Commentary

Commentary: A Belmont Report for Animals: An Idea Whose Time Has Come

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Animals who are held and used in laboratories suffer tremendously as a result of the extreme privation of their impoverished living conditions. Deprived of companionship, sufficient space, access to outdoor spaces, opportunities for exercise, and sufficiently complex environments—and assaulted by loud, distressing noises and manipulated by unpredictable, intimidating humans who may conduct confusing, terrifying, and sometimes painful procedures on them—animals in laboratories are physiologically and psychologically compromised.[1]

As detailed below, the current system of oversight of animal use in laboratories has failed to provide adequate protections for animals. Experiments on animals indulge scientific curiosity that is justified by claims of human benefit, but oversight bodies responsible for evaluating and granting permission to proposed experimental protocols have tended to minimize, or ignore outright, harms done to animals while exaggerating any anticipated benefits. At the root of the failure to fairly balance harms inflicted on animals against promised benefit to humans is a lack of basic moral consideration to beings who have the capacity to suffer, and a failure to accord respect for the integrity and autonomy of animals.

In their groundbreaking paper, *A Belmont Report for Animals?,* Hope Ferdowsian, *et al.* observe that "the lack of a fundamental effort to explore the ethical issues and principles [guiding] decisions about the potential use of animals in research has led to unclear and disparate policies" that "have done relatively little to address ethical problems within research involving nonhuman animals."[2] The authors discuss the publication of the Belmont Report, in 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and describe the principles established in the report: "respect for persons (generally articulated as respect for autonomy), obligations to beneficence and justice, and special protections for vulnerable individuals and populations."[3] Noting that these principles for human research "provide a base from which actionable and robust operational requirements—namely, informed consent, assessment of risks and benefits, and selection of subjects rationally flow," the authors forward the bold and critically important proposition that the principles of the Belmont Report could be applied to animals.[4] Such a proposition would address many of the current problems within animal research, as noted below, for a range of species—including those who are most commonly used in research, and those who are most closely related, in evolutionary terms, to humans.

Oversight of Animal Use in Laboratories: A Threadbare Patchwork Quilt

As Ferdowsian, *et al.* note, in the United States, the treatment of animals in laboratories is governed by a patchwork of laws, regulations, guidelines, policies, and principles—each pertaining to a different subset of animals.

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The Animal Welfare Act (AWA) is the only federal law that stipulates legally-enforceable standards in the care and use of animals held for experimental purposes. This law infamously excludes mice of the genus *Mus,* rats of the genus *Rattus,* birds bred for use in experimentation, fishes, reptiles, amphibians, and all animals used in agricultural experiments—an exclusion that is especially troublesome given that rats and mice make up an estimated 95 percent of the animals used.[5]

The Health Research Extension Act of 1985 (HREA) mandates protections—specified in the *Guide for the Care and Use of Laboratory Animals*, the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*, and the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*—for all vertebrate animals used in federally funded experimentation, but these guidelines, polices, and principles do not carry the force of law.[6]

Whether covered by the AWA or excluded from it, virtually nothing is prohibited in laboratories, no matter how cruel or pointless, so long as the paperwork is in order. Experimenters can and do routinely subject animals to electroshocks, deprive them of food or water if it is a part of the experimental design, infect them with diseases, subject them to psychological trauma like maternal separation, and poison them to death with experimental chemicals or drugs. Experimenters can and do withhold pain relief and veterinary care from animals if such intervention is deemed to interfere with the "scientific objectives" of the experiment.[7] And even when a clearly validated and accepted nonanimal alternative exists to a particular test or experiment, laboratories are not required to use it.

Confinement in Ethologically Inappropriate Environments

The minimalist design of animal housing in laboratories would suggest a belief that animals bred in laboratory settings are physiologically and psychologically distinct from their free-roaming counterparts. There is no scientific basis for such a belief. Instead, animals in laboratories endure lives of privation, extreme frustration, stress, trauma, and depression even before they are enrolled in protocols. For example, monkeys and other nonhuman primates who might travel miles each day in the wild and who would spend hours engaged in grooming one another are confined, often alone, to cages just slightly larger than their bodies. In most laboratories, rats and mice are denied a place to dig and hide, despite research conducted by Oxford behavioral scientist Manuel Berdoy indicating that the desire to dig, hide, swim, and select mates is not bred out of rats even after 100 generations of laboratory breeding.[8] Likewise, rabbits, dogs, cats, and other animals are naturally gregarious, athletic animals, but are often housed alone in laboratories in small cages that thwart the animals' natural behaviors.

