 17, 2007).

[93] *Northern Spotted Owl v. Hodel*, 716 F. Supp 479, 480 (W.D. Wash 1988) (finding that the U.S. Fish and Wildlife Service refused to consider any of the expert opinion concluding the northern spotted owl was becoming extinct, and thus its decision not to list the species as endangered was contrary to law); *Defenders of Wildlife v. Andrus*, 627 F.2d 1238, 1250 (D.C. Cir. 1980) (overturning a federal district court's decision requir-

serve species and the environment supporting them from extinction by predatory and agricultural activities of the human species.[94]

And so, an ethical commitment to the natural order of things is not only a part of our national and natural ethic, but is, in multiple instances, a part of our national public policy. It is this same ethic which opposes transgenic cloning and the creating of new species.[95] This ethic is not a utilitarian philosophy, but an *a priori* commitment to the natural scheme of things, the balance of nature, and to the wisdom we have gained, however painfully, from our multiple disasters in disturbing that balance.

B. Specific Steps for Protection

What, then, might this ethic require of human experimenters dealing with animals? First, of course, we should ban inflicting pain and bodily harm. The baboon experiments at the University of Pennsylvania, employing physical torture and neurological abuse, illustrate the danger posed and the limits required.[96] We need particularly to

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ing the Secretary of the Interior to write an environmental impact statement, as demanded by environmentalists, before allowing the state of Alaska to engage in a targeted wolf hunt); *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 153 (1978) (finding that pursuant to the Endangered Species Act's explicit provisions, the survival of a relatively small number of fish required the permanent halting of a virtually completed dam for which Congress had expended and continued to appropriate large sums of public money).

[94] Kenya is widely known for its efforts to restore elephant populations. One of the many examples of elephant conservation initiatives in the country is the Kenya Wildlife Service (KWS) Elephant Programme, which

> falls under KWS Research and Planning Department and is responsible for coordinating management, research and monitoring elephants throughout the country. This include[s] coordinating and participating in all national elephant issues, community outreach, ensuring elephant security, problem animal control and reducing conflict with people. Given the broad range of elephant related activities, the Elephant Programme works closely with members of other KWS Departments, NGOs, local people and other stakeholders. . . . The objective of the Programme during its initiation in 1989 was to protect the elephants from the danger of extinction that was posed by the poachers.

Kenya Wildlife Serv., *Elephant Programme*, http://www.kws.org/elephant.html (accessed Nov. 15, 2007).

[95] In fact, a 2005 study showed that the majority of Americans strongly oppose transgenic cloning. The Pew Initiative on Food and Biotechnology, *Recent Findings*, http://pewagbiotech.org/research/2005update/2005summary.pdf (Nov. 7, 2005) (showing that fifty-five to sixty-one percent of those surveyed opposed transgenic cloning, regardless of the participant's knowledge of the science).

[96] In 1984, People for the Ethical Treatment of Animals (PETA) released sixty hours of graphic video footage documenting the appalling treatment of primates at the University of Pennsylvania head-injury laboratory that resulted in government fines and the loss of funding for the study. Dick Pothier, *Animal-Research Aid Cut Off at Penn*, Phila. Inquirer A1 (July 19, 1985) (reporting on the federal government's order to suspend the one million dollar-a-year grant the University of Pennsylvania receives for a controversial head-injury research project); James J. Kilpatrick, *Champions of Humane Research Win Belated Victory over Brutality*, Orlando Sentinel A15 (July 23, 1985)

guard against experiments whose very purpose and methodology are the infliction and measuring of pain, or the confusing of the consciousness of sentient animals. The United States is now embroiled in a national debate about the uses of torture—we do not need to learn more by torturing animals. Any prohibition might be graded in terms of the sentience of the creatures, with primates at the high end and mice at the low end.

Second, we should require Environmental Impact Statements (EIS) when the experiments pose a risk to the species being tested on or to others coming in contact with the species.[97] This has been urged on a number of occasions, most significantly when the HIV virus was being experimented with in mice.[98] Implicit in the conventional environmental impact process is a balancing test: what is the likely impact and how does it compare with the benefit sought? The EIS methodology for animal experimentation would be quite similar to the conventional process, where environmental impact statements are required and projects may affect the environment. The difference would be that the statement would be required, and the investigation conducted, as to the impact on species potentially affected by the animal experimentation.

Third, notice to animal rights and animal welfare groups, such as the HSUS, the Society for the Prevention of Cruelty to Animals, the National Wildlife Foundation, and local or state chapters of interested groups such as the Audubon Society, should be routinely required whenever an application is filed for federal or state funding to experiment on animals. This procedure is novel and no analogue exists for experimentation with humans. But the reason for requiring extraordinary notice and hearing opportunities is that the safeguards in place for humans, the IECs and the IRBs, have virtually no application to animal experimentation. Thus, if the safeguards and the guardians are to be replicated for animals, it must be on the front end, when applications are filed and before they are granted.

(describing how members of the Animal Liberation Front used more than sixty hours of videotapes of animal experiments to launch a campaign to halt further federal grants to the Head Injury Clinical Research Center at the University of Pennsylvania). Most recently, allegations of abuse were lodged against the Oregon National primate Research Center by PETA, when an undercover employee reported, with video, on abuses to a number of the 4200 primates lodged there, violating the federal Animal Welfare Act. *See* The Oregonian D5 (Nov. 13, 2007).

97 Section 102(2)(c) of the National Environmental Protection Act requires environmental impact statements (EIS) to be included in "every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment." 42 U.S.C.A. § 4332(C) (West 2003). Regulations promulgated by the Council on Environmental Quality delineate the components of an EIS. These include the purpose of and need for the action being considered, alternatives including the proposed action, the environment affected by the proposed action and environmental consequences of the proposed action. 40 C.F.R § 1502.10 (2006).

98 *See Found. on Econ. Trends v. Bowen*, 722 F. Supp 787 (D.D.C. 1989) (finding the NIH's filing of an environmental assessment sufficient to fund AIDS research involving cloning HIV genes into mice, and an EIS not required).

Fourth, there must be an effective mechanism for informed consent by and on behalf of the animals. As noted earlier, this is the frontline protection for humans.[99] It is totally missing with animals for the simple reason that they lack capacity to consent. Further, if animals had it, they would hardly be likely—any more than you or I—to consent to pain and death. In the *Grimes* and *Burton* cases, children were being put at risk through experimentation, at ages when they, like animals, were unable to give informed consent.[100] Parents might give consent, although a court would only reluctantly concede this, and would probably require guardians and hearings, as with an incapacitated person, such as Nancy Beth Cruzan.[101] If it is possible for those acting in *parens patria* to give informed consent as to children, then animal advocacy groups may have a similar role to play as guardians *ad litem* for animals.

Fifth, nations that raise the very animals involved in animal experimentation have a legitimate and important interest in their welfare and a responsibility for assuring humane treatment. Treaties on international trade in the subjects of animal experimentation, monkeys, gorillas, chimpanzees, and other primates for example, should assure a role of parens patria to the nations of origin.[102] They have a special interest in the well-being of the creatures indigenous to their lands and thereby entrusted to their care. It would seem particularly appropriate to grant them oversight of the methods and purposes of experimentation, as well as the identities of the experimenters, before their creatures are put at risk or harmed or killed.

Sixth, animal experimentation takes place in real institutions, in real communities, subject to local laws and legal agency oversight. As with children, the aged and the infirm, and the mentally or emotionally at risk populations, so also with animals may we properly look to the equity jurisprudence enforced by state attorneys general to provide

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99 *See Burton*, 452 N.Y.S.2d at 875 (hospital doctors did not adequately warn of the risks involved with high oxygen treatment for infants, which prevented the parents from giving informed consent); *Grimes*, 782 A.2d at 838 (parents in Baltimore were not fully warned of the dangers of lead paint in their low-income houses and, therefore, could not give informed consent to what amounted to human testing of lead exposure); *Cincinnati*, 874 F. Supp at 816 (patients who were told they were receiving treatment for cancer had no ability to provide informed consent to the "treatments," since, in reality, they were the subjects of radiation experimentation).

100 *Burton*, 452 N.Y.S.2d at 878; *Grimes*, 782 A.2d at 812.

101 After an auto accident left Nancy Beth Cruzan in a persistent vegetative state, her family fought in courts for three years to have her feeding tube removed. The Supreme Court denied the family's request citing lack of evidence of Cruzan's wishes, but the family ultimately prevailed by providing additional evidence. On Dec. 14, 1990, the tube was removed and she died twelve days later. *Cruzan v. Director, Mo. Dept. of Health*, 110 S. Ct. 2841 (1990); William H. Colby, *Long Goodbye: The Deaths of Nancy Cruzan* 42, 357, 362, 391 (Hay House, Inc. 2002).

102 Convention on International Trade in Endangered Species of Wild Fauna and Flora (Mar. 3, 1973), 993 U.N.T.S. 243.

protection to animals.[103] It is not a very large expansion to include animals in their equity jurisdiction. Indeed, here in Portland, Oregon, over the past year, local and state agencies have proceeded on behalf of horses, dogs and rabbits neglected by their human caretakers, in much the same way the agencies responsible for child welfare act on behalf of children.[104]

Finally, a particularly significant line of attack could be based on the charitable status of most of the institutions conducting animal experimentation. Many of these are hospitals or medical schools or scientific institutions formed for charitable purposes under state law.[105] They depend heavily upon favorable tax treatment as non-profit institutions, both in terms of exempting their income and property from taxation and, as well, treating gifts as taxable deductions.[106] In the world of health law, advocacy groups have challenged the failure of hospitals to provide charitable care for the poor as being inconsistent with the tax status of non-profit hospitals.[107] A similar challenge could be directed at institutions that engage in abuse or the needless infliction of pain or the pointless imposition of death in animal experimentation, funded and justified as part of the charitable status and mission of the institution.[108] The risk of losing millions of dollars in

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[103] The concept of "informed consent" is embodied in the statutes of the majority of states. In general, these statutes provide that a physician must advise a patient of the procedures the physician contemplates, the risks involved, and alternatives. Arthur B. LaFrance, *Bioethics: Healthcare, Human Rights and the Law*, 808 n.7 (2d. ed., LexisNexis 2006). Certain populations are particularly subject to abuse and thus are afforded additional protection in most states through patient bills of rights. *Id.* at 865.