The bleak caging that is the standard for animals in laboratories has been designed primarily for the convenience of humans. The relative deficit in concern for harms to animals has resulted in animals exhibiting behavioral and physiological responses indicative of compromised welfare. As a result, ethologists have argued that "housing animals under standard conditions causes suffering."[9] In their 2002 review of 40 studies on housing modifications for animals in laboratories, Anna Olsson, *et al.* wrote, "[B]ehaviour is severely restricted under standard housing conditions. Despite generations of reproduction in captivity, domestic animals still show behavioural adaptation to natural habitats. … If the animals are

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not able to carry out behaviours that they are highly motivated to perform, their welfare will be compromised."[10] This point was corroborated in a 2006 report published by the Federation of European Laboratory Animal Science Associations (FELASA): "Animals housed in unenriched laboratory animal housing often develop abnormal behaviour, such as stereotypies, excessive aggression or self-injurious behaviour and these are usually signs that the housing is not meeting the animals' needs."[11]

Next of Kin: Primates in Laboratories

It is well established that when primates are deprived of companionship, sufficient space, and sufficient environmental complexity, they experience chronic stress and develop behavioral abnormalities, including stereotypic and self-injurious behaviors. The scientific literature is replete with evidence that the current manner in which primates are held in U.S. laboratories—in universities, contract testing firms, and private companies—is wholly inadequate for ensuring the psychological well-being of primates. Published journal articles document a grim reality for primates in laboratories. For example, stereotypic behavior indicative of psychopathology is common in individually housed macaques.[12] As Corrine Lutz and colleagues have noted, "Macaques can exhibit a wide range of stereotypies that include pacing, rocking, back-flipping, swaying, eye-covering, digit-sucking, self-clasping, and hair-pulling, as well as idiosyncratic ritualized movements."[13] Surveys of large macaque colonies have determined that "approximately 5.7-15% of singly-housed animals had a record of self-inflicted wounding."[14] The sensory deprivation that accompanies cage environments can induce a "cage stereotypy," considered to be the result of the living environment of an animal.[15] As Georgia Mason and Jeffrey Rushen have noted:

> Repeated or sustained uncontrollable stress is a risk factor for the development of some primate abnormal behaviour … For instance, the prevalence of self-injurious behaviour ('SIB', e.g. self-biting, self-slapping and head-banging) in rhesus monkeys is predicted by the age at which they are placed in those conditions, and also by the number of veterinary procedures experienced (e.g. venipunctures) … Furthermore, much converging evidence suggests that acute stress also triggers bouts of both stereotypies and SIB in laboratory primates … For instance, both stereotypies and SIB increase during increased sound levels … and in the presence of a technician wearing black 'catch gloves' as if preparing for capture … Monkeys with SIB often seem to self-bite in response to environmental change: for example, increases in SIB has been associated with temporary social separation or movement to a novel testing room … and even fairly routine husbandry events such as moving monkeys to a new cage or changing their location within their room. Self-biting also varied as a function of animal caretaker activity.[16]

A 2003 survey of 362 rhesus macaque monkeys at the now-shuttered New England Regional Primate Research Center determined that 89 percent of the monkeys "exhibited at least one abnormal behavior," and identified numerous risk factors common to laboratories including "housing and protocol conditions, such as individual housing at an early age, longer time housed individually, greater number

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of blood draws, and nursery rearing."[17] The 2003 survey also revealed that "14 percent of the individually housed monkeys [had] a veterinary record for self-inflicted wounding"—including hair-plucking, head-banging, and self-biting.[18] Accordingly, self-induced alopecia has been a persistent concern in captive primate populations, with several studies reporting prevalence rates in rhesus macaques between 20 and 86 percent.[19]

The alarming situation for primates in U.S. laboratories is not surprising when one considers that many of them are held alone in barren steel cages with little more than a scratched mirror or a plastic ball as "enrichment" and with little or no control over their environment. Although the science of captive primate welfare fills the pages of a library's worth of journals, the findings of this body of work have not yet translated into the laboratory or federal regulations. This disparity was well articulated by Kate Baker *et al.* in 2007:

> It has been 20 years since the 1985 amendment to the Animal Welfare Act was passed. This amendment established Animal Welfare Regulations that mandated programs to provide for the psychological well-being of nonhuman primates … Over the past two decades, considerable efforts have been expended to address these legal requirements with respect to both research and implementation. Currently, a wealth of published research results is available to guide the design and development of environmental enhancement programs. However, journals and guides illuminate what is practical or possible, rather than what is actually practiced. Little information exists that characterizes and quantifies the actual implementation of enrichment programs. *However, a determination of what is considered 'currently accepted professional standards' inevitably involves perceptions of common practice. The lack of information quantifying common practice poses several challenges. As the U.S. Department of Agriculture (USDA) Draft Policy on Environmental Enhancement for Nonhuman Primates [USDA, 1999] pointed out, '...there has been considerable disagreement in various sectors of the public over the adequacy of the performance standards in Sec. 3.81, as well as confusion among the regulated public concerning on what basis they will be judged by inspectors as meeting or not meeting the requirements. Our inspectors requested information and clarification on how to judge whether someone was meeting the requirements of Sec. 3.81'* (Emphasis added).[20]

The absence of clear standards for what would qualify as an ethologically appropriate environment for primates has heretofore been interpreted by experimentation facilities as a license to cage primates, often alone, in small and sterile cages—with little consideration for the impact of such bleak conditions on the welfare of the animals. A 2007 survey of environmental enhancement programs for primates in laboratories analyzed the "management of 35,863 primates in 22 facilities" and revealed serious, systemic problems in the approach taken by facilities. The survey documented that there was "continued prevalence of single housing"; "enrichment devices were used on a less widespread basis within facilities"; and "positive reinforcement programs that involved dedicated training were rare," "despite the experimental evidence of its ability to reduce stress."[21] Similarly, through its eyewitness investigations of laboratories, People for the Ethical Treatment of Animals (PETA) has documented primates languishing in barren steel and cement cells, without anything to engage their minds. At universities

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and contract testing laboratories, PETA has revealed that for monkeys, laboratory life reduces miles of lush forested terrain to a small metal cage; a cornucopia of fruits, leaves, and insects to a handful of monkey chow; and a network of intricate relationships to the loneliness of a solitary existence.[22] Presumably, principles such as respect for autonomy and beneficence would generally prevent the confinement of animals in ethologically inappropriate environments, and resulting pathologies from occurring.

Implications of the Exclusion of Mice and Rats from the U.S. Animal Welfare Act

Over 100 million mice and rats are killed in U.S. laboratories every year.[23] They are used in all manner of experiments from toxicology tests, in which they are slowly poisoned to death, to painful burn experiments, in which large areas of their bodies are given third degree burns, to psychological experiments that induce fear, anxiety, depression, and helplessness in the small animals. They are deliberately electroshocked in pain studies, mutilated in experimental surgeries, and they have everything from cocaine to methamphetamines pumped into their bodies. They are inflicted with cancerous tumors and injected with human cells in genetic manipulation experiments aimed at making mice more like men.

One of the world's largest breeders of mice for use in experimentation specializes in the genetic manipulation of animals. In order to produce transgenic animals, experimenters add foreign DNA to a fertilized egg and then implant the altered egg into a surrogate mother. For example, human growth hormone could be injected into the fertilized egg of a mouse, and then the altered egg is implanted into a female mouse's uterus. In this process, most of the fetuses are not viable, but result in miscarriages. The surviving offspring harbor painful genetic defects that scientists admit they cannot predict and that seem to adhere to no pattern. Transgenic animals are born with lungs that do not inflate. Other transgenic animals cannot stand up. Yet others suffer heart abnormalities, gastrointestinal tract problems, and so on.