[104] *See* Sarah Hunsberger, *Hoofbeats of Hell in Horse Heaven*, Oregonian B1 (Mar. 29, 2006) (reporting that the Oregon Humane Society continually investigates cases of owners neglecting horses and that prosecutions increase during winter months); Elizabeth Suh, *City Takes Charge of 150 Rabbits Discovered in Hillsboro House*, Oregonian B5 (Oct. 18, 2006) (reporting that the city of Hillsboro took possession of more than 150 rabbits—some of which were dead and stored in a freezer—after a woman was charged with neglect of animals); *Woman with 99 Dogs Accused of Animal Neglect*, Oregonian D3 (Mar. 19, 2006) (reporting that a woman who kept ninety-nine dogs in an unsanitary environment was charged with multiple counts of animal neglect).

[105] OHSU gets much support from its 501(c)(3) organization. "About 22,640 philanthropic donors provide financial support to OHSU each year through the OHSU Foundation and Doernbecher Children's Hospital Foundation." Or. Health Sci. U., *OHSU at a Glance*, http://www.ohsu.edu/about/atEcon.cfm (accessed Nov. 18, 2007).

[106] *See* Julie Appleby, *Scales Tipping Against Tax-Exempt Hospitals*, USA Today B1 (Aug. 24, 2004) (estimating non-profit hospitals save "billions" each year due to their tax-exempt status, while often providing minimal charitable services to the local community in order to justify such status).

[107] *See* Theo Francis, *Lawmakers Question if NonProfit Hospitals Help the Poor Enough*, Wall St. J. (E. Addn.) A5 (July 20, 2007) (citing an IRS report "noting that many hospitals spend 3% or less of total revenue on care for the poor and others who don't pay").

[108] As of October, 2007, the IRS is considering revisions to Form 990, evaluating the public service commitments of institutions, such as research hospitals claiming 501(c)(3) and (4) charitable tax treatment. *See* 16 Health Law Rprtr 1171, 1188 (Oct. 4, 2007).

favorable tax treatment might perhaps be the most effective club animal advocates could wield.

IV. CONCLUSION

Many of these comments may seem visionary, others, cynical; they are both. Our experience in protecting, or failing to protect, the human subjects of experimentation is not grounds for optimism. To provide similar or enhanced protection for animals requires enhanced mechanisms and expanded vigilance. The prospects are not good and the road is not easy. While I would assert that animal experimentation is sometimes justified, I would argue at the same time that pain, abuse, and death are rarely, if ever, justified. For that reason, expanded oversight, participation, and intervention by advocacy organizations is not only necessary but also desirable and should be actively institutionalized along some of the lines suggested above.

As this article was being finalized in October 2007, the Nobel Prize Committee announced awards to geneticists in Wales and the United States, for research conducted on mice.[109] The resulting "knockout mice" lack a gene which allows for modeling of human disease to become possible.[110] The work has important implications for human health and welfare. All of the evidence suggests the experiments are conducted humanely, with no needless pain. Surely, few would oppose such fundamental research. Yet, the proposals and concerns discussed above remain important. Abuse of animals in research remains as much a danger as with humans. There is a fundamental pressure to view experimental subjects as "instruments," not creatures. The Helsinki Convention and the European Compact on Human Experimentation have compromised the safeguards of Nuremberg and the Common Rule. If this is the risk with humans, how much greater is it with animals?

In the natural order of things, many animals as individuals lack the sentience, awareness, and consciousness we prize in higher animals. Perhaps some of the safeguards proposed above might be reserved for the latter. Even then, we must carefully consider our obligations to entire *species* of creatures. Far too many have been exterminated by humanity's carelessness for us to pursue genocide of any kind, as deliberate policy or as a byproduct of experimentation.

It would be tempting to close with a quotation from the author E.B. White, in *Charlotte's Web* or *Stuart Little*, or perhaps from author A.A. Milne and *Winnie the Pooh*.[111] The danger, however, in using an-

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109 Lawrence K. Altman, *3 Share Nobel in Medicine for a Breakthrough Gene Technique*, http://query.nytimes.com/gst/fullpage.html?res=9E04E1DE173DF93AA35753C1A9619C8B63&sec=&spon=&partner=permalink&exprod=permalink (accessed Nov. 17, 2007).

110 *Id.*

111 E.B. White, *Charlotte's Web* (Harper Collins 1952); E.B. White, *Stuart Little* (HarperTrophy 1945); A. A. Milne, *Winnie-the-Pooh* (Methuen & Co. Ltd. 1926).

thropomorphic sentiments is exactly that: they are simply sentiments. Our focus should be more profound, looking toward the eternal, and so let me close simply with the observation that in both the Old Testament and the New, God entrusted to humanity the care and stewardship of all of God's creatures.[112] It is true today as surely as it was ever true, as long ago as the beginning of time.

[112] Genesis 2:15 (King James) (entrusting Adam with the care of Eden).