Beyond the unpredictable animal welfare problems associated with gene tinkering, companies deliberately "engineer" mice to have systemic defects, a form of pathogenic vulnerability described by Ferdowsian and colleagues, with particular ethical implications. Companies have produced mice who are genetically predisposed to developing cancerous tumors; to becoming obese; to having depressed immune systems; and to experiencing high levels of anxiety and depression. One company has also developed transgenic mice who have the outward appearance of amyotrophic lateral sclerosis in humans, "becoming paralyzed in one or more limbs with paralysis due to loss of motor neurons from the spinal cord."[24]

Throughout all of these procedures, mice and rats are excluded from the minimal protections of the AWA, leaving them vulnerable to egregious abuse and neglect. The absence of legal protection for mice and rats is apparent in the appalling failure on the part of experimenters to provide post-procedural analgesia to mice and rats who are subjected to experimental surgeries and other painful procedures. According to a 2009 survey, post-procedural analgesics were provided to mice and rats undergoing surgical procedures only 20 percent of the time, while anesthetic agents with analgesic properties were administered only 34 percent of

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the time.[25] A 2005 paper estimated that 50 to 60 percent of mice and rats used in painful experiments—laparotomies, craniotomies, skin incisions, burn studies, thoracotomies, and orthopedic studies—received *no pain relief*. [26]

The differential treatment of rats and mice within federal laws and guidelines has had additional implications for their welfare. Institutions that receive federal funding from the National Institutes of Health (NIH) must comply with federal animal welfare guidelines in their treatment of all vertebrate animals; and when an institution violates these guidelines—by carrying out procedures on animals without approval from the Institutional Animal Care and Use Committee (IACUC), by deviating from IACUC-approved protocols, or by subjecting animals to conditions that jeopardize their health or well-being, beyond that which has been approved by the IACUC—the institution must submit a written report of the violation to NIH. Using the Freedom of Information Act, my colleagues and I collected and analyzed violations reports for the 20 institutions that receive the most funding from NIH. Sifting through hundreds of pages of documents, with a focus on incidents involving mice and rats, we catalogued 430 violations at the 20 institutions over the 27-month period from January 1, 2015, to April 1, 2017.[27] The 430 violations included 97 incidents in which animals were subjected to experimental procedures that had not been vetted or approved; 74 incidents in which animals received inadequate pain relief; and 56 incidents in which animals suffered from dehydration, starvation, or inadequate ventilation.[28] In its eyewitness investigations at multiple universities, PETA documented severe misery and prolonged suffering for mice and rats as a result of overcrowded cages. Mice were burdened with tumors so large that the animals had difficulty walking; some tumors had ulcerated and burst. Incompetence, indifference, and neglect forced many of the mice and rats to endure severe trauma, prolonged suffering, and agonizingly slow and grisly deaths.[29]

The acute suffering of animals in laboratories is all the more concerning in light of our evolving understanding of who animals are. For example, mice and rats are highly intelligent, profoundly social, and keenly sensitive animals. They understand abstract concepts and have preferences. Mice empathize with other mice who are in pain. Rats not only express empathy when another rat or a human they know is in distress, but actually exhibit altruism, putting themselves in harm's way rather than allowing distress to another.[30] Attention to principles such as beneficence and a corresponding assessment of risks and benefits—as well as the particular vulnerabilities of these and other animals—would offer far more appropriate protections than they currently receive.

Conclusion

The permissive approach toward animal experimentation must end. At the very least, we must stop casually giving the green light to the bottomless pit of questionable animal tests that mislead researchers, waste precious resources, and inflict pain and misery on animals.

Any ethical framework must reflect our evolving understanding of the biological, psychological and social characteristics and needs of animals. Ferdowsian, *et al.* have charted a path forward and explained how the application of principles similar to those outlined in the Belmont Report could help to address the ethical deficiencies in the enterprise of animal experimentation.

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28. At some institutions, violations were repeated, but federal oversight authorities took no meaningful corrective action. Some incidents reflected pain and suffering for many animals. For example, in just one of 60 incidents at the University of Minnesota, 75 rats were used in experimental surgeries but were given no post-operative pain relief. In just one of 53 incidents at the University of Pittsburgh, 83 pairs of mice were surgically joined together via parabiosis without analgesia. In one of 39 incidents at Yale University, a mouse rack with 141 cages was found disconnected from the automatic watering system. Eight mice died from dehydration, another had to be euthanized, and 93 were found hunched and dehydrated. At the University of North Carolina at Chapel Hill, 11 mice starved when workers did not feed them. At the University of Michigan, tumors in mice were not adequately monitored and were allowed to exceed the protocol endpoint limits—increasing the pain and distress suffered by the animals. A rat who had not been euthanized properly at the University of Michigan was found dead at the bottom of a cooler after having chewed through a bag.
